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GENFIT Reports Full-Year 2021 Financial Results and Provides Corporate Update

- Cash and cash equivalents totaled €258.8 million as of December 31, 2021
- Major financial achievements in 2021 include landmark strategic partnership deal with Ipsen, successful convertible debt renegotiation and non-dilutive funding through French State-Guaranteed Loans
- Important R&D milestones reached in 2021, including launch of Phase 1 in acute on chronic liver failure (ACLF), in-licensing of GNS561 (a novel molecule) in cholangiocarcinoma (CCA) and recognition of NIS4® technology's unique performance by FNIH NIMBLE study
- Outlook 2022
 - Elafibranor in Primary Biliary Cholangitis (PBC): commitment for topline data readout in the second quarter 2023 reaffirmed
 - NTZ in ACLF: Phase 1 data expected by third quarter 2022
 - GNS561 in CCA: target to start Phase 1b/2 trial by fourth quarter 2022
- Conference call (English and French) on April 8, 2022 at 8am ET / 1pm GMT / 2pm CET

Lille, France; Cambridge, MA; April 7, 2022 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases, today announced annual financial results for the year ended December 31, 2021. A summary of the consolidated financial statements is included below.

Pascal Prigent, CEO of GENFIT, commented: "2021 was a pivotal year for us. We are pleased to have delivered on our key commitments which were to improve our financial situation, pursue our Phase 3 trial and strengthen our pipeline. We are grateful to our dedicated team for their efforts in realizing these objectives and our investors for their continued support. We start 2022 having made great progress regarding ELATIVE™, and our improved financial visibility will enable us to grow our pipeline and

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accelerate our existing programs, as we continue to seek therapeutic and diagnostic solutions that can improve the health and quality of life of patients affected by severe chronic liver diseases.”

Financial results*

KEY FIGURES (CONSOLIDATED) (in € thousands, except earnings per share data)	31/12/2020	31/12/2021
Revenues and other income	7 758	85 579
Research and development expenses	(59 097)	(35 166)
General and administrative expenses	(14 270)	(16 153)
Marketing and market access expenses	(11 216)	(1 539)
Reorganization and restructuring expenses	(5 308)	(142)
Other operating income (expenses)	(764)	(763)
Operating income (loss)	(82 897)	31 816
Financial income	6 544	44 780
Financial expenses	(25 296)	(7 122)
Financial profit (loss)	(18 752)	37 658
Net profit (loss) before tax	(101 649)	69 474
Income tax benefit (expense)	428	(2 215)
Net profit (loss)	(101 221)	67 259
Basic earnings (loss) per share (€/share)	(2,60)	1,51
Diluted earnings (loss) per share (€/share)	0,00	1,23
Cash, cash equivalents and current financial assets	171 029	258 756

* Unaudited financial statements. The audit procedures by the Statutory Auditors are underway.

Revenue and other operating income

Revenue and other operating income for 2021 amounted to €85.6 million compared to €7.8 million for 2020.

Revenue for 2021 amounted to €80.1 million, mainly from the receipt of the €120.0 million upfront payment from Ipsen, out of which €80.0 million is recognized as 2021 revenue, after deduction of €40.0 million deferred revenue, which will gradually be recognized as revenue following the completion of the ELATIVE™ double-blind study. Other revenue recognized in 2021 is related to licensing agreements with Labcorp for the deployment of NIS4® technology in NASH.

Revenue for 2020 amounted to €0.8 million, mainly from the license agreements with Labcorp, as well as one-time sales of goods and services within the scope of the collaboration and license agreement with Terns Pharmaceuticals.

Other operating income included mainly the research tax credit (known as *Crédit d'Impôt Recherche* or CIR) granted by the French tax authorities, which amounted to €5.3 million for 2021 compared

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with €7.9 million for 2020, which was reduced by a €1.9 million expense following the settlement of a dispute relating to the CIR for 2010, 2011, 2012 and 2014.

Operating expenses and operating result

Operating expenses for 2021 amounted to €53.8 million compared to €90.7 million for 2020.

