# NERVIANO MEDICAL SCIENCES

PART OF NMS GROUP

### Financial Statement at December 31,2021

#### SUMMARY

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Nerviano Medical Scientilla Viale L. Pasteur, 10 20014 Nerviano (MI) P.IVA 04379750963



#### **CORPORATE BODIES OVERVIEW**

#### **Board of directors**

Chairman and CEO Hugues Dolgos

Director Barbara Marenco

#### **Board of Statutory auditors**

Chairman Mario Tagliaferri

Statutory auditors Stefano Sacchi

Massimo Venuti

Substitutes Salvatore Marco Fiorenza

Giovanni Ghelfi

#### **Audit firm**

PricewaterhouseCoopers S.p.A.: Mandate for the three-years period 2020-2022

Nerviano Medical Sciences srl Viale L. Pasteur, 10 20014 Nerviano (MI) P.IVA 04379750963



#### MAIN ECONOMIC AND FINANCIAL DATA

(in millions of EuroS)

(minimum or Euros)		
ECONOMIC DATA	31/12/2021	31/12/2020
Value of production	20,6	29,6
Gross operating result	(20,3)	(9,7)
Amortisation depreciation and write-downs	(2,0)	(2,2)
Net operating result	(22,3)	(11,9)
Operating result before taxes	(20,3)	(13,4)
Net profit	(13,9)	(10,2)

Dati Patrimoniali	31/12/2021 31/	2/2020
Net invested capital	98,8	68,2
Provisions for risks and charges and Severance Indemnity	(4,1)	(4,8)
Net financial position	(59,5)	(14,2)
Net Equity	35,2	49,1
Investments	0,5	3,6
Average no. of employees	141	136

Nerviano Medical Sciences S.
Viale L. Pasteur, 10
20014 Nerviano (MI)
P.IVA 04379750963



#### **DIRECTORS' REPORT**

#### 1. THE COMPANY

Nerviano Medical Sciences S.r.l. (NMS S.r.l. or NMS) is the Company of NMS Group involved in the research and development of new oncology drugs and represents the innovative heart of the Group. The activities of more than 135 researchers, with years of experience and multidisciplinary scientific skills in the field of chemical and biological research, are focused on research of innovative molecules target to cancer. NMS is able to cover the entire drug development chain, from the research phase, which involves the choice of a specific pharmacological target for the tumor and the identification of a molecule capable of inhibiting it, to the preclinical and then clinical development phase, including the production of the active ingredient, with the support of the other companies in the Group for the last two phases.

Its business model can be considered hybrid: on the one hand, the licensing of molecules at various stages of development to pharmaceutical and/or biotech companies so that they can complete clinical development up to registration and subsequent marketing, against payment of progress milestones and royalties on future turnover, on the other hand, the intention to develop its own proprietary oncology pipeline in order to maximize value by deciding, product by product, the best strategy to apply: licensing to third parties or in-house development at least until the end of phase II clinical development. This balanced strategic vision of the business, resulting from the entry of the new Chinese Partner in 2018, will require a major financial commitment from the current ownership for all those activities that will be decided to develop internally with a positive impact on the creation of value that is intrinsic in oncology molecules that manage to reach the market partially balanced by licensing agreements that will allow an optimization of portfolio management and finance.

#### 2. MAIN EVENTS OF THE YEAR 2021

During the year, the new centralized treasury model implemented in 2020 with the aim of improving and optimizing the use of the Group's financial resources, including through the use of the "zero balance" cash pooling tool, signed amongst NMS Group S.p.A. (treasury company), Nerviano Medical Sciences S.r.l., Simis S.r.l., Accelera S.r.l. and Nerpharma S.r.l. (secondary companies) and Intesa Sanpaolo S.p.A., has permitted efficient and rapid management of cash flows with an impact



on the Company's net financial position and net working capital, which will be analysed in the Supplementary Notes.

For important events in the business area, see paragraph 4. THE STATE OF THE "PIPELINE" AND SCIENTIFIC RESEARCH STRUCTURES (BUSINESS UNIT ONCOLOGY - discovery area).

#### 3. ECONOMIC AND FINANCIAL PERFORMANCE

Nerviano Medical Sciences S.r.l. Balance Sheet is summarized as follows - values in thousands of Euros:

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	31/12/2021	31/12/2020
Fixed assets	86.158	87.690
Net working capital	12.687	(19.507)
Net invested capital	98.845	68.183
Provisions for risks and charges and Severance Indemnity	(4.101)	(4.797)
Net invested capital and funds	94.744	63.386
financed by:		
Net financial position	(59.504)	(14.246)
of which		
Financial assets that are not fixed assets	59	35
Cash and cash equivalents	2.089	18.159
Other loans	=	(28)
Use of credit line for cash elasticity and short-term/medium/long-term debts	(17.824)	(20.500)
Financial receivables and payables vs parent companies and subsidiaries	(4.629)	(4.629)
receivables and payables by cash pooling	(39.198)	(7.283)
Net Equity	35.239	49.140

The fixed assets equal to 86.158 thousand Euros mainly include the value of the financial assets in the subsidiary companies, net of the provision for the write-down of investments, one investment in other companies, the value of licenses, software projects, trademarks and tangible assets located within the site.

Net working capital, is positive and equals to 12.687 thousand Euros, includes:

- advances payments to suppliers for 1.783 thousand Euros,
- receivables due from clients for 3.869 thousand Euros, net of related provision,
- receivables due from subsidiaries for 2.480 thousand Euros, of which 2.240 thousand Euros related to the security deposit paid with regard to outstanding lease agreements with Simis S.r.l.,
- receivables due from associate companies for 1.855 thousand Euros, of which 795 thousand Euros to Accelera S.r.l., 1.027 thousand Euros to NerPharMa S.r.l. and finally 33 thousand Euros to Consorzio Infra in Liquidation.,



- receivables due from parent companies NMS Group S.p.A. for 9.852 thousand Euros.
- tax receivables for 10.259 thousand Euros,
- other receivables for 1.310 thousand Euros,
- accrued income and prepaid expenses fo 542 thousand Euros

#### net of:

- advances payments from suppliers for 392 thousand Euros,
- payables due to suppliers for 6.153 thousand Euros,
- payables due to subsidiaries Simis S.r.l. for 1.188 thousand Euros,
- payables due to associate companies 9.334 thousand Euros, of which 6.413 thousand Euros due to Accelera S.r.l. (of which 932 thousand Euros for invoices to be received) and 2.921 thousand Euros to Nerpharma S.r.l. (of which 1.747 thousand Euros for invoices to be received),
- payables due to parent companies for invoices to be received equal to 552 thousand Euros:
- tax payables and payables due to social security institutions for 796 thousand Euros.
- other payables for 818 thousand Euros,
- accrued liabilities and deferred charges for 30 thousand Euros.

For further details of the above items, please refer to the section entitled "ANALYSIS OF THE BALANCE SHEET AND THE INCOME STATEMENT ITEM" in the Supplementary Notes.

The Employee Severance Indemnity Fund (so called TFR) amount to 2.056 thousand Euros and the total provisions for risks and charges amounts to approximately 2.045 thousand Euros.

Net equity amounts to 35.239 thousand Euros, which includes the loss for the period ended December 31, 2021. The Share Capital (consisting of a single share) amounts to 1.040 thousand Euros and is entirely held by the parent company, NMS Group S.p.A..

The net financial position shows a negative balance of 59.504 thousand Euros, composed of:

- ✓ financial assets in bank accounts, amounting to 2.089 thousand Euros,
- ✓ financial assets not constituting fixed assets for an amount of 59 thousand
  Euros.
- ✓ a credit line for cash elasticity with Banca Popolare di Sondrio for an amount
  of 17.824 thousand Euros, consisting of two loans stipulated with Banca



- Popolare di Sondrio on May 31, 2017 for a residual value at December 31, 2021 of 12,5 thousand Euros and on September 23, 2020 for a residual value at December 31, 2021 of 5,3 thousand Euros,
- √ financial payables to the parent company NMS Group S.p.A. for 5.318 thousand Euros,
- ✓ financial receivables from the subsidiary Simis S.r.l. for 83 thousand Euros and financial receivables due from the subsidiary Accelera S.r.l. for 606 thousand Euros,
- ✓ cash pooling payables due to parent company NMs Group S.p.A. of 39.198 thousand Euros.

The economic situation of Nerviano Medical Sciences S.r.l. is summarized as follows - values in thousands of Euro:

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· 中国中国的中国中国中国中国中国中国中国中国中国中国中国中国中国中国中国中国中国	31/12/2021	31/12/2020
Value of production	20.628	29.631
Costs of production	(40.890)	(39.282)
Gross operating result (E.B.I.T.D.A.)	(20.262)	(9.651)
Amortisation depreciation and write-downs	(2.039)	(2.220)
Net operating result (E.B.IT.)	(22.301)	(11.871)
Net financial charges	2.017	(1.507)
Value adjustments of financial assets	24	2
Profit before tax	(20.260)	(13.376)
Current taxes	6.359	3.209
Net profit	(13.901)	(10.167)

In 2021 The value of production amounts to 20.628 thousand Euros and mainly includes royalties from the license agreement for the two products currently on the market, revenues generated by services provided to third party customers, revenues from the recharging of technical costs to Group Companies and revenues from the recovery of R&D tax credits in 2021. For further details on the above items, please refer to section A - PRODUCTION VALUE of the Notes to the Financial Statements. Costs of production amount to 40.890 thousand Euros and include:

- a) cost for primary, ancillary materials, consumables and goods for 1.290 thousand Euros,
- b) costs for services 28.316 thousand Euros,
- c) costs for use of third-party goods for 1.851 thousand Euros,
- d) staff costs for 9.374 1 thousand Euros,
- e) other operating expenses for 59 thousand Euros.

For further details of the above items, please refer to the section entitled "B - COST OF PRODUCTION" of the Supplementary Notes.



The charges for current taxes, which amount to 6.359 thousand Euros, are mainly related to the determination of the IRES (income taxes) as a result of the application of the tax regime envisaged by the national tax consolidation scheme.

