PRESS RELEASE

GENFIT Reports Full-Year 2023 Financial Results and Provides Corporate Update

- **Cash and cash equivalents totaled €77.8 million as of December 31, 2023**
- **Revenues amounted to €28.6 million as of December 31, 2023 including a milestone payment of €13.3 million**
- **Topline interim data for Phase 2 UNVEIL-IT® trial in ACLF expected in 2H24**
- **FDA PDUFA action date for elafibranor in PBC: June 10, 2024**

Lille, France; Cambridge, MA; Zurich, Switzerland; April 4, 2024 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced annual financial results for the year ended December 31, 2023. A summary of the consolidated financial statements is included below.

Pascal Prigent, CEO of GENFIT commented:

> *"A remarkable milestone was reached by GENFIT in 2023 with the announcement of positive topline data for our Phase 3 ELATIVE® trial evaluating elafibranor in Primary Biliary Cholangitis. We are now fast approaching the PDUFA[1] action date for elafibranor and this means that, in 2024, GENFIT could reach another key milestone with the first molecule developed in-house being made available to patients. Approval and commercialization would mean that we would receive additional milestones and a regular stream of royalty payments, which will be used to finance our pipeline now mainly focused on Acute-on-Chronic Liver Failure. Looking ahead in 2024, GENFIT will continue to strengthen its leadership in ACLF and intensify collaboration with leading academic institutions and research foundations such as EF CLIF. We are confident that our success in PBC can be replicated in this therapeutic area where the unmet medical need is huge."*

I. 2023 Key highlights

Primary Biliary Cholangitis (PBC): positive results for Phase 3 ELATIVE® trial followed by the validation of the Marketing Authorization Application (MAA) for elafibranor by the FDA, EMA and UK MHRA, and publication in the *New England Journal of Medicine*

In June 2023, GENFIT and Ipsen announced positive 52-week topline data from the pivotal ELATIVE® Phase 3 trial evaluating elafibranor in PBC. In the trial, significant treatment benefit was achieved with elafibranor, with a high responder rate, and a low placebo effect on the primary composite endpoint (a 47% placebo-adjusted difference ($p<0.0001$) between patients on elafibranor 80mg (51%) compared with patients on placebo (4%) achieving a biochemical response). The key secondary endpoint on serum alkaline phosphatase (ALP) normalization was achieved – despite a high baseline ALP level – with high statistical significance. On the other key secondary endpoint using the PBC Worst Itch NRS score, the reduction of pruritus observed for elafibranor versus placebo was not statistically

[1] *Prescription Drug User Fee Act*

significant. Two other secondary patient-reported outcome measures were used to assess itch, and greater reductions in pruritus were observed with elafibranor compared with placebo at Week 52, according to the itch domain of PBC-40 quality of life questionnaire and 5-D Itch total score. Elafibranor was generally well-tolerated with a well-documented safety profile consistent with previous trials.

Full results from the pivotal Phase 3 ELATIVE® trial of elafibranor in PBC were presented as late breaking data at the AASLD congress (Boston, MA) and published in the *New England Journal of Medicine* in November 2023.

These data were used to support submissions to regulatory authorities worldwide for elafibranor as a treatment for patients with PBC having inadequate response or intolerance to ursodeoxycholic acid, the current first-line treatment for PBC.

The US Food and Drug Administration (FDA) granted Priority Review for New Drug Application (NDA) in December 2023, and the European Medicine Agency (EMA) also validated the Marketing Authorization Application (MAA) for elafibranor. A third simultaneous regulatory filing of elafibranor was validated for review by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Acceptance of filings in the US and Europe triggered the first milestone payment for GENFIT, which was received in February 2024, in accordance with the Collaboration and Licensing Agreement signed with Ipsen in 2021.

Acute-on-Chronic Liver Failure (ACLF): GENFIT strengthened leadership and added additional assets to its ACLF franchise

In May 2023, GENFIT licensed the exclusive worldwide rights of ASK1 inhibitor SRT-015 (injectable formulation in acute liver disease) from Seal Rock Therapeutics, a Seattle, Washington (USA) based clinical stage company developing potential first-in-class and best-in-class kinase inhibitors. This was followed by another asset acquisition in July 2023, where GENFIT licensed the exclusive worldwide rights of CLM-022, a potential first-in-class inflammasome inhibitor, from Celloram. Inc., a Cleveland, Ohio (USA) based biotechnology company. GENFIT will leverage Celloram's acquired scientific insights on this molecule to finalize Investigational New Drug (IND) enabling studies of this preclinical stage asset and secure an IND for future clinical trials.