R&D expenditures, general and administrative expenses, marketing and market access expenses and other operating expenses decreased in 2021 compared to the previous year, amounting to €53.6 million compared to €85.3 million for 2020. This decrease mainly reflected the effects of the reorganization and restructuring plan, which was initiated during the fourth quarter 2020 and throughout 2021. The non-recurring costs associated with the implementation of the reorganization and restructuring plan decreased significantly from €5.3 million in 2020 to €0.1 million in 2021, consisting primarily of fees related to the renegotiation of the convertible bonds, partially offset by the reversal of certain impairment losses and provisions previously booked in 2020.

In 2021, GENFIT generated a consolidated operating result of €31.8 million compared to an operating loss of €82.9 million in 2020.

Financial result

2021 resulted in a financial income of €37.7 million compared to a financial loss of €18.8 million in 2020.

This variation was mainly due to the €35.6 million one-time bonus relating to the partial buyback of the convertible bonds (OCEANE) and to the decrease in expenses related to financial interest from €11.6 million in 2020 to €4.8 million in 2021.

The foreign exchange result on cash and cash equivalents was a net gain of €6.7 million in 2021, compared to a net loss of €8.5 million in 2020. This mainly resulted from the effect of the exchange rate fluctuations on the cash investments held in US dollars, which have been kept in their original currency since they were invested. In connection with the preceding, €5.9 million out of the total 2021 foreign exchange result is qualified as unrealized.

Cash and cash equivalents

As of December 31, 2021, the Company's cash and cash equivalents amounted to €258.8 million compared with €171.0 million as of December 31, 2020.

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This is mainly the result of:

- The €120.0 million non-refundable initial payment received from Ipsen pursuant to the license agreement signed in December 2021, further increased by €24.0 million of collected VAT;
- Ipsen's €28.0 million equity investment in GENFIT's share capital received in December 2021;
- The reimbursement in October 2021 of the 2020 CIR for €7.9 million;
- The granting of two State-guaranteed loans and a subsidized loan in June, July and November 2021 for a total amount of €15.2 million;
- €47.5 million (not including transaction expenses) disbursed for the partial buyback of the OCEANE convertible bonds in January 2021; and
- Cash used in operating activities over the period.

Note: taking into account the partial buyback of the OCEANES and the conversions into shares that have taken place since the renegotiation of the convertible debt, which gave rise to the creation of 6,941,875 new shares, the residual convertible bond debt amounts to a nominal amount of €56.9 million as of April 7, 2022, i.e. less than a third of the amount of the initial nominal debt of €180.0 million. The number of OCEANES remaining in circulation is 1,923,662, representing a maximum dilution in the event of conversion of all convertible bonds of 17.52% (in % of capital held as of April 7, 2022).

2021 Key Highlights

Financial - key highlights

↳ **Successful convertible debt renegotiation**

We successfully restructured the convertible debt at the end of January 2021 with a partial buy-back and extended the maturity to October 2025. At the end of 2021, the outstanding nominal debt was approximately €56.9 million, i.e. less than a third of the initial nominal debt of €180.0 million.

↳ **Non-dilutive State-Guaranteed Loans for a total amount of €15.2 million**

In 2021, GENFIT secured €15.2 million non-dilutive loans granted in the context of the COVID-19 pandemic, of which €13 million are guaranteed up to 90% by the French state.

↳ **Long-term strategic partnership with IPSEN**

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In December 2021, GENFIT entered into an exclusive, worldwide¹ licensing agreement with IPSEN for elafibranor, a Phase 3 asset evaluated in Primary Biliary Cholangitis (PBC). Under the terms of the agreement, GENFIT received an upfront cash payment of €120.0 million and is eligible for regulatory, commercial and sales-based milestone payments of up to €360.0 million. GENFIT is also eligible to receive tiered double-digit royalties of up to 20%. In addition to global commercialization², IPSEN will be responsible for all clinical development of elafibranor following completion of the ELATIVE™ double-blind period, including completion of the long-term open-label extension period of the ELATIVE™ trial. To underscore GENFIT and Ipsen's long-term partnership, Ipsen has taken an 8% ownership stake for €28.0 million. Ipsen has now become GENFIT's largest shareholder.