In order to complete the analysis of the Company's business, the progress status relating to completed and on-going financed projects by NMS S.r.l. shall now be summarized:

- 1. With respect to the 2009 decree entitled "Identification and development of a new platform for an integrated system of technologies in the oncology area" and for the training "New advanced technology specialists for research into new anti-cancer drugs", the scientific activities of which were completed at the end of 2012, the Company, following the positive conclusion of the preliminary investigation carried out by the Ministry of Research and University, opened a negotiating table with the credit institute that has entered into an agreement with the Company in order to check the parameters of financial reliability and the related issue of creditworthiness, a fundamental step towards the positive conclusion of the process and the issue of a new decree with a reduction in the amount of aid from the 44 million Euros originally planned to 38 million Euros related to the new eligible costs.
- 2. About the funded project which ended in June 2009 concerning "Identification of innovative anti-cancer drugs: from genomics to therapy", on September 6, 2021, the Company signed a loan agreement with Intesa San Paolo S.p.A. in the form of a contribution to costs pursuant to Legislative Decree no. 297/1999, which amounted to 1.244 thousand Euros, while on October 25th the Company signed a loan agreement with the same bank, that also acts as agent for Cassa Depositi e Prestiti, pursuant to Law no. 311 of December 30, 2004, , granted a subsidized loan of 6.304 thousand Euros and a bank loan of 705 thousand Euros, with a 10-year term and half-yearly repayments at a rate of 0.5% for the former and 1.50% for the latter.. The payment of these amounts is subject to the positive conclusion of the accounting and scientific audit carried out respectively by the auditor and the scientific project manager, as provided for in the regulations. These activities, which began in February 2022, are expected to be completed in the late spring of the sameyear allowing the Company to collect by the end of the fiscal year.



#### 4. UPDATE ON THE DRUG DISCOVERY PIPELINE

#### 4.1 Executive Summary

At December 31st, 2021, the NMS Srl pipeline included the following assets:

#### > Outlicensed products (paragraph 4.2):

- Encorafenib, (BRAFTOVI®, a product sold by Pfizer),
- Entrectinib (Rozlytrek® a product sold by Roche),
- · Milciclib in development at Tiziana Life Sciences,
- · Onvansertinib in development at Cardiff Oncology,
- IDH Follow on in development at Nanjing Hicin Pharmaceutical Co.Ltd.,
- · Nuovo Target in coodevelopment with Merck KGaA.

#### > NMS Internal products (paragraph 4.3):

- NMS-153 (MPS1 inhibitor),
- NMS-088 (FLT3/KIT/CSF1R inhibitor),
- NMS-293 (PARP1 inhibitor),
- NMS-812 (PERK inhibitor),
- NMS-173 (IDH inhibitor),
- · CDC7 inhibitor,
- · SYK inhibitor,
- NMS-338 (RET inhibitor),

#### > Other preclinical programs (paragraph 4.4):

- Target 1
- Target 2
- Target 3
- New Projects and Target ID
- ADC platform

In the last few years NMS srl has implemented an internal reorganization, updating and expanding the different functions in order to better support a new drug development paradigm which, rather than out-licensing proprietary molecules for clinical development, is instead focused on a seamless R&D process from discovery to preclinical into clinical development.

This has included creation of a new Global Clinical Development (GCD) function in order to support a clinical pipeline under expansion and a development approach



that foresees global clinical studies comprising Europe, US and China, starting from the earliest clinical development stages.

Consolidation of the new GCD function has continued in 2021 with key hirings, including an MD Research Physician, an experienced Research Scientist and an experienced Clinical Trial Manager to strengthen the support to clinical development of NMS molecules.

In 2021, we also hired an experienced Quality Assurance (QA) manager as Head a new QA function, reporting to NMS s.r.l. CEO. The QA function will be responsible for implementing and leading all Quality Management System programs and assuring compliance with all relevant local and international quality and industry regulatory guidelines as they pertain to Company product candidates and medicinal product development processes. It will, also, oversee that functional departments and project teams implement systems and processes that meet applicable legal, regulatory and ethical obligations and standards.

Furthermore, in 2021 we continued to consolidate the new "Global Alliances" (GA) function in order to support clinical development of NMS projects, by building a network of KOLs (Key Opinion Leaderds) and potential PIs (Principal Investigators) in US and Europe, to promote and facilitate collaborations between NMS and the academic or industrial world, identify and to coordinate external opportunities as well as providing business intelligence on internal projects and out-licensed products.

During 2021, we also continued to expand the use of external contract research organisations (CROs) to accomplish services for NMS Discovery as well as for GCD, in order to complement and reinforce internal capacities and capabilities.

In 2021, we completed relocation of Biotechnology Labs and personnel from Bdg 71 and the Discovery function is now consolidated in Bdg 75.In addition, discovery competences were augmented and refreshed through the hiring of several new young scientists across all functions.

The pipeline progress in 2021 of the outlicensed products as well as the most advanced NMS proprietary projects is described below.

In 2021 encorafenib (BRAFTOVI), and entrectinib (ROZLYTREK) have initiated new trials in different clinical settings, while the increasing global sales in already approved global indications continue to generate royalties for NMS.

The NMS internal clinical pipeline has been advancing significantly, with NMS-088 (FLT3 inhibitor) and NMS-153 (MPS1 inhibitor) progressing toward the end of Phase I and identification of RP2D with early objective observation of efficacy for both



compounds. Both projects should start Phase II by the second half of 2022. Also, NMS-293 (PARP inhibitor) has progressed through Phase I dose escalation after the implementation of a new BID dosing regimen and is foreseen to start the expansion phase in selected cohorts in 2022. New combination studies were additionally started for NMS-088 and NMS-293, in order to maximize the chance of success of these molecules. In 2021, NMS-812, a proprietary PERK inhibitor with potential for First in Class, already approved to start clinical development in US, also obtained authorization in EU and should start enrolling in Italy/US in Q1 2022. The dual IDH1/2 inhibitor NMS-173 was also advanced towards initiation of clinical development, which should occur in 2022. Finally, the CDC7 inhibitor, NMS-341, initiated GLP enabling studies and the remaining preclinical pipeline also progressed significantly, including the opening of a new discovery project.

#### 4.2 Outlicensed products

#### Encorafenib (BRAFTOVI™)

Encorafenib (BRAFTOVI ™) is a B-Raf inhibitor which was the object of an NMS licensing agreement of enabling IP rights for commercialization, in return for milestones and royalties, made originally with Novartis. Encorafenib is currently commercialized by Pfizer, Pierre-Fabre and Ono. It is approved in major markets in combination with binimetinib for the treatment of patients with unresectable metastatic melanoma with B-Raf mutations and in combination with cetuximab in B-Raf mutant pre-treated colorectal (CRC) patients. NMS receives revenues from global sales of encorafenib in B-Raf mutant metastatic melanoma, as well as in 2nd/3rd line CRC metastatic settings.

Pfizer is continuing to invest in the development of encorafenib combinations in different solid tumors. In particular, in 2021 Pfizer started two Phase III trials in CRC and in melanoma. The BREAKWATER study will compare encorafenib in combination with cetuximab +/- chemotherapy to standard of care in first line BRAF V600E mutated CRC, in order to potentially validate encorafenib as a best in class therapy for B-Raf driven CRC. The STARBOARD study will compare the triplet encorafenib plus binimetinib plus pembrolizumab to placebo plus pembrolizumab in patients with metastatic or unresectable locally advanced BRAF V600E/K mutation-positive melanoma.

In mid-2022 key pivotal readouts of the phase 2 PHAROS trial assessing the activity/safety of encorafenib plus binimetinib in patients with metastatic BRAFV600-mutant Non-Small Cell Lung Cancer (NSCLC) will be available. This study



may lead to a new indication for encorafenib, NSCLC Braf-mut, eventually increasing the royalty stream.

#### Entrectinib (ROZLYTREK™)

Entrectinib is a Ros1, Trk and Alk inhibitor invented and initially developed into Phase I by NMS, then licensed in 2013 to Ignyta (San Diego, CA, USA), which was acquired by Roche in 2017. In 2018 Roche sublicensed to its subsidiary, Chugai Pharmaceutical Co. the exclusive entrectinib rights for Japan. In 2019 entrectinib received two independent marketing approvals in the US: TRK-mutant tumors (agnostic label), as well as ROS1 mutant NSCLC.

In 2020 entrectinib was also approved for both TRK and ROS1 indications in Europe and in other countries, including Japan. These approvals triggered milestone payments in 2020 and contribute to the royalties stream.

In November 2021, Roche started a Phase III study to compare the efficacy and safety of entrectinib vs crizotinib in in first line patients with advanced or metastatic ROS1 mutant NSCLC with and without CNS metastases, potentially validating entrectinib as best in class treatment for this indication.

Other clinical trials were ongoing in 2021, investigating additional settings, including an agnostic ROS indication, potentially triggering an additional milestone.

In September 2021, the Italian Medicines Agency (AIFA) approved the reimbursement of entrectinib for both indications: adult and pediatric population with NTRK fusion-positive solid tumors (tissue agnostic indication) and adult patients with ROS1-positive metastatic NSCLC.

In November 2021, entrectinib won the Prix Galien Italia 2021 award as an antitumor therapy with agnostic indication in the category of chemically synthesized drugs, underlining the innovative nature of entrectinib.

#### Milciclib (PHA-848125/TZLS-201)

Milciclib is an orally available pan-cyclin dependent kinases (CDKs) inhibitor as well as of other selected protein kinases responsible for controlling tumor cell growth and proliferation.

It was invented and initially developed by NMS, then out-licensed in 2015 to the UK biotechnology company Tiziana Life Sciences (TLSA), quoted in London and at NASDAQ, which is developing the drug mainly in hepatocellular carcinoma (HCC).

In September 2021, Tiziana Life Sciences announced that it had executed an agreement with Takanawa Japan for a strategic business development plan to



Identify a clinical partner in Japan and other Asian countries for further clinical development of Milciclib in HCC.

#### Onvansertinib (NMS-937/ PCM-075)

Onvansertib is a 3rd generation, first in class, orally available, potent and highly selective inhibitor of the PLK1 kinase, a master regulator of mitotic progression which is overexpressed and activated in proliferating cancer cells.

The drug was invented and developed into Phase I by NMS, then licensed in 2017 to the US Biotech Trovagene, which in 2020 became Cardiff Oncology.

Clinical development is currently ongoing with promising results in Phase I/II studies in combination, including:

- Phase Ib/II study with FOLFIRI/bevacizumab in metastatic KRAS mut CRC
- Phase II study with abiraterone and prednisone in metastatic castration resistant prostate cancer (mCRPC),

Phase II study with nanoliposomal Irinotecan and 5-FU in Metastatic pancreatic ductal adenocarcinoma (PDAC).

The lead program is the metastatic Kras mut CRC, for which promising preliminary data have been presented at ASCO GI in January 2022. A follow-up Phase III study is planned to start in mid 2022, which would trigger a development milestone for NMS. Phase II data release from the mCRPC and PDAC studies is also expected by mid 2022.

At the end of 2021 Cardiff Oncology received \$15 Million Equity Investment from Pfizer with the aim to support its clinical development programs. In January 2022 Tod Smeal, who previously served as CSO of Cancer Biology at Eli Lilly and as director of Pfizer Oncology Research, was appointed as Cardiff Oncology CSO.

#### IDH follow on

IDH1 and IDH2 are metabolic enzymes frequently mutated in acute myeloid leukemias, in cholangiocarcinomas, sarcomas and gliomas, and with lower frequencies also in other solid tumors. The mutation of these enzymes alters their biological function by inducing the production of an active oncometabolite. NMS is pursuing the development of a dual IDH1/IDH2 inhibitor (see below).