GENFIT's ACLF franchise now includes the following five assets based on differentiated mechanisms of action leveraging complementary pathways.

- VS-01-ACLF (a liposomal-based technology designed to remove ammonia and other ACLF toxins from the blood). IND was in effect as of April 17, 2023 and the first patient was randomized in the UNVEIL-IT® Phase 2 trial in July 2023. UNVEIL-IT® is an open-label, randomized, controlled, multi-center, proof of concept study to assess efficacy, safety, and tolerability in addition to standard of care (SOC), compared to SOC alone, in adult patients with ACLF grades 1 and 2 and ascites.
- NTZ (anti-bacterial agent with anti-inflammatory and hepatoprotective effects).
- SRT-015 (injectable formulation): an ASK1 inhibitor with multi-system benefits.
- CLM-022 (NLRP3 inflammasome inhibitor aimed at inhibiting systemic inflammation and cell death).
- VS-02-HE (small molecule aiming at reducing hyperammonemia, stabilizing blood ammonia and preventing hepatic encephalopathy).

PRESS RELEASE

Diagnostics: publications in leading scientific journals

2023 was a successful year for NIS2+® with several papers published in leading scientific journals such as the *Journal of Hepatology*, *Journal of Hepatology Reports* and *Hepatology Communications*, which all recognized the performance and precision of GENFIT's diagnostic technology.

ESG achievements: recognition by independent bodies

Ethifinance upgraded GENFIT's ESG performance level from bronze to gold and accorded GENFIT a two out of 75 biopharmaceutical sector ranking. Furthermore, GENFIT was classified by ODDO Research as "Best-in-Class" in its sector, based on two main criteria: activity impact and ESG maturity. GENFIT equally obtained a "Prime status" label by ISS ESG, upgrading its corporate rating from C to C+.

Corporate governance updates

At the Company's Annual Shareholders' Meeting held on May 24, 2023, all of the resolutions endorsed by the Board of Directors were adopted by a significant majority of the votes cast. This includes the renewal of financial authorizations. In June 2023, Sandra Silvestri, M.D., Ph.D., replaced Steven Hildemann M.D., Ph.D., on the Board of Directors of the Company as representative of Ipsen, the legal entity that holds the board seat. In the first half of 2023, Sakina Sayah Jeanne and Tom Huijbers joined GENFIT's Executive Committee as Executive Vice-President Research & Translational Science and Executive Vice-President Regulatory, respectively.

II. Outlook 2024

PBC: major catalyst with potential to trigger a new revenue stream

Regulatory filing acceptance has been obtained in the US, Europe and the United Kingdom and a Priority Review has been granted for an NDA by the FDA for elafibranor in PBC with a PDUFA target action date of June 10, 2024.

Execution of R&D roadmap

In 2024, GENFIT will prioritize the execution of its clinical development programs, as well as research programs focused on pre-clinical/non-clinical development.

ACLF: key milestones

GENFIT will also continue its efforts to further strengthen its position as scientific leader in the field of ACLF. GENFIT's R&D efforts have pivoted from chronic to acute liver diseases, with a strong focus on ACLF where the unmet medical need is very important and for which there are currently no approved therapies. Our therapeutic candidates have been strategically selected based on the pathophysiology of ACLF to address the most relevant pathways via differentiated and complementary modes of action.

- VS-01-ACLF: Phase 2 initiated with interim data readout targeted for 2H24
- NTZ in ACLF: reformulation and Phase 2 under preparation in 2024 with a proof-of-concept study initiation targeted for 1H25
- SRT-015: First-in-Human study initiation targeted 1Q25
- CLM-022: preclinical Proof of Concept expected to be obtained by end of 2024
- VS-02-HE: IND enabling studies starting in 2024 with completion expected in 2025

Other life-threatening diseases franchise: key milestones

GNS561 in cholangiocarcinoma (CCA)

The GNS561 Phase 1b/2a clinical trial is currently ongoing and preliminary data from Phase 1b is targeted by the end of 2024.

VS-01-HAC

Following completion of the non-clinical feasibility study, we plan to develop formulation optimization for specific pediatric implementation and conduct IND enabling nonclinical studies with a target to complete such studies in 2024.