Pipeline development - key highlights

↳ **Elafibranor development program in PBC**

Despite the COVID-19 pandemic, patient enrolment for the Phase 3 ELATIVE™ clinical trial progressed well throughout 2021, with positive Data Safety Monitoring Board (DSMB) outcomes. In February 2021, the Company announced the publication, in the *Journal of Hepatology*, of the positive results of the Phase 2 clinical trial evaluating elafibranor in patients with PBC and an incomplete response to ursodeoxycholic acid (UDCA). These results show a clinically significant improvement on the primary and composite biochemical evaluation criteria which is the primary endpoint of the pivotal trial to support accelerated approval. In addition, the results showed a positive trend on the improvement of pruritus, while preserving a favorable tolerability profile.

↳ **Significant progress made in implementing our new pipeline strategy**

In May 2021, we announced our new strategic direction in R&D which centers around refocusing our efforts in two new franchises with significant unmet medical needs: Acute on Chronic Liver Failure (ACLF) and cholestatic diseases.

In November 2021, we announced the first patient first visit for the evaluation of NTZ in subjects with hepatic impairment and we are currently initiating a Phase 1 study in renal impairment as part of our ACLF program. ACLF is a severe liver disease with a high unmet need. These Phase 1 studies represent a key milestone in the Company's pipeline development and, upon completion

¹ With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor.

² Idem.

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and if positive, will enable GENFIT to progress towards a proof-of-concept study in patients with acute decompensated cirrhosis and ACLF.

In December 2021, GENFIT strengthened its cholestatic disease franchise through the in-licensing of exclusive rights from Genoscience Pharma to develop and commercialize the investigational drug GNS561 in cholangiocarcinoma (CCA) in the United States, Canada and Europe, including the United Kingdom and Switzerland.

On the diagnostics side of the business, in November 2021, a study undertaken by the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE), an initiative of the Foundation for the National Institutes of Health's Biomarkers Consortium (FNIH) confirmed that NIS4® technology demonstrates a unique performance in identifying patients with at-risk Non-Alcoholic Steatohepatitis (NASH), and provided evidence that it had the best results of the five blood-based biomarker panels which were assessed in this study, for the diagnosis of fibrosis stage \geq 2. The FNIH NIMBLE findings will have a strong utility for the whole NASH field and practitioners, and could potentially pave the way for regulatory qualification for non-invasive tests in NASH. NIS4® technology is currently powering a test called NASHnext™ commercialized by our partner Labcorp in the U.S. and Canada.

Organizational and governance updates

In March 2021, Jean-François Tiné was appointed Member of the Board of Directors, replacing Philippe Moons.

In April 2021, GENFIT appointed Thomas Baetz as Chief Financial Officer.

In 2021, GENFIT added four new members to its Executive Committee: Pascal Caisey (hired as Chief Commercial Officer and promoted Chief Operating Officer in February 2022), Stefanie Magner (Chief Compliance Officer and VP International Legal Affairs), Philippe Motté (Chief Regulatory and Quality Officer) and Thomas Baetz (Chief Financial Officer).

In October 2021, the Environmental Social Governance (ESG) Committee was created following new recommendations of the Middlednext Code. The aim of the committee is to measure and track GENFIT's non-financial performance on an annual basis. Ms. Catherine Larue serves as Chairwoman on the ESG Committee.

Outlook 2022

Building on our strengths to execute our strategy

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We believe our strengths, listed below, provide the foundation that will allow us to successfully expand our activities in 2022 and beyond:

- Experience in bringing early-stage assets into late development stages, with expertise ranging from research to pre-commercialization, and including clinical development and regulatory affairs;
- A portfolio rationalized in 2021, focusing on disease areas with high unmet needs and high market potential;
- Choosing partners with a strong commercial track-record; and
- A robust financial situation with a strong cash position.

Continuing elafibranor development program in PBC

As previously communicated, we saw a disruption in our clinical operations at the end of last year due to the COVID pandemic and specifically the rise of the Omicron strain. However, our recruitment numbers rebounded significantly in the first quarter 2022 as the situation normalized. Screening of patients will stop next week as end of enrollment is now imminent.

This means that we remain committed to deliver topline data readout in the second quarter 2023, in line with our previous guidance.