In 2019, an agreement was made with Nanjing Hicin Pharmaceutical Co. Ltd a Shenzhen-listed Chinese firm. to deliver an IDH inhibitor distinct from the molecule selected for development by NMS. Activities performed under this agreement resulted in the successful identification of a candidate molecule which in 2021 was accepted as PC by Hicin, which triggered the corresponding milestone payment.



#### **Nuovo Target**

This enzyme is involved in the repair of DNA damage that arises during the replication process. It was identified and validated in-house by NMS as a highly innovative anticancer target in selected tumors, with potential for development of a First in class inhibitor. At the end of 2018, an agreement was signed with Merck KGaA, which acquired the rights to the inhibitors of the target against an upfront payment, followed by progress milestones and future royalties on revenues. Under the agreement, preclinical research activities are performed at NMS in collaboration with Merck.

In 2020, the DPHO (Hit to Lead) transition milestone was achieved, triggering a milestone payment. During 2021, significant progress has been made towards the identification of potent compounds with acceptable in vivo PK/ADME properties. Activities will continue with the ultimate goal to identify a clinical candidate (PC).

#### 4.3 NMS internal product pipeline

#### NMS-153 (MPS1 inhibitor)

This molecule is an inhibitor of MPS1, a kinase that plays a fundamental role in the control of chromosome separation during cell division, a mechanism relevant for tumor growth. The molecule has potential for First-in-Class. Based on preclinical profile and previous Phase I clinical data in solid tumors, NMS is currently developing NMS-153 in a Phase I-II study in hepatocellular carcinoma (HCC), which started in Italy in Q4 2020.

During 2021, the molecule was advanced through the Phase I portion of the study with promising signs of efficacy and a manageable safety profile. Establishment of the RP2D is currently foreseen in Q2 2022, which will allow transition into Phase II during the year. In 2021 the study was approved also by the Spanish regulatory authorities and the study is already recruiting in Spain.

#### NMS-088 (FLT3, KIT, CSF1R inhibitor)

NMS-088 is a potent inhibitor of FLT3, KIT and CSF1R kinases. Activating mutations of FLT3 are involved in the pathogenesis of about 30% of acute myeloid leukemia (AML), while KIT mutations are present in a small subset of AMLs and are the main drivers of GIST gastrointestinal tumors. Furthermore, there is a rationale for use of the molecule in Chronic Myelomonocytic Leukemia (CMML) on the basis of the observed effects of CSF1R inhibition, a highly expressed and activated target in this type of tumor. In preclinical studies the drug is the most active among the FLT3



comparators tested, also in the presence of the gatekeeper mutation of resistance observed after treatment with the other FLT3 inhibitors.

Based on these observations, in 2019 a Phase I/II study in relapsed/refractory AML and CMML was initiated in Italy, encompassing a Phase I dose escalation and a Phase II part comprising a cohort of AML FLT3 mutated patients and a cohort of patients with CMML.

In 2021, the project successfully advanced in Phase I through multiple dose levels, due to its extremely favourable safety profile, with early observation of efficacy, including complete responses (CRi) in FLT3 mutated patients. In 2021 to accelerate enrolment the study was expanded to include Spain, where a leading site at international level is already recruiting. Establishment of the RP2D is currently foreseen in Q2 2022.

Based on these promising results, a second study was planned in 2021 in combination with azacitine, a SOC agent for AML, which is expected to start in Q1-2 2022.

#### NSM-293 (PARP inhibitor)

PARP inhibition is clinically effective in patients with defects in the BRCA genes, due to the simultaneous impairment of two complementary DNA repair pathways.

NMS-293 is a novel PARP inhibitor that differentiates from other approved or advanced molecules for its PARP1 selectivity vs other PARP family members and low DNA trapping, both features potentially linked to lower haematological toxicity and higher potential for combination with other drugs. In addition, it also has a superior ability to penetrate the blood brain barrier, a characteristic enabling its utilization in CNS tumors and brain metastases.

In 2019, a Phase I single agent first-in-human study was initiated in patients with solid tumors, comprising a dose escalation, followed by a dose-expansion enrolling patients with different BRCA mutated tumors. This study was initiated in US and Italy and in 2021 it also achieved regulatory approval from Chinese health authority (NMPA), making this NMS's first truly global clinical trial. During 2021, a BID dosing regimen was introduced in the dose escalation which is approaching preclinically efficacious exposures with confirmation of dose-dependent biomarker modulation in treated patients. The RP2D with this schedule is currently foreseen in Q3 2022, which will trigger the transition to the dose expansion phase of the study.

The high brain penetration observed for NMS-293 in preclinical studies and the clinical safety profile of the molecule provide a strong rationale for investigating the potential efficacy of this agent against CNS tumors in combination with SOC. For



this reason, in 2021 a second global study investigating combination of NMS-293 with temozolomide in glioma was initiated and is currently recruiting in US and EU. IND approval of the study in China was also obtained in 2021.

In 2021 a major European pharma has expressed interest in the molecule and business discussions on potential out-licensing of the molecule are ongoing.

#### NMS-812 (PERK inhibitor)

PERK is a kinase that plays a fundamental role in the regulation of protein production and degradation, which is particularly important for the survival of tumors that produce and secrete high amounts of proteins, such as antibody-secreting multiple myeloma (MM). PERK inhibition induces death of MM cancer cells due to proteotoxicity in preclinical studies.

NMS-812 is an extremely potent PERK inhibitor with good efficacy and tolerability in MM models, also in combination with standards of care, with potential for first in class.

A Phase I clinical study of the compound in the indication of relapsed/refractory multiple myeloma as single agent and in combination was approved by FDA in late 2020 and in Europe in 2021. The study is expected to start enrolling in Q1 2022 in Italy and in US.

#### NMS-173 (IDH1/2 inhibitor)

IDH1 and IDH2 are metabolic enzymes frequently mutated in acute myeloid leukemia, cholangiocarcinomas, sarcomas and gliomas, and with lower frequencies also in other solid tumors. The mutation of these enzymes alters their biological function by inducing the production of an active oncometabolite, 2-hyroxyglutarate (2HG).

NMS-173 is a proprietary molecule able to potently down modulate the 2HG oncometabolite both in vitro and in vivo, with good tolerability and different/improved features with respect to first generation IDH inhibitors, which was selected as Product Candidate (PC) at the end of 2019. NMS-173 has a good ADME and toxicology profile and, differently from advanced competitors, is a potent dual inhibitor of mutant IDH 1 and IDH2, with superior in vivo activity against tumor models, including cholangiocarcinoma.

IND enabling studies were initiated in 2020 and completed in 2021. Authorization to start a Phase I study in selected IDH mutant tumor types was obtained in US in 2021, with several KOL/centers of excellence involved in the trial, and it is currently foreseen in EU in Q1 2022.



#### NMS-341 (CDC7 Inhibitor)

NMS has contributed to establish CDC7 kinase as an anticancer target due to its role in DNA replication, DNA damage response and repair and other intracellular processes.

During 2020, NMS-341, an orally available proprietary compound, with potential for "First in class" was identified as preclinical candidate (PC). NMS-341 has subnanomolar activity against CDC7, acceptable ADMET properties and efficacy in vivo against different tumor models, as single agent and in combination with a range of standard care agents, During 2021, GLP tox studies were performed in rat. Execution of the studies in NHP was delayed due to a wwide general shortage, which required the identification of an outsourcing partner for this activity, resulting in a study that was initiated externally in Jan 2022. Furthermore, identification of a suitable oral formulation for clinical studies by NPM has been unsuccessful and will require identification of an external provider, which is currently ongoing.

#### NMS-963 (inibitore SYK)

SYK is a cytoplasmic tyrosine kinase that plays a key role in immunoreceptor signalling, with preclinical and clinical evidence indicating that it is a potential therapeutic target in several haematological oncology indications, as well as in certain autoimmune diseases.

In 2020, a Syk inhibitor Product Candidate (PC), NMS-963 was identified, with low nanomolar biochemical potency on target, excellent selectivity vs other kinase, potent antiproliferative activity against SYK-dependent cell lines and efficacy both as single agent and in combination with standard of care agents in diverse tumor models of hematological diseases. The candidate possesses good ADME/PK and exploratory tolerability profile and has potential for First/Best in Class. During 2021 GLP toxicity studies were conducted in rat and in dog, which required additional studies to investigate unexpected toxicities. API production has been put on hold, pending further investigation of the therapeutic window. The program may eventually be considered as an outlicensing opportunity.

#### NMS-338 (RET inhibitor)

RET kinase activating mutations are present in about 50% of sporadic cases of medullary thyroid tumors, and in lower percentages in papillary thyroid tumors, lung and colorectal tumors and other solid tumors and leukemias. NMS-338 is a very potent and efficacious RET inhibitor, active also on the recently identified solvent-front mutation G810, a resistance mechanism to the approved RET inhibitors



selpercatinib and pralsetinib. Due to serious safety concerns emerging during GLP tox studies, it was decided to abandon internal development of the drug in favour of an out-licensing approach. In 2021, a possible partnership was explored without positive outcome, efforts will continue to seek partners for outlicensing.

#### 4.4 Other preclinical programs

#### Target 1

This target is a family of growth factor receptor kinases, which are ofen activated in different tumors. In 2019, NMS identified a chemical series of covalent inhibitors, binding with an unconventional mode within the ATP pocket and active against two members of the Target kinase family. Initial compounds also possessed preliminary efficacy in target-dependent models and potential for activity against resistance mutants. Based on these data, the project was transitioned into Lead Optimization. Activities performed in 2021 led to the identification of Lead compounds with preferential activity against one family member kinase in particular. However the growing external competition on this project, with several molecules in clinical trials within a limited indication setting, would require for NMS inhibitors to demonstrate improved biochemical and biological potency, together with improved ADME properties. A focused chemical expansion plan has been established, and a stop/go decision will be taken within early 2022. The program may eventually be considered as an outlicensing opportunity.

#### Target 2

This is a kinase involved in immune regulation, including regulation of antitumor responses. Both external and internal data provide evidence that inhibition of this target result in enhancement of the host antitumor immune response. During 2021 the project advanced in the Lead optimisation phase and a promising early candidate has recently been identified which possesses promising in vitro/vivo properties, comprising biochemical potency and selectivity, favourable PK/ADME properties including oral availability in the mouse, and both single agent and combination (with anti-PD-L1 therapy) antitumor activity against a murine syngeneic tumor model. Competition on the target is growing rapidly, but is still limited, with the most advanced competitors having recently entered in Phase I trials. NMS still has potential for First-in-Class in this "hot" area of Oncology drug development, comprising multiple therapeutic opportunities for clinical application and this target



is therefore considered as a high priority program within the general early/middle pipeline portfolio. Achievement of PC is expected within 2022.