Diagnostics franchise

NIS2+®: first-ever approved drug for MASH could lead to an increased need for a non-invasive test

On March 14, 2024, Madrigal Pharmaceuticals announced FDA approval of Rezdiffra™ (resmetirom) in conjunction with diet and exercise for the treatment of adults with non-cirrhotic MASH with moderate to advanced liver fibrosis. Rezdiffra™ is thus the first-ever approved drug for the treatment of MASH, which should increase the focus on diagnosis over the coming years.

Our aim is to pursue our scientific publication plan, particularly focusing on the capabilities of NIS2+® as a potential tool to monitor a patient's response to treatment, and also to move forward with the development of an IVD version of the test, either in collaboration with a commercial partner or by ourselves, in order to make NIS2+® accessible to as many patients as possible worldwide.

PRESS RELEASE

TS-01: in development for measuring blood ammonia levels

The development of TS-01, a device based on the polymersome technology, is being carried out in collaboration with ZHAW School of Engineering and intends to measure ammonia in the blood. The next steps include validation of the test in blood and further miniaturization of the device.

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III. Financial results (*)

(in € thousands, except earnings per share data)	31/12/2022	31/12/2023
Revenues and other income	**26,566**	**38,176**
Research and development expenses	(35,818)	(46,503)
General and administrative expenses	(16,405)	(17,741)
Marketing and market access expenses	(992)	(876)
Reorganization and restructuring expenses	11	505
Other operating income (expenses)	(652)	(141)
Operating income (loss)	**(27,289)**	**(26,580)**
Financial income	8,212	3,680
Financial expenses	(4,758)	(5,614)
Financial profit (loss)	**3,453**	**(1,934)**
Net profit (loss) before tax	(23,836)	(28,514)
Income tax benefit (expense)	116	(380)
Net profit (loss)	**(23,719)**	**(28,894)**
Basic/diluted earnings (loss) per share (€/share)	(0.48)	(0.58)
Diluted earnings (loss) per share (€/share)	(0.48)	(0.58)
Cash, cash equivalents and current financial assets	140,551	77,789

(*) Audit procedures on the Consolidated Financial Statements have been substantially completed. The Report of Independent Registered Public Accounting Firm is forthcoming.

Revenues and other incomes

Revenue and other operating income for 2023 amounted to €38.2 million compared to €26.6 million for 2022.

Revenue amounted to €28.6 million in 2023 compared to €20.2 million in 2022.

Revenue for 2023 is primarily composed of the following:

- €13.3 million was attributable to a milestone invoiced to Ipsen in December 2023 in accordance with the Collaboration and Licensing agreement signed in December 2021. This milestone was earned following the NDA filing acceptance by the FDA and MAA filing acceptance by the EMA for accelerated approval of elafibranor.

- €8.7 million was attributable to previously deferred revenue of €40 million from 2021, in line with the progress in the ELATIVE® clinical study and related expenses incurred during the period.
- €6.5 million in revenue was generated from the services rendered under the Transition Services Agreement and Part B Transition Services Agreement, signed in April 2022 and September 2023 respectively by GENFIT and Ipsen, in order to facilitate the transition of certain services related to the Phase 3 ELATIVE® clinical trial until the complete transfer of the responsibility of the trial to Ipsen.
- €0.1 million was attributable to other ancillary activities.

Other operating income amounted to 9.6 million in 2023 compared to 6.4 million in 2022, and is primarily composed of the following:

- The research tax credit (CIR) amounting to €5.8 million.
- Government grants and subsidies amounted to €3.3 million in 2023 (€34 thousand in 2022). This increase is due to a one-time cancellation of €3.2 million refundable government grant from Bpifrance (the BPI France IT-DIAB) as part of a framework innovation aid agreement involving several scientific partners and for which GENFIT was the lead partner. The program related to this cancellation ended in 2014.

Operating results and expenses

Operating expenses for 2023 amounted to €64.8 million compared to €53.9 million for 2022. This is comprised of research and development expenses, general and administrative expenses, marketing and market access expenses, reorganization and restructuring expenses, and other operating expenses.

The increase is due to multiple factors:

- An increase in research and development costs of €10.7 million, explained by the increase in costs related to new programs and product candidates, in particular VS-01 and GNS561, offset by a reduction in study costs related to NTZ.
- An increase in general and administrative expenses of €1.3 million, explained by increased headcount.
- A decrease in marketing and market access expenses of €0.1 million.
- A decrease in reorganization and restructuring charges of €0.5 million, consisting of unused office space provision reversals as the RESOLVE-IT® study is complete.
- A decrease in other operating expenses of €0.5 million.

In 2023, GENFIT generated a consolidated operating loss of €26.6 million, compared to an operating loss of €27.3 million in 2022.