Pursuing the execution of existing programs

Our second objective is to continue the execution of the following programs:

- NTZ in ACLF: following encouraging pre-clinical results, we are moving forward with the Phase 1 trial in hepatic impairment, aiming for data readout by the third quarter 2022. We are also initiating a Phase 1 study in renal impairment, with data anticipated in the fourth quarter 2022. If positive, both the hepatic and renal studies will be supportive of the ACLF Investigational New Drug application and proof-of-concept study.
- GNS561 in CCA: we intend to start a Phase 1b/2 trial by the second half 2022.
- NASH Diagnostics: our goal is to further establish NIS4™ technology through scientific publications and increased use in the field.

Pipeline strategy and impact on financial outlook

GENFIT will continue to grow and diversify its pipeline in 2022 by leveraging its expertise in bringing early-stage assets to late-development stages. To achieve this goal, we follow a dual-track

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approach based on repurposing of molecules approved in other indications and in-licensing of molecules developed by other companies.

As we continue our efforts to identify product candidates with the highest potential, conduct pre-clinical studies and clinical trials and advance the development of our diagnostic test, we expect that our cash used in operational activities will increase to €65 million in 2022 (excluding exceptional items of €30.0 million payable in 2022 in relation to the upfront payment received from Ipsen in late 2021, i.e. primarily VAT collected and corporate income tax, as well as potential costs and expenses in future business development activities such as in-licensing).

GENFIT will host a conference call in English and in French on April 8, 2022 at 8.00am ET / 1:00pm GMT / 2:00pm CET

Both the English and French conference calls will be accessible on the investor page of our website, under the events section at <https://ir.genfit.com/> or by calling 800-239-9838 (toll-free U.S and Canada), 0800 358 6377 (toll-free UK) or 0805 101 219 (toll-free France) five minutes prior to the start time (confirmation code: 9241456). A replay will be available shortly after the call.

APPENDICES

Consolidated Statement of Financial Position*

ASSETS (in € thousands)	As of	
	31/12/2020	31/12/2021
Current assets		
Cash and cash equivalents	171 029	258 756
Current trade and others receivables	11 919	7 236
Other current assets	1 765	2 101
Inventories	4	4
Total - Current assets	184 717	268 097
Non-current assets		
Intangible assets	297	174
Property, plant and equipment	11 648	9 015
Non-current trade and other receivables	0	3
Other non-current financial assets	1 458	4 431
Deferred tax assets	0	0
Total - Non-current assets	13 403	13 623
Total - Assets	198 119	281 720

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway

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SHAREHOLDERS' EQUITY AND LIABILITIES (in € thousands)	As of	
	31/12/2020	31/12/2021
Current liabilities		
Current convertible loans	1 313	415
Other current loans and borrowings	3 035	1 773
Current trade and other payables	25 564	40 988
Current deferred income and revenue	124	14 298
Current provisions	1 031	313
Other current tax liabilities	0	5 051
Total - Current liabilities	31 067	62 837
Non-current liabilities		
Non-current convertible loans	169 470	47 682
Other non-current loans and borrowings	11 873	24 365
Non-current trade and other payables	451	450
Non-current deferred income and revenue	0	25 821
Non-current employee benefits	922	864
Deferred tax liabilities	767	602
Total - Non-current liabilities	183 482	99 786
Shareholders' equity		
Share capital	9 722	12 454
Share premium	379 057	444 438
Retained earnings (accumulated deficit)	(303 897)	(405 076)
Currency translation adjustment	(92)	22
Net profit (loss)	(101 221)	67 259
Total shareholders' equity - Group share	(16 430)	119 097
Non-controlling interests	-	0
Total - Shareholders' equity	(16 430)	119 097
Total - Shareholders' equity & liabilities	198 119	281 720

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway

Statement of Operations*

(in € thousands, except earnings per share data)	Year ended	
	31/12/2020	31/12/2021
Revenues and other income		
Revenue	765	80 069
Other income	6 993	5 510
Revenues and other income	7 758	85 579
Operating expenses and other operating income (expenses)		
Research and development expenses	(59 097)	(35 166)
General and administrative expenses	(14 270)	(16 153)
Marketing and market access expenses	(11 216)	(1 539)
Reorganization and restructuring expenses	(5 308)	(142)
Other operating income (expenses)	(764)	(763)