#### Target 3

This is a kinase, currently unexploited at the pharmaceutical level, which regulates RNA splice variation. Target identification/validation studies conducted at NMS demonstrated that downregulation of this target results in inhibition of cell proliferation through multiple mechanisms which include induction of apoptosis through downregulation of the anti-apoptotic protein MCL1. No inhibitors of this kinase are described to date, and excellent opportunity for this target therefore exists for First-in-Class. Drug discovery efforts conducted at NMS have resulted in the identification of potent and selective ATP-competitive inhibitors which recapitulate the mechanisms of action observed during siRNA target validation studies and which broadly inhibit tumor cell proliferation. The most promising inhibitors identified have shown in vitro and in vivo antitumor efficacy but lack oral availability. During 2021, intense optimisation efforts have been made to identify orally available prodrugs of the lead molecule, but these have been unsuccessful. During 2022, efforts will be focussed towards further investigation of sensitive tumor indications for development of the lead compound as an iv formulation and potential drug combinations, with the aim of achieving a PC within the course of the year.

#### **New Projects and Target ID**

know-how of NMS in the field The strong tradition and target identification/validation and discovery of innovative drug candidates continues and has resulted in the progression during 2021 of two early hit-to-lead programs which are expected to enter into Lead Optimisation within 2022. Beyond this, target identification efforts continue in the areas of inflammation/immunoncology, DNA damage, tumor metabolism and oncogene signalling. These efforts, which capitalise upon NMS's proven know-how, most notably the Kinase Platform, along with our drug conjugates platform and further technology areas which are currently being potentiated, continue to yield a steady flow of innovative drug discovery initiatives and candidate targets, with around three new projects expected to be opened within the course of the year 2022.

#### The ADC platform

An "Antibody-Drug Conjugate" (ADC) is a molecule composed of a cytotoxic conjugated via a linker to an antibody that recognizes a tumor-specific antigen and



allows to selectively deliver the cytotoxin to the tumor, sparing the healthy tissue and thus increasing the therapeutic window. The approved/most advanced ADCs are based on different antibodies conjugated to a few cytotoxic drug. NMS has leveraged in house expertise on cytotoxics to develop an innovative and proprietary chemical class of thienoindole molecules amenable to conjugation with antibodies, with different mechanisms of action with respect to the most used toxins. In 2021 a second, distinct and innovative chemical class suitable for ADC development was identified and preliminary IP has been deposited.

In 2021, collaborations with third parties were continued as part of exploratory agreements for possible joint development of new ADCs: these included exploratory collaborations with new potential partners in China, where some key leaders in the sector are located, which are still ongoing. In 2021 to maximize the chances of success of the platform it was decided to explore the possibility to initiate development of a proprietary ADC which could be developed in the clinic with an external partner. To the same, an interesting novel tumor antigen has been identified and exploratory studies are ongoing.

#### 5. HUMAN RESOURCES AND INDUSTRIAL RELATIONS

The Company recognizes that human resources are a key factor for its activities and therefore the motivation and commitment of its employees are considered crucial elements for the achievement of the Company's objectives.

In this context, human resources activities continued to be focused on developing skills (also through the introduction of new resources), improving the wellbeing of employees, increasing the efficiency of organizational processes, ensuring the personnel costs optimization in order to enhance the Company's competitiveness against the major market players.

In the early months of 2020, following the merger that took place on December 31, 2019 between Nerviano Medical Sciences S.r.l and Clioss S.r.l., the Company defined the new organizational structure and the needs in terms of new skills to be implemented for the new Global Clinical Development organization.

During the year 2021, Nerviano Medical Sciences S.r.l., constantly, monitored the evolution of the pandemic, taking measures to protect the health of its employees. The closing year, as already happened in 2020, has been strongly influenced by the COVID-19 pandemic.

The new waves of infections related to the pandemic emergency and the spread of new variants of the virus have determined the need for the government to



implement strong restriction measures at national and local level despite the progressive consolidation of the vaccination campaign.

During the month of July 2021, the extension of the state of emergency in Italy until December 31, 2021 was approved (then further extended until March 31, 2022) and subsequently introduced the obligatory green pass (vaccination certificate) for access to workplaces.

In this context, Nerviano Medical Sciences S.r.l. has, constantly, continued to manage the COVID-19 emergency by implementing and enforcing specific safety protocols, in compliance with governmental provisions, in collaboration with the Competent Physician, the RSPP (Prevention and Protection Service Managers) and the RLS (Workers' Safety Representatives). A primary aim of the Company and of the entire NMS Group has been to guarantee its employees a suitable working environment in order to protect the health and safety of personnel and to preserve production capacity and operational continuity, limiting the risk of spreading the infection as much as possible. To this end, the monitoring and prevention system, already introduced during the year 2020, has been kept in place to ensure the maximum safety of activities on campus, providing for specific actions such as:

- > The management of the Competent Physician for the return of personnel showing flu symptoms or returning from sick leave,
- > The provision of swabs based on the assessment of the Competent Physician,
- > Distribution of masks.
- > Sanitization of work environments and common areas,
- > Incentive to use smart-working mode (where in line with the activities carried out).

As of October 15, 2021, in compliance with the provisions of Decree-Law 127/2021, the Company has adopted a system for detecting the green pass possession of its employees and all those (consultants, guests) who have access to the Company site, through the installation at the site entrance of special readers that allow access only in case of possession of a valid green pass. Finally, the Company has identified resources to carry out additional sample checks on vaccination certificates in the workplace.

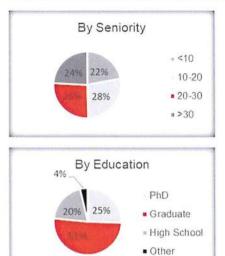
The Company extended the skin cancer prevention campaign for the year 2021 as part of its employee health protection project.

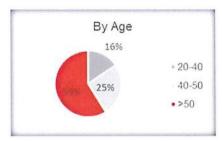
At December 31, 2021 the number of Nerviano Medical Sciences' employees is 141.



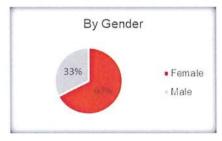
The average age and seniority of employees demonstrate the Company's commitment to retain its employees, key skills and professionalism developed over time, with – at the same time – some new hiring of young resources.

Detail of Nerviano Medical Sciences employees at 31/12/2021:





In Nerviano Medical Sciences, the presence of women at different levels of responsibility shows the Company's focus on equal opportunities. The composition of the Company's population is shown in the graph below.



Also for 2021, the Company has confirmed its collaboration with a number of Italian universities, with which it has had agreements in place for years to host thesis candidates and interns in order to exchange knowledge and create synergies with the academic world.

#### 6. <u>INVESTMENTS</u>

During the year, investments were made for a total amount of 532 thousand Euros, mostly for the benefit of the Chemistry, Biology and Biotechnology departments. We point out in particular for the benefit of the Chemistry department:

 the purchase of an automatic system for weighing and dissolving samples from the compound collection (195 thousand Euros),



• the purchase of a system for the analysis and processing of biological and analytical data (167 thousand Euros).

As regards the Biology department we point out the purchase of a low-flow liquid chromatography system (71 thousand Euros).

Moreover, the registration of the Nerviano Medical Sciences S.r.l. brand in various European and Asian countries was carried out for 19 thousand Euros.

#### 7. PRIVACY AND PERSONAL DATA PROTECTION

Nerviano Medical Sciences S.r.l., as owner of the processing of data, including sensitive data of its employees/co-workers, has transferred the relative processing operations to the parent company NMS Group S.p.A.

As far as GDPR compliance is concerned, the Company has been involved in commercial relations with its customers, who during contractual negotiations have requested the assumption of certain obligations on the part of the Company in terms of guarantees and safeguards to ensure that data processing is carried out in line with the principles of EU Regulation no. 679/2016.

#### 8. CORPORATE CRIMINAL LIABILITY (Italian Legislative Decree 231/01)

Nerviano Medical Sciences S.r.l. is governed by the "Organization, Management and Control Model" provided for in Article 6 of Legislative Decree 231/2001 on the "Discipline of the Administrative Responsibility of Legal Persons" which expresses the commitments and ethical responsibilities in the conduct of business activities undertaken by directors and employees.

The Model was introduced in 2012 and revised in 2016 and finally, later in 2018-19. The e-learning training on the current Model for all employees and collaborators started at the end of 2020 and was completed in 2021.

#### INFORMATION ON THE PROTECTION OF HEALTH AND SAFETY IN THE WORKPLACE

Nerviano Medical Sciences S.r.l. is committed to promoting a culture of safety and health in the workplace. In 2021, it implemented the reorganization of the Environmental, Health and Safety (EHS) area and the introduction of the new figure of the EHS Manager, aimed at controlling and monitoring all those activities with a significant environmental impact or that most expose workers to risks and to ensure that management and environmental parameters are always administered in the correct way, guaranteeing continuity of operations.

Company processes are managed in compliance with current regulations on health and safety at work and the environment in accordance with criteria of transparency.



No non-conformities incidents or significant observations were noted during the year. Peculiarity of the Company is the synthesis of new molecules, for which it is expected to be managed in accordance with REACH and CLP regulations, as far as applicable, and to be handled under safe conditions for both workers and the environment. In further detail, we would like to list the activities that have positively contributed to promoting and reinforcing, among all personnel, a sensitivity to environmental protection, safety in the workplace and aimed at strengthening awareness of the particular professional activities carried out within the Group:

- Updating and disseminating NMS Group EHS procedures and issuing new procedures to ensure greater coverage of environmental and safety aspects,
- Updating and issuing new Risk Assessment Documents,
- Inspections/Audits of work environments and systematic management of corrective and improvement actions through the exchange of reports between the EHS department and the relevant internal figures,
- Mapping and census activities of Individual Protection Devices (PPE) and Collective Protection Devices (CPD) aimed at the optimization of resources and the improvement of their management according to the law,
- Increase internal legislative compliance monitoring tools by periodically checking thematic EHS checklists,
- Introduction of periodic monthly meetings with the figures responsible for ensuring the maintenance of EHS standards within the Company and in identifying possible actions to improve environmental and safety performance,
- Active worker participation in reporting, investigating and disseminating incidents and near misses,
- Collaboration with other corporate departments in charge of COVID-19 emergency management and regular updating of anti-contagious protocol,
- Specific environmental and safety training for employees.
- · Reorganization of the Emergency Team,
- Appointment of the Mobility Manager and drafting of the Homework Displacement Plan (Legislative Decree May 19, 2020, No. 34),
- Active participation in meetings with public bodies responsible for the verification and control of EHS activities, aimed at verifying the correct application of regulatory requirements, and/or for the improvement of internal management procedures,
- Reorganization of the Emergency Team,



- Start of procedure for decommissioning high activity sealed radioactive sources no longer in use,
- Reorganization of the collection system for waste assimilated to urban ones, which provides for greater involvement of the municipal Company and employees with benefits in both environmental and economic terms.