Financial results

2023 resulted in a financial loss of €1.9 million compared to a financial profit of €3.5 million in 2022.

Our net financial loss for 2023 consisted primarily of €0.5 million in foreign exchange gain on cash and cash equivalents, €3.2 million in interest income, offset by €4.6 million of interest expense, and €1.0 million in foreign exchange losses.

Cash position

As of December 31, 2023, the Company's cash and cash equivalents amounted to €77.8 million compared with €136.0 million as of December 31, 2022.

This amount does not include the receipt in February 2024 of a €13.3 million milestone payment from Ipsen, which was invoiced in December 2023, triggered by the acceptance of the NDA filing by the FDA and MAA by the EMA for accelerated approval of elafibranor in PBC in December 2023.

As previously indicated in past communications[2], in 2024 GENFIT expects to receive total milestone payments of approximately €89 million (including the €13.3 million milestone already received in February 2024), subject to the approval and commercialization of elafibranor in PBC.

The decrease in cash and cash equivalents takes into account our continued research and development efforts, notably for:

- UNVEIL-IT®, our Phase 2 clinical trial evaluating VS-01 in ACLF;
- Our cholangiocarcinoma program evaluating GNS561;
- Our ACLF program evaluating NTZ;
- Our non-clinical trial of SRT-015 in ACLF; and
- ELATIVE®, specifically the portion of the Phase 3 clinical trial evaluating elafibranor in PBC that has not yet been transferred to Ipsen.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until approximately the fourth quarter of 2025. This is based on current assumptions and programs, and does not include exceptional events. This estimation includes our expectations to receive future milestone revenue in 2024, subject to approval by applicable regulatory authorities and US and European commercial launches of elafibranor in PBC, representing a total of approximately €75.2 million.

[2] https://ir.genfit.com/news-releases/news-release-details/genfit-updates-2024-outlook-following-acceptance-elafibranor

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Consolidated Statement of Operations*

	Year ended	
(in € thousands, except earnings per share data)	**31/12/2022**	**31/12/2023**
Revenues and other income		
Revenue	20,195	28,565
Other income	6,371	9,610
Revenues and other income	***26,566***	***38,176***
Operating expenses and other operating income (expenses)		
Research and development expenses	(35,818)	(46,503)
General and administrative expenses	(16,405)	(17,741)
Marketing and market access expenses	(992)	(876)
Reorganization and restructuring income (expenses)	11	505
Other operating expenses	(652)	(141)
Operating income (loss)	***(27,289)***	***(26,580)***
Financial income	8,212	3,680
Financial expenses	(4,758)	(5,614)
Financial profit (loss)	***3,453***	***(1,934)***
Net profit (loss) before tax	***(23,836)***	***(28,514)***
Income tax benefit (expense)	116	(380)
Net profit (loss)	**(23,719)**	**(28,894)**
Basic and diluted earnings (loss) per share		
Basic earnings (loss) per share (€/share)	(0.48)	(0.58)
Diluted earnings (loss) per share (€/share)	(0.48)	(0.58)

(*) Audit procedures on the Consolidated Financial Statements have been substantially completed. The Report of Independent Registered Public Accounting Firm is forthcoming.

Consolidated Statement of Financial Position*

Assets

(in € thousands)	As of 31/12/2022	31/12/2023
Current assets		
Cash and cash equivalents	136,001	77,789
Current trade and others receivables	15,906	32,707
Other current financial assets	4,550	0
Other current assets	1,998	2,615
Inventories	4	4
Total - Current assets	***158,459***	***113,115***
Non-current assets		
Intangible assets	43,957	48,761
Property, plant and equipment	8,210	7,872
Other non-current financial assets	4,914	4,125
Total - Non-current assets	***57,081***	***60,758***
Total - Assets	**215,540**	**173,872**

(*) Audit procedures on the Consolidated Financial Statements have been substantially completed. The Report of Independent Registered Public Accounting Firm is forthcoming.