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Operating income (loss)	(82 897)	31 816
Financial income	6 544	44 780
Financial expenses	(25 296)	(7 122)
Financial profit (loss)	(18 752)	37 658
Net profit (loss) before tax	(101 649)	69 474
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Net profit (loss)	(101 221)	67 259

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Statement of Cash Flows*

(in € thousands)	Year ended 31/12/2020	Year ended 31/12/2021
Cash flows from operating activities		
+ Net profit (loss)	(101 221)	67 259
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Depreciation and amortization on tangible and intangible assets	3 559	2 742
+ Impairment and provision for litigation	3 015	(1 996)
+ Expenses related to share-based compensation	1 236	470
- Gain on disposal of property, plant and equipment	80	420
+ Net finance expenses (revenue)	10 335	4 663
+ Income tax expense (benefit)	(428)	2 215
+ Other non-cash items including Research Tax Credit litigation including Research Tax Credit litigation and Income incurred by renegotiating the convertible bond debt OCEANE	(1 818)	(35 538)
Operating cash flows before change in working capital	(85 242)	40 235
Change in:		
Decrease (increase) in trade receivables and other assets	318	4 344
(Decrease) increase in trade payables and other liabilities	(11 447)	55 335
Change in working capital	(11 129)	59 680
Income tax paid	0	0
Net cash flows provided by (used in) in operating activities	(96 371)	99 915
Cash flows from investment activities		
- Acquisition of property, plant and equipment	(900)	(537)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	0	309
- Acquisition of financial instruments	(66)	(3 148)

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Net cash flows provided by (used in) investment activities	(966)	(3 377)
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	7	27 972
+ Proceeds from subscription / exercise of share warrants	0	0
+ Proceeds from new loans and borrowings net of issue costs	0	15 270
- Repayments of loans and borrowings	207	(48 436)
- Payments on lease debts	(2 150)	(1 887)
- Financial interests paid (including finance lease)	(7 762)	(2 109)
+ Financial interests received	1 442	274
Net cash flows provided by (used in) financing activities	(8 256)	(8 916)
Increase (decrease) in cash and cash equivalents	(105 593)	87 622
Cash and cash equivalents at the beginning of the period	276 748	171 029
Effects of exchange rate changes on cash	(126)	105
Cash and cash equivalents at the end of the period	171 029	258 756

*Unaudited financial statements. The audit procedures by the Statutory Auditors are underway

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic 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. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D is focused on three franchises: cholestatic diseases, Acute on Chronic Liver Failure (ACLF) and NASH diagnostics. In its cholestatic diseases franchise, ELATIVE™, a Phase 3 global trial evaluating elafibranor³ in patients with Primary Biliary Cholangitis (PBC) is well underway following [a successful Phase 2 clinical trial](#). Topline data is expected to be announced in the second quarter 2023. In 2021, GENFIT signed an exclusive licensing agreement with IPSEN to develop, manufacture and commercialize elafibranor in PBC and other indications.⁴ GENFIT is also developing GNS561¹ in cholangiocarcinoma following the acquisition of exclusive rights in this indication from

³ Elafibranor and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority

⁴ With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor

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Genoscience Pharma in 2021⁵. In ACLF, a Phase 1 clinical program with nitazoxanide has been initiated with data expected as early as the third quarter 2022. As part of its diagnostic solutions franchise, the Company entered into an agreement with Labcorp in 2021 to commercialize NASHnext®, powered by GENFIT's proprietary diagnostic technology NIS4® in identifying at-risk NASH.

GENFIT has facilities in Lille and Paris, France, 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. www.genfit.com

GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding timelines for patient enrolment completion and topline data readout for our ELATIVE™ Phase 3 trial, timelines for data readout for our Phase 1 studies in ACLF and the start of the Phase 1b/2 trial in CCA, the commercial uptake for tests powered by NIS4™ technology, our financial outlook including cash flow and cash burn projections and business activity expansion projections for 2022 and beyond. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, impact of the ongoing COVID-19 pandemic, exchange rate fluctuations, the granting of the research tax credit by the French tax authorities, extensions of State guaranteed loans maturity and the Company's continued ability to

⁵ Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland

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raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French *Autorité des Marchés Financiers* ("AMF"), including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, 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 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021 and subsequent filings and reports filed with the AMF or SEC, 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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