#### 9. COMPLIANCE

NMS Group S.p.A., the holding company of NMS, has set up a system of internal controls ("Internal Control System" or "ICS") consisting of activities, procedures, behavioural rules, service communications and organisational structures with the aim of monitoring the Group's risks, as better described and detailed in the general part of the Organisation, Management and Control Model of NMS Group adopted pursuant to Legislative Decree no. 231, June 8th, 2001.

As early as the second half of fiscal year 2019, on the initiative of the CEO then in office, the parent company, began a preparatory project for the redefinition and optimization of this control system, which until then existed embryonically in the internal organizational structure.

This project, which saw the subsidiaries of NMS Group, including Nerviano Medical Sciences S.r.l., supported by a leading management consulting Company, started from the comparison between the procedures "in place" at the time of the survey, with the most internationally recognized reference models for the establishment, updating, analysis and assessment of control systems with regard to both financial and non-financial reporting, generating an analysis report that would highlight any discrepancies ("Gap Analysis").

Current company controls were reviewed and analysed both at entity level (ELC - Entity Level Controls, i.e., those controls that operate across the board with respect to the reference entity, i.e., the individual company), and at process level (PLC - Process Level Controls) in order to verify the adequacy of the design and the effective operation. With a view to optimizing the ICS, it was also considered appropriate to introduce one or more organizational reference models for each company process, represented by RACI diagrams (an acronym for "Responsible, Accountable, Consulted, Informed"), which include for each activity indications of the roles and responsibilities of each team involved.

Throughout the year ended December 31, 2021, company management dedicated itself to pursuing an operational plan aimed at resolving the deficiencies highlighted



within the internally shared Gap Analysis documents, namely the Gap Report and the NMS Group Policy Framework.

In particular, the refinement work of the ICS took the form of the drafting of new or improved procedures with respect to those already existing, the consolidation of the principle of functional segregation of authorization, operating and control activities, as well as the implementation of additional controls - automated or not - that appear suitable for strengthening the control objectives relevant to the Group's business, the size of the Company and the context of the requirements and risks to be monitored.

With a view to giving new impetus to the growth in the level of maturity of the Internal Control System, as well as to further strengthening the Group's organizational structure, a new Compliance function was created in the second quarter of fiscal year 2021.

This function is responsible for the correct application and compliance with the reference regulatory framework, its consistent interpretation at Group level and the identification, assessment, prevention and monitoring of the Group's overall compliance risks. Actions aimed at providing the Group with new figures and/or new controls to assess the effectiveness of the Internal Control System in relation to the specific nature of the NMS Group and the risk profile assumed by the latter, as well as the definition of methodologies for measuring it, verifying compliance with the limits assigned to the various operational functions and controlling the consistency of the operations of the individual functions with the risk objectives assigned, cannot be excluded for the near future.

The ICS optimization project described above has been, and will be, appropriately shared with all the main players involved in its design and management (Boards of Directors or, in any case, top management bodies of Group companies, Boards of Statutory Auditors, Management, Supervisory Bodies pursuant to Legislative Decree no. 231/2001, etc.)

#### 10. ACCOUNTING OF RESEARCH AND DEVELOPMENT COST

The core activity of NMS S.r.l. is to find new therapeutic strategies to meet the needs of cancer patients, this applied research and development activity generates the largest part of the total costs incurred by the group.

For the current year, in compliance with the provisions of the regulations in force for the preparation of financial statements, the Management has not capitalized these costs, which are therefore fully expensed in the income statement.



#### 11. INFORMATION ON RISKS AND UNCERTAINTIES

Nerviano Medical Sciences S.r.l., given its specific field of activity, is subject to risks associated with external factors (typically related to clinical and preclinical development activities) and financial risks (liquidity risks, credit risk, interest rate risk and exchange rate risk).

#### RISKS ASSOCIATED WITH EXTERNAL FACTORS

#### 1. Risks associated with products undergoing clinical development

Company products undergoing clinical development, given the specific nature of this activity, could cause - during the trial phases - damages due to side effects, or prove to be ineffective in combating the target in question and/or not receiving the approvals from the competent bodies (national and international). The clinical trial could also be suspended at any stage of progress by decision of the Company or by the competent bodies, if it is believed that patients are exposed to high health risks. In particular, on a monthly basis, the Strategic Scientific Committee (SSC) (a meeting attended by all the heads of function of the same business unit, in addition to the research manager) assesses the progress of the work, the data and information received from the project monitors and, based on these, defines the strategies and, if necessary, the closure of the project. Finally, the Company, as required by current regulations, uses insurance policies with leading companies for each individual trial/country in which it operates.

#### 2. Risks associated with sector legislation

The nature of the activities carried out by Nerviano Medical Sciences S.r.l. subjects the Company to strict legislation, both nationally and internationally. All competent bodies (Ministry of Health – AIFA – EMEA – FDA or other similar bodies in other countries) governing the manufacturing and marketing activities provide, in order to obtain the necessary authorizations, for long and complex procedural processes, which could lead to delays in the initiation and conduct of clinical trials.

#### **FINANCIAL RISKS**

#### 1. Liquidity risk

Liquidity risk is the risk that the available financial resources may be insufficient to finance normal operations and to develop the Company's own research activities. The typical nature of the Company leads to a high incidence of operating costs (staff, services, purchase of laboratory materials, clinical trial costs) compared with the revenue dynamics. The liquidity necessary for the development of the Company's



activities is guaranteed by the recapitalization operations carried out by the owners during the various financial years, by direct loans from the shareholders or by the shareholders' guarantees on bank loans.

Liquidity risk is substantiated by the need to find adequate resources to finance the Group's operations, in addition to the need for an effective management of the short-term funding lines.

#### 2. Credit risk

Credit risk is the exposure to potential losses resulting from non-compliance with the obligations assumed by the counterparties. Outstanding receivables at the end of the financial year are mainly commercial credits from national and international biotech companies and major pharmaceutical groups. Credit risk is therefore considered low.

#### 3. Exchange rate fluctuation risk

The exposure of the Company to the risks of exchange rate fluctuations at December 31, 2021 is not relevant from a debtor point of view since there are no significant positions, while from a creditor point of view, the Company is exposed to the effect of the bank account in foreign currency with Banca Intesa and Banca Popolare di Sondrio. The trend in the Euro/Dollar exchange rate at the end of the year led the Company to have a negative impact of approximately 77 thousand Euros.

#### 4. Interest rate fluctuation risk

The Group uses external financial resources in the form of debt and uses the available liquidity in monetary and financial market instruments (e.g. bank deposits). All loans obtained from Nerviano Medical Sciences S.r.l. provide for variable interest rates. This risk is represented by the exposure of financial flows to interest rate fluctuations. The performance of interest rates is constantly monitored by the Management of Nerviano Medical Sciences S.r.l. which controls its effects on the forecast cash flows ready to carry out interventions to hedge this risk.

Pursuant to Article 2428, paragraph 3, point 6-bis, of the Italian Civil Code, it should be noted that the Group companies have not used or issued financial instruments relevant for the purposes of assessing of the equity and financial situation.



#### 12. BUSINESS OUTLOOK

Nerviano Medical Sciences S.r.l. has maintained its commitment to all the research activities currently underway for the 2021 financial year. For the 2022 financial year, in addition to the normal continuation of scientific activities in the preclinical area, the strategic objective of starting and/or continuing new clinical trials in humans on at least two oncological targets is confirmed. Management's plans presuppose a commitment to strengthen the composition of the capital of NMS Group companies in order to ensure business continuity and financial self-sufficiency in subsequent years. In this regard, reference should be made to the section on going concern in the Supplementary Notes to the financial statement.

#### 13. OTHER INFORMATIONS

Nerviano Medical Sciences S.r.l. has been subject to management and coordination by NMS Group S.p.A. in accordance with article 2497 of the Italian Civil Code since December 16, 2009.

The cost of remuneration for the members of the Board of Directors totals 202 thousand Euros, that for the members of the Board of Statutory Auditors amounts to 73 thousand Euros, and that for the independent auditors amounts to 93 thousand Euros.

NMS S.r.l. purchases services related to its corporate purpose from the Group companies Accelera S.r.l. and NerPharMa S.r.l., and purchases mainly administrative and maintenance services from the parent company and from the affiliate Simis S.r.l. the Company holds 10% of the shares in Consorzio Infra and carries out its entire activity at the site in Nerviano, Via L. Pasteur, 10.

Nerviano, May 30th, 2002

The Chairman and CEO

(Hugues Dolgos)

Nerviano Medical Sciences srl Viale L. Pasteur, 10 20014 Nerviano (MI)

P.IVA 04379750963



## Financial Statement at December 31, 2021 and Supplementary Notes



#### BALANCE SHEET - Assets

Euros)			Financial Year	Financial Year	Differences
	vables due fron	n shareholdere	2021	2020	
	assets	n shureholders		•	
	ntangible Fixed	Assets			
3		patent and intellectual property rights	249.381	157.957	91,424
4	)	licences trademarks and similar rights	91.475	79.191	12.284
6		fixed assets in progress and advances	167.232	184.888	(17.655
7)		other intangible fixed assets	1.934.999	2.244.999	(310.000
	otal		2.443.087	2.667.035	(223.948
	angible Fixed A				
1)		land and buildings			
2		plants and machinery	58.113	73.587 2.180.759	(15.474
3; 4;		industrial and commercial equipment other assets	2.012.113 69.162	88.835	(168.64)
5		fixed assets in progress and advances	4.252	1.108.248	(19.67)
	otal	Tixed dasets in progress and devances	2.143.640	3.451.429	(1.307.78
1.50	inancial fixed a	ssets	211401040	014011425	(11301114
1)		Equity investments	81.571.095	81.571.095	-
a)		Investments in subsidiaries	78.553.486	78.553.486	
		Simis S.r.l. investment	102.600.000	102.600.000	- 8
		Centro Ricerca life Lab Srl investment			
		Consorzio Infra investment	50.000	50.000	*
		Provision on investmens in subsidiaries	(24.096.514)	(24.096.514)	±1
d	l-bis)	Investements in other companies	3.017.609	3.017.609	
		Tiziana Life Sciences PLC investment	3.017.609	3.017.609	•
2		Receivables	688.934	688.934	-
a)	)	from subsidiaries	83.000	83.000	
		- due within the next year	83.000	83.000	-
20		- due beyond the next year			-
d	1)	from companies subject to the control of the parent company	605.934	605.934	
		- due within the next year	605.934	605.934	50
	otal	- due beyond the next year	82,260,029	82.260.029	
7.0	fixed assets		86.846.756	88.378.493	(1.531.73
	nt assets		80.840.750	66.376.433	(1.331.13
0.3737777	nventory		1.782.559	1.606.763	175.79
1)		subsidiary materials and consumables			
2		products in progess and finished products	-		*:
3		work in progress on order		2.00	
5	i)	advances to suppliers	1.782.559	1.606.763	175.79
II) C	rediti				
1) d	lue from clients	i —	3.868.583	3.799.856	68.72
		- due within the next year	3.868.583	3.799.856	68.72
		- due beyond the next year	-	-	-
2) d	lue from subsid		2.479.833	2.351.631	128.20
		- due within the next year	2.479.833	2.351.631	128.20
		- due beyond the next year			
4) d	lue from parent		9.852.556	5.212.606	4.639.95
		- due within the next year	9.852.556	5.212.606	4.639.95
5) d	lua fram cubeld	- due beyond the next year	1.855.793	966.538	000.05
3) u	lue from subsid	- esigibili entro l'esercizio successivo	1.855.793	966.538	889.25 <i>889.25</i>
		- esigibili oltre l'esercizio successivo		500.555	003.20
5 bits	ax credits	esignati ottre i esercizio successivo	10.258.987	7.938.303	2.320.68
0 0	ar or conto				
		- due within the next year	10.258.987	7.938.303	2,320.66
E 0: d	lus from others	- due beyond the next year	1.310.168	1.287.074	23.09
o qua	lue from others	- due within the next year	1.310.168	1.287.074	23.09
		- due beyond the next year	1.510.100	1.201.014	23.00
т	Total	- due beyond the next year	29.625.921	21.556.008	8.069.91
		that are not fixed assets		2,10001000	5.000.0
6		other securities	58.963	35.420	23.54
	Totale		58.963	35.420	23.54
	ash and cash e	quivalents			
1)		bank and post office deposits	2.086.897	18.156.429	(16.069.53
3		cash on hand	1.779	2.664	(88)
	Total		2.088.675	18.159.092	(16.070.41
Total	l current assets		33.556.118	41.357.283	(7.801.16
Accru	ued income and	l prepaid expenses			
	occrued income		93	582	(48
	orepaid expense		541.661	419.613	122.04
	nrenald evnen	ses and accrued income	541.754	420.195	121.55
Total	c brebaid exheir				