Liabilities

(in € thousands)	As of 31/12/2022	31/12/2023
Current liabilities		
Current convertible loans	415	415
Other current loans and borrowings	4,665	7,510
Current trade and other payables	14,845	18,799
Current deferred income and revenue	14,479	11,692
Current provisions	61	40
Other current tax liabilities	4,906	23
Total - Current liabilities	***39,370***	***38,480***
Non-current liabilities		
Non-current convertible loans	49,861	52,206
Other non-current loans and borrowings	20,334	10,047
Non-current trade and other payables	448	0
Non-current deferred income and revenue	9,706	3,755
Non-current employee benefits	782	978
Deferred tax liabilities	510	455
Total - Non-current liabilities	***81,641***	***67,441***
Shareholders' equity		
Share capital	12,459	12,459
Share premium	444,683	445,261
Retained earnings (accumulated deficit)	(337,550)	(361,870)
Currency translation adjustment	(1,344)	996
Net profit (loss)	(23,719)	(28,894)
Total - Shareholders' equity	***94,528***	***67,951***
Total - Shareholders' equity & liabilities	**215,540**	**173,872**

(*) Audit procedures on the Consolidated Financial Statements have been substantially completed. The Report of Independent Registered Public Accounting Firm is forthcoming.

Statement of Cash Flows*

(in € thousands)	Year ended 2022/12/31	Year ended 2023/12/31
Cash flows from operating activities		
+ Net profit (loss)	(23,719)	(28,894)
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Depreciation and amortization on tangible and intangible assets	1,832	1,654
+ Impairment and provisions	(179)	(392)
+ Expenses related to share-based compensation	245	578
- Loss (gain) on disposal of property, plant and equipment	(16)	(81)
+ Net finance expenses (revenue)	2,042	485
+ Income tax expense (benefit)	(116)	380
+ Other non-cash items	2,210	(878)
Operating cash flows before change in working capital	**(17,702)**	**(27,148)**
Decrease (increase) in trade receivables and other assets	(8,565)	(17,418)
(Decrease) increase in trade payables and other liabilities	(46,226)	(10,397)
Change in working capital	**(54,791)**	**(27,815)**
Income tax paid	(145)	(465)
Net cash flows provided by (used in) in operating activities	**(72,638)**	**(55,429)**
Cash flows from investment activities		
- Acquisition net of cash acquired (Versantis)	(41,525)	0
- Acquisition of other intangible assets	0	(2,074)
- Acquisition of property, plant and equipment	251	(414)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	20	172
- Acquisition of financial instruments	(5,012)	(12)
+ Proceeds from disposal of financial instruments	0	4,562
Net cash flows provided by (used in) investment activities	**(46,266)**	**2,234**
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	5	0
+ Proceeds from new loans and borrowings net of issue costs	0	89
- Repayments of loans and borrowings	(628)	(3,619)
- Payments on lease debts	(1,120)	(1,075)
- Financial interests paid (including finance lease)	(2,180)	(2,201)
+ Financial interests received	137	1,709
Net cash flows provided by (used in) financing activities	**(3,786)**	**(5,098)**
Increase (decrease) in cash and cash equivalents	**(122,690)**	**(58,292)**
Cash and cash equivalents at the beginning of the period	258,756	136,001
Effects of exchange rate changes on cash	(66)	80

Cash and cash equivalents at the end of the period	**136,001**	**77,789**

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ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Today, GENFIT has a growing and diversified pipeline with programs at various development stages. The Company's area of focus is Acute on Chronic Liver Failure (ACLF). Its ACLF franchise consists of five assets in development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE. These are all based on differentiated mechanisms of action leveraging complementary pathways. Other assets target other life-threatening disease indications such as cholangiocarcinoma (CCA) and Urea Cycle Disorders (UCD)/Organic Acidemias (OA). GENFIT's track record in bringing early-stage assets with high potential to late development and pre-commercialization stages is highlighted in the successful 52-week Phase 3 ELATIVE® trial evaluating elafibranor in PBC. Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on Metabolic dysfunction-associated steatohepatitis (MASH) previously known as nonalcoholic steatohepatitis (NASH) and ammonia. GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. For more information, visit .www.genfit.com

GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about key milestones relating to its clinical and pre-clinical programs, in particular, data availability for UNVEIL-IT® and the clinical trial of GNS561 in CCA, potential approval by the FDA and other regulatory authorities of elafibranor for the treatment of PBC, expectations to receive milestones and royalty payments subject to approval and commercialization of elafibranor in PBC, the future and development of NIS2®, the development of TS-01, commercial perspectives for elafibranor and its potential as a therapeutic option for patients, our financial outlook including cash flow and cash burn projections and business activity projections for 2023 and beyond. The use of certain words, including "believe", "potential," "expect", "target", "may" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among other things, the uncertainties inherent in research and development, including in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, which is available on the Company's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC") including the Company's 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023 and subsequent filings and reports filed with the AMF or SEC including the Half-Year Business and Financial Report at June 30, 2023 or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of

results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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