Nerviano Medical Sciences sri Viale L. Pasteur, 10 20014 Nerviano (MI) P.IVA 04379750963



#### BALANCE SHEET - Liabilities

in Euros	;)		Financial Year 2021	Financial Year 2020	Differences
1)	Net Equi	tv			
•	1)	Share capital	1.040.000	1.040.000	-
	II)	Quota premium reserve	28.094.746	28.094.746	-
	111)	Riserve di rivalutazione	-	-	-
	IV)	Legalreserve	7.385.663	7.385.663	-
	VI)	Other reserves	65.732.247	65.732.247	-
	VIII)	Profits (losses) carried forward	(53.112.643)	(42.945.636)	(10.167.007)
	IX)	Profit(loss) for the year	(13.900.579)	(10.167.007)	(3.733.572)
	Total Ne		35.239.434	49.140.013	(13.900.579)
)		ns for risks and charges			
	2)	for taxes			-
	4)	other	2.045.315	2.841.531	(796.216)
	7 mg (mg 100 mg 100 mg	ovisions for risks and charges	2.045.315	2.841.531	(796.216)
)	Employe Payable	e severance indemnity	2.055.812	1.955.335	100.476
))	3)	s payables to shareholders for loans	5.318.291	5.31 8.291	_
	3)	-due within the next year	5.318.291	5.318.291	-
		-due beyond the next year	-	-	-
	4)	payables due to banks	17.824.309	20.500.000	(2.675.691)
	35	-due within the nextyear	3.564.968	2.691.878	873.090
		-due beyond the next year	14.259.341	17.808.122	(3.548.781)
	5)	payables to other funders	7	27.809	(27.809)
		-due within the nextyear	-	27.809	(27.809)
		-due beyond the next year	₩	-	-
	6)	advances received from clients	392.385	392.385	-
		-due within the nextyear	392.385	392.385	-
		<ul> <li>due beyond the next year</li> </ul>	-		-
	7)	payables due to suppliers	6.1 53.31 3	7.660.273	(1.506.961)
		-due within the nextyear	6.153.313	7.660.273	(1.506.961)
		-due beyond the next year			
	9)	payables due to subsidiaries	1.188.280	8.264.918	(7.076.638
		-due within the next year	1.188.280	8.264.918	(7.076.638
		-due beyond the next year	20.750.000	7.812.030	31.938.249
	11)	payables due to parent companies	39.750.280 <i>39.198.089</i>	7.282.950	31.915.140
		of which by cash pooling -due within the nextyear	39.750.280	7.81 2.030	31.938.249
		-due beyond the next year	35.730.230	7.872.000	57.555.245
	11-bis)	payables due to subsidiaries	9.333.639	24.437.339	(15.103.700
	11 013)	-due within the next year	9.333.639	24.437.339	(15.103.700
		-due beyond the next year	-	177 (1881) (1897) (1897) (1897)	
	12)	taxes due	203.630	254.623	(50.993
		-due within the nextyear	203.630	254.623	(50.993
		-due beyond the next year	-	194	-
	13)	payables due to social security institutions	591.627	578.417	13.210
		-due within the next year	591.627	578.417	13.210
		-due beyond the next year	-	-	-
	14)	other payables	817.890	955.027	(137.136
		<ul> <li>due within the nextyear</li> </ul>	817.890	955.027	(137.136
		-due beyond the nextyear	-	-	_
	Total pa		81.573.643	76.201.112	5.372.531
)	Accrue	d liabilities and deferred charges	Speciment and		
		Accrued liabilities	30.424	17.979	12.445
	w. 4. 1	2) Deferred charges	-	17.070	12.445
	Totalac	crued liabilities and deferred charges	30.424	17.979	12.445

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#### Income Statement

Income St	tatement			
(in Euros)	<b>这种,是是这种种的。</b>	Financial Year 2021	Financial Year 2020	Differences
A) Value	of production			
1)	revenue from sales and services	10.484.029	23.115.931	(12.631.902)
5)	other revenue and income	10.143.533	6.515.173	3.628.360
Total	value of production	20.627.562	29.631.104	
	of production	20.627.562	25.631.104	(9.003.541)
6)	for primary,ancillary materials,consumables and goods	(1.290.196)	(4 024 022)	640.836
7)	costs for services		(1.931.032)	
8)	costs for use of third party goods	(28.315.657)	(25.681.573)	(2.634.083) 250.445
9)	staffcosts:	(1.851.184)	(2.101.629)	113.779
9)		(9.373.482)	(9.487.261)	
	-wages and salaries	(6.634.900)	(6.753.884)	118.984
	- social security contributions	(2.162.279)	(2.151.820)	(10.459)
	<ul> <li>severance indemnity</li> <li>other staff costs</li> </ul>	(545.888)	(516.775)	(29.114)
4.0\		(30.415)	(64.782)	34.367
10)	amortisations/depreciations and write-downs:	(2.038.604)	(1.588.933)	(449.671)
	-amortisations of intangible fixed assets	(41 0.01 4)	(372.831)	(37.183)
	- amortisations of intangible fixed assets	(1.628.589)	(1.216.101)	(41 2.488)
	- write-downs of fixed assets	-	7.	
102040	- write-downs of current assets' receivables		-	
11)	changes in inventory of raw materials	*	( <del>+</del> )	-
12)	risk provisions	-	(631.251)	631.251
14)	other operating expenses	(59.141)	(80.341)	21.200
	costs of production	(42.928.263)	(41.502.020)	(1.426.242)
	ence between value and cost of production (A-B)	(22.300.700)	(11.870.917)	(10.429.784)
	cial income and expenses			
15)	Income from investments	-		-
	a) From subsidiaries	•	-	
16)	other financial incomes:	268.386	789	267.596
	<ul> <li>a) from receivables entered in the fixed assets</li> </ul>	-	-	=
	b) from securities entered in the fixed assets	-	_	-
	c) from securities entered in the current assets	<u>.</u>	-	0
	d) income other than the above from third parties	268.386	789	267.596
	Others	268.386	789	267.596
17)	Interestand other financial expenses:	733.774	(322.509)	1.056.283
	s) utili Profits and losses of currency exchange	1.015.222	(1.184.843)	2.200.065
	financial income and expenses	2.017.381	(1.506,563)	3.523.944
	adjustments of financial assets			
18)	Revaluations	23.543	1.787	21.756
19)	write-downs	-	(99)	99
Total	value adjustment of financial assets	23.543	1.688	21.855
Resu	It before taxes	(20.259.777)	(13.375.792)	(6.883.984)
20)	Income tax for the year	6.359.198	3.208.785	3.150.412
	- prepaid taxes	1.5	-	273
	- deferred taxes	₩:	₩/	***
	-irap	20	<u>≅</u>	-
	-ires	6.205.682	3.210.281	2.995.401
	- tax adjustments of previous years	153.516	(1.496)	155.011
21)	Profit (loss) for the year	(13.900.579)	(10.167.007)	(3.733.572)

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#### **CASH FLOW STATEMENT**

#### CASH FLOW STATEMENT

(in Euro)

医多克尔氏试验检 医多种性性 医多种性神经炎 医克勒氏性 医神经 医外肠管 计	2021	2020
A. Cash flow generated from operating management		
Profit (loss) for the year	(13.900.579)	(10.167.007)
+ income tax	(6.359.198)	(3.208.785)
+ interests payable/(interests receivable)	(2.017,381)	1,506,563
- (dividends)	(2.57,1551)	-
+ capital losses	-	000
- capital gain from transfer of assets	2	_
Profit (loss) for the year before taxes, interests,		
= dividends and capital interests dividends and	(22,277,158)	(11.869.229)
capital gains/losses from transfer	and the second second	The state of the s
Adjustments for non-monetary elements that were		
not offset in the net working capital		
+ allocation to funds	545.888	1.148.026
+ amortisation/depreciation fixed assets	2.038.604	1.588.933
+ write-downs for impairment	•	99
+ Other adjustments for non-monetary elements	(23.543)	(3.072)
Financial flows prior to adjustments of NOWC	(19.716.209)	(9.135.243)
Changes in net working capital		
+ Decrease/(increase) inventory	(175.796)	(1.550.228)
+ Decrease/(increase) of receivables due from clients	(68.727)	(1.134.372)
- Decrease/(increase) of payables due to suppliers	(1.506.961)	1.260.045
+ Decrease/(increase) of accrued income and prepaid expenses	(121.559)	101.818
- Decrease/(increase) of accrued liabilities and deferred charges	12.445	(7.235)
- Other changes in net working capital	(23.948.593)	209.175
Financial flows following adjustments of NOWC	(45.525.400)	(10.256.042)
Other adjustments for non-monetary elements		
- Interests collected/(paid)	2.017.381	(1.506.563)
- (Income taxes paid)	3 <b>-</b>	-
- Dividends collected	-	(4)
+ (Use of provisions)	(1.241.627,92)	(1.124.614,09)
Financial flows following adjustments	(44.749.647)	(12.887.219)
Cash flows from operations	(44.749.647)	(12.887.219)
B. Financial flows from investment activities		
Investments in tangible and intangible fixed assets	(532.410)	(3.565.224)
Other financial assets		-
Equity investments		128.931
Dividends collected by the Subsidiaries	-	-
Changes from the sale of fixed assets		-
Financial flows from investment activities	(532.410)	(3.436.293)
C. Financial flows from investment activities		
Opening of new loans		5.500.000
Cash pooling	31.915.140	7.282.950
Spin-off reserve	=	183.976
Capital increase	2	-
Capital increase to subsidieries company	-	-
Loan repayments	(2.703.500)	(2.555.617)
		-
Divigends paid	29.211.640	10.411.308
Dividends paid  Financial flows from financing activities		
= Financial flows from financing activities	(16.070.417)	(5.912.204)
	(16.070.417) 18.159.092	(5.912.204) 24.071.296

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### ACCOUNTING PRINCIPALS FOR THE PREPARATION OF THE FINANCIAL STATEMENTS AT DECEMBER 31, 2021

The Supplementary Note constitutes an integral part of the financial statement as at December 31, 2021 and contains information required by Art. 2427 of the Italian Civil Code, which is in line with the regulation changes introduced by Italian Legislative Decree no. 139/15 and in compliance with the provisions of the accounting principle issued by the Italian GAAP.

In drawing up the financial statement, the principles indicated in Art. 2423 and subsequent of the Italian Civil Code have been complied with, as reformed by Italian Legislative Decree no. 139/15 in carrying out the European Directive 2013/34, and reference was made to the interpretations and integrations established by the Accounting Standards of Chartered Accountants and Accounting Experts and O.I.C documents (Italian GAAP).

The valuations of the individual balance sheet items were made based on the principle of prudence and with a view to going concern.

The Financial Statement for the period from 1/1/2021 to 31/12/2021 is composed by the Balance Sheet, the Income Statement, the Supplementary Notes and the Cash Flow Statement.

Income and charges were considered on an accrual basis independent of their financial manifestation; costs and revenue were considered pertinent although the same refer to events occurring subsequent to the date of the Financial Statement closure.

Moreover, Supplementary note provides information which are deemed essential to give a true and fair view of the economic - equity and financial situation of the Company.

At the end of the period, the Company is 100% controlled by NMS Group S.p.A.

#### **GOING CONCERN**

During the year 2021, the Group NMS, by which the company is held, continued to carry out its business. At consolidated level, the Group NMS closed the year with a total loss of EUR 28.3 million, with a positive net equity of EUR 39.7 million.

As already analyzed in the Notes to the Financial Statements 2020, the Consolidated Business Plan (2021-2025), approved on 4 June 2021, confirmed the main strategies set out since 2018 by the new ownership with the aim of enhancing the company's assets with particular attention to the intangible assets of Nerviano Medical Sciences S.r.l. (the so-called "pipeline") and the intention to consolidate the



reference markets in which the subsidiaries Accelera and NerPharMa operate, with a positive impact in terms of profitability and financial position.

This intention was not only confirmed, but also strengthened following in December 2021, the entry of a new private equity fund (PAG III Nemo Holding I Limited) into the shareholding structure of the parent company NMS Group S.p.A., which acquired the 90% majority stake held by the previous pool of Chinese investors.

Following the entry of the a new Group's shareholder, a new management team and a new CEO have been appointed. Hugues Dolgos, the new CEO, a manager with international experience in pharma companies and biotech, initiated a process of analysis of operational activities strengthened the structures. The inclusion of new strategic figures in Nerviano Medical Sciences S.r.l., including a Chief Medical Officer (CMO), with significant international experience in large pharmaceutical groups, and the definition of new professional figures such as the CSO (Chief Scientific Officer) and the GAL (Global Head of Assets Leadership) has the aim of strengthening the company's internal competencies with the aim of transforming it into a top-performing biotech company recognized worldwide.

Jointly, the subsidiaries Accelera S.r.l. and Nerpharma S.r.l. have started a phase of revision of their sales and production process (the so-called "transformation plan") to define new business strategies, both through the exploration of new markets in which to operate by creating new partnerships with international operators and a new commercial strategy, and to define a new sales strategy, also by revising the organization and production processes with the aim of recovering efficiency.

In order to provide financial support for the implementation of the Plan described above, the Board of Directors of the parent company NMS Group S.p.A., held on 24 May 2022, approved and signed a new loan agreement with the parent company Luxembourg Investment Company 240 S.a.r.l. for a total value of 61 million Euros, of which:

- ✓ 20 million Euros for the repayment of the bank loan signed between NMS Group S.p.A. and Bank of China maturing on 31 May 2022;
- ✓ 21 million Euros for the early termination of the shareholder loan received on 7 December 2021 and expiring on 1 June 2023 with the simultaneous stipulation of a new debt to the parent company of the same amount and nature;
- ✓ 20 million Euros for the business continuity.



This shareholder loan, bearing interest at 8.1%, will expire on 1 June 2023, by which date it must be repaid in full together with accrued interest.

In light of the above, the holding company NMS Group S.p.A. updated the Group's financial plan, confirming that the cash flows deriving from this new loan enable the Group's financial needs to be met at least until the end of the financial year 2022.

In the coming months, the Directors will evaluate new forms of capital/financial support to ensure the sustainability of the Group's business in the medium-long term.

As a result of this analysis, the Board of Directors of the parent company NMS Group S.p.A. believes that the shareholder loan ensures the business continuity of the holding company and the entire NMS Group in the foreseeable future and at least until 31 December 2022 and, therefore, allows for the preparation of the financial statements on a going concern basis as there are no significant uncertainties.

### **Accounting standards**

### B I) INTANGIBLE FIXED ASSETS

Intangible fixed assets are booked at the original purchase cost and amortized on a straight-line basis relevant to the period of expected future use. The rates used are proportional to a period not exceeding five years.

Costs for pure research applied relevant to the pre-clinical and clinical trial stages of Phase I and II of each product are recorded in the Income Statement for the period in which they are incurred.

In compliance with the new accounting standard OIC 9, if there is an impairment loss, regardless of the amortization already recorded in the balance sheet, the Company will estimate the recoverable amount of the fixed assets, that is accordingly written off.

The recoverable amount of an asset or cash generating unit is the higher between its value in use and its fair value, net of sales costs. An impairment loss is the decrease in value that expresses the recoverable amount of a fixed asset, determined with a long-term perspective, lower than its net accounting value.

The original value, net of the amortization that would have been calculated if no write-down had been booked, is recovered when the reasons for the value adjustment no longer exist.



Pursuant to art. 2427, sub. 3-bis of the Italian Civil Code, it is noted that the intangible fixed assets did not suffer any impairment losses, except for those relevant to amortizations.

### **B II) TANGIBLE FIXED ASSETS**

Tangible fixed assets are booked at purchase or production cost and the relevant depreciation was calculated on the basis of the residual useful life of the asset.

The purchase or production cost includes accessory charges and costs incurred for the amount reasonably attributable to the asset until the date of entry into operation of the same.

Fixed assets that, at the closing date of the financial year, were found to be of a lower value than that determined in accordance with the above principles were recorded at this lower value. However, pursuant to the art. 2427, sub. 3-bis of the Italian Civil Code, it is noted that, over the period, tangible fixed assets did not suffer any impairment losses, except for those relevant to depreciations. It is specified that the tangible fixed assets have never been subject to revaluation procedures pursuant to specific laws, and to re-evaluation processes carried out for other purposes.

Maintenance and repair costs with conservative effects are charged to the Income Statement for the period in which they were incurred on an accrual basis. Those of an incremental nature, in that they are aimed at extending the useful life of the asset or its technological adaptation, are attributed to the asset to which they refer to.

The cost of fixed assets with limited use over time is depreciated on a straight-line basis of the economic technical rates determined in relation to the residual useful life.

The following rates, which reflect the result of the technical depreciation schedules, were applied, since the same were considered representative of the effective deterioration.

The depreciation rates applied to the values of assets not fully depreciated existing as at December 31, 2021, unchanged compared to the previous year, are highlighted here below:



Asset class	% amort/dep
Buildings	5,50%
Temporary constructions	10,00%
Generie Systems	10,00%
Plant and machinery scarcely corrosive	12,00%
Waste water treatment	15,00%
Laboratory and Miscellaneous equipment	40,00%
Office fumishing and machinery	12,00%
Electronic machines	20,00%
Trucks	25,00%
Internal transport vehicle	20,00%

### Impairment loss

At each closing date of the financial year, the existence of indicators that indicate the probability that a fixed asset may have undergone impairment is assessed.

Should such indicators exist, goodwill, other intangible assets and tangible assets are subjected to an "impairment test" in order to verify that the recoverable value of such assets, defined as the higher value between the value in use and the fair value ("fair value") less costs to sell, is higher than their book value.

In the event that the recoverable amount is lower than the net book value, it is reported at the recoverable value, recognizing the loss in value, as a general rule, in the Profit and Loss under the item "Other write-downs of fixed assets". The original value is reinstated if the reasons for the impairment are no longer valid (with the exception of any write-downs made with regard to goodwill).

### **B III) FINANCIAL FIXED ASSETS**

The shareholding in the subsidiary Simis S.r.l. has been entered, as it is a long-term investment, under financial fixed assets. The shareholdings in subsidiaries are valued at cost. The Company reserves the right to carry out an impairment test at year-end to verify any losses in value.

### CI - 3 and 4) INVENTORY

Inventory of raw materials, semi-finished and finished products are evaluated at the lower value between the purchase or manufacturing cost and the estimated realizable value inferable from the market trend. Specifically, the purchase cost was used for materials of direct or indirect use purchased and used in the production cycle. The cost of production was, however, used for finished products or that are being obtained from the manufacturing process. For the determination of the purchase cost the price effectively paid, net of any commercial discounts, was taken into consideration.



For the cost of production, instead, other than the cost of materials used, as above defined, the directly and indirectly charged industrial costs were taken into consideration.

The obsolete warehouse inventory and slow turnaround are measured at their presumable realization value, for this purpose their value is adjusted by a provision for obsolescence.

### C II) RECEIVABLES

Receivables are recognized according to the amortized cost method, taking into consideration the time factor and the estimated realizable value. In particular, the initial value is represented by the nominal value of the credit, net of all premiums, discounts and rebates, and including any costs directly attributable to the transaction that generated the credit.

Transaction costs, any commission income and expenses and any difference between the initial value and the nominal value at maturity are included in the calculation of the amortized cost using the effective interest criterion.

The Company has chosen to use the optional exception provided by Legislative Decree no. 139/15, which introduced the criterion for the evaluation of the amortized cost to be used for the representation of receivables, payables and fixed assets represented by securities, which allows not to apply the amortized cost criterion for receivables, payables and fixed assets represented by securities registered in the 2015 balance.

Consequently, the positions that arose from January 1, 2016 have been valued using the amortized cost criterion, while the positions which arose prior to January 1, 2016 have been accounted for using the old rules.

Any estimates of losses are based on the analytical valuation of receivables that present risks of non-collectability.

### CIII) CURRENT FINANCIAL ASSETS

The shares held in Banca Popolare di Sondrio are recorded, given that they are not long-term investments, under current financial assets and valued at cost or, if lower, at market value.

### B) PROVISIONS FOR RISKS AND CHARGES

Provisions for risks and charges are set aside to cover losses or debts of a specific nature, certain or probable at the end of the financial year, but whose amount or



date of occurrence is uncertain. The provisions reflect the most reliable estimate on the basis of available information.

### C) EMPLOYEE SEVERANCE INDEMNITY (T.F.R.)

The provision represents that actual debt accrued towards all employees as at year-end and was calculated according to the provisions contained in Law no. 297 of May 29, 1982, in accordance with the national collective labour agreement and supplementary Company agreements. The provisions correspond to the total of individual indemnities accrued in favour of employees as at the date of the financial statements, net of advances paid, and is equal to what should have been paid thereto in the event of termination of the employment relationship as at that date.

### D) PAYABLES

Payables are recognized in the financial statements according to the amortized cost method, taking into consideration the time factor, and the estimated realizable value. In particular, the initial value is represented by the nominal value of the debt, net of all premiums, discounts and rebates, and including any costs directly attributable to the transaction that generated the debt.

Transaction costs, any commission income and expenses and any difference between the initial value and the nominal value at maturity are included in the calculation of the amortized cost using the effective interest criterion.

The Company has chosen to use the optional exception provided for by Legislative Decree no. 139/15, which introduced the criterion for the evaluation of the amortized cost to be used for the representation of receivables, payables and fixed assets represented by securities, which allows not to apply the amortized cost criterion for receivables, payables and fixed assets represented by securities registered in the 2015 balance. Consequently, the positions that arose from January 1, 2016 have been valued using the amortized cost criterion, while the positions which arose prior to January 1, 2016 have been accounted for using the old rules.

### E) ACCRUED LIABILITIES AND DEFERRED INCOME

The criteria for entering accruals and deferrals in the balance sheet were based on the principle of accrual and calculated in accordance with Art. 2424 bis 6 c., Italian Civil Code. These items include amounts attributable to the period that are due in subsequent periods or incurred before the end of the period but relate to subsequent periods. These items include only portions of economic items, common to several years, the size of which varies over time.

### REVENUES AND COSTS FOR THE YEAR

Costs and revenues are recorded in the financial statements on an accrual basis. Revenues from the sale of products were recognized at the time of transfer of ownership, which normally corresponds to delivery or shipment, whilst revenues from services were recognized based on the progress of works. Revenues and income, costs and charges relating to foreign currency transactions are determined at the exchange rate in effect on the date on which the transaction was performed.

### **TAXES**

The calculation of the tax burden and, as a result the relevant payable due to the tax authorities, is carried out on the basis of a realistic forecast of the taxes to be paid, in application of the applicable tax laws in force.

The Company has elected, together with Simis S.r.l., Accelera S.r.l. and NerPharMa S.r.l. to be subject to the National Tax Consolidation filed by the parent company NMS Group S.p.A. on October 27, 2017, for the three-year period 2017-2019 which was followed by a tacit renewal valid for the three-year period 2020-2022.

Regarding deferred taxes was applied the provision of the accounting standard OIC 25 "Accounting treatment of income taxes" for the determination and recognition of the advance and deferred taxes resulting from the temporary differences between the amounts recorded in the accounting values and the amounts recognized for tax purposes.

For the principle of prudence, any advance taxes are recorded only where a reasonable certainty exists for recovery of the same based on the results relevant for tax purposes expected for the following yearse.

### FOREIGN CURRENCY TRANSACTIONS

Receivables and payables originally expressed in foreign currency are booked in the financial statements using the spot exchange rate in force as at December 31, 202, the relevant profits and losses on exchange rates are charged to the Income Statement and any net profits are allocated to a specific non-distributable reserve until realization.

During the period no transactions were executed for the hedging of specific exchange risks relevant to commercial transactions with clients and suppliers.



### ANALYSIS OF THE ITEMS OF THE BALANCE SHEET AND INCOME 1

The most relevant items of the Balance Sheet and Income Statement are analyzed in the Supplementary Note in thousands of Euros and they are compared with the previous year's value.

The items in the Balance Sheet and Income Statement that do not appear have a zero balance.

### INFORMATION ON THE BALANCE SHEET

### **B.I - INTANGIBLE FIXED ASSETS**

Net intangible assets at December 31, 2021 amount to 2.443 thousand Euros. Changes are shown in the table below:

为其是有多种的	31/12/2020	Purchase	Transfer from assets under construction	Write-downs	Amortisations	31/12/2021
Patent and intellectual property rights	158	-	168		(77)	249
Licenses and projects software	158	4	168		(77)	249
License, brands and patents	79	19	17	-	(23)	91
Brands	79	19	17		(23)	91
Other immaterial assets	2.245	-			(310)	1.935
Goodwill	-	-		-		-
Intangible fixed assets under development	185	167	(185)	:=	1. <del>-</del> 1	167
Total						
A STATE OF THE STA	2.667	186	是可以是		(410)	2.443

for further details see paragraph 6 "INVESTMENTS" in the Directors' Report

### **B.II - TANGIBLE FIXED ASSETS**

Net tangible assets at December 31, 2021 amount to 2.144 thousand Euros. Depreciation was determined based on rates in line with the residual possibility of use of the assets. The transactions made during the year are summarized as follows:

		31/12	/2020									31/12	/2021	
	Historical	Revaluation	Amort Fund	Valuation	Puchases	Transfer from	Trans	sfer	A STATE OF	Revaluation	Historical	Revaluation	Amort Fund	Valuation
<b>医性性</b> 医二乙基	value	(write-downs)	Fund	at balance		assets under construction	Costs	Fund	Amortisation	(write-downs)	value	(write-downs)	Fund	at balance
Plants and machinery	11.692		(11.618)	73		-		-	(15)		11.692		(11.634)	56
General machinery	11.346		(11.273)	73		2	-	-	(15)	-	11.346		(11.289)	56
Machinery for slightly corrosive processing	339		(339)	0		90		20	-		339	2	(339)	-
Machinery for highly corrosive processing	2	190	(2)					80	(0)		2	94	(2)	10
Waste water treatments machinery	4		(4)			-		-			4	-	(4)	-
Industrial and commercial equipment	23.390		(21.210)	2.181	317	1.098	(1.469)	1.469	(1.583)		23.336	-	(21.324)	2.012
Laboratory equipments	23.390		(21.209)	2.181	317	1.098	(1.469)	1.469	(1.583)		23.336	2	(21.324)	2.012
Other assets	1,388	-	(1.298)	89	9	2	(7)	7	(30)		1,390		(1.321)	70
Transport vehicles	0		(0)			-				100	0	*	(0)	
Automotives	19		(19)			_		-			19		(19)	
Ordinary office furniture and machinery	269		(269)	1		-	-	-	(0)		269	-	(269)	
Office electors. Equip.	1.099		(1.010)	89	9	2	(7)	7	(30)	100	1.102		(1.032)	
Fixed assets in progress and advances	1.108			1.108	21	(1.099)	(26)	-	-		4	-	-	4
Fixed assets in progress and advances	1.108	-	- 4	1.108	21	(1.099)	(26)				4			4
Total	37.578		(34.125)	3.451	346	CONTRACTOR OF THE	(1.502)	1.476	(1.629)	Shirkly than	36.422	- 100 VIII W	(34.279)	2.144

<sup>&</sup>lt;sup>1</sup> Any increase or decrease of 1 unit is due to rounding.

X

The main difference compared to the value recorded at December 31, 2020 is due to the value of amortization and depreciation, amounting to 1.629 thousand Euros and investments made during the year amounting to 346 thousand Euros, details of which are provided in paragraph "6. Investments" in the Directors' report.

### **B.III - FINANCIAL FIXED ASSETS**

Financial fixed assets amount to 82.260 thousand Euros and are composed by investments and by financial receivables due from subsidiaries.

Equity investments amounted to 81.571 thousand Euros and are represented in the table below:

### investments in subsidiaries (value in Euros)

	Site	Net Equity	PN 31/12/2021	Profit (loss) for the period 31/12/2021	% ownership	Balance Value
Simis Sit	Viale Pasteur 10, 20014 Nerviano	50.000	54.607	222	100	78.503
Consorzio Infra in liquidazione Tতাহা	Viale Pasteur 10, 20014 Nerviano	100	558	(2)	10	50 78.553
Denomination		% ownership		shares value		Balance Value
Tiziana Life Sciences Ltd		4.233.616		0		3.01 8
					otal	81.571

Financial receivables amount to 689 thousand Euros and include receivables due from Simis S.r.l. (83 thousand Euros) and financial receivables due from the subsidiary company Accelera S.r.l. (606 thousand Euros).

	31/12/2021	Changes for the period	31/12/2020
Financial receivable from controlled	83	-	83
Financial receivable from subsidiary	606	-	606
Total	689 *	for -	689

Simis S.r.l. is the company that owns the real estate assets of the research center and that is specialized in the maintenance and management of real estate and scientific pharmaceutical and research facilities and equipment.

The book value at December 31, 2021 of the investment in Simis S.r.l. was equal to 78.503 thousand Euros net of a write-down of 24.097 thousand Euros.

Following the entry of a new investor into the NMS Group in March 2018, it had become necessary to perform, as required by international accounting standards, the calculation of the so-called "Purchase Price Allocation" (PPA), that is the process of assigning a "fair value" to all the major assets and liabilities acquired and within the same the consultant assigned a higher value to the industrial land and buildings held by the subsidiary Simis S.r.l. (net of the effect of deferred taxes) of approximately 24.828 thousand Euros before depreciation.

Considering the value of the Net equity of the company at December 31, 2021 and the higher value to be paid to land and buildings not stated in the subsidiary's financial statements, the Net Equity adjusted for the analysis of the impairment test is congruent compared with the carrying amount of the investment, taking into account



the fact that the appraisal on the full value of the industrial land and buildings was not updated as at December 31, 2021 and, in addition, that the subsidiary recorded a profit in 2021. Based on the forecasts of the subsidiary's financial performance in the following years, the subsidiary will continue this positive trend.

The item Investments in Other Companies, amounting to 3.018 thousand Euros, represents the possession of 4.233.616 shares in Tiziana Life Sciences Plc, acquired in 2015 following the licensing agreement, equivalent to approximately 2,18% of the company's capital. The shares, as provided for by the agreement, were recorded at a unit value of half a pound sterling, equal to approx 2.138 thousand of Pounds equivalent to approximately 3 million Euros, equal to the value reported in the agreement. The agreement also provides for success-based milestones equals to 35 million Dollars, plus royalties in case of sale of the product on the market. Tiziana shares, received as upfront fees, are not negotiable before the completion of at least one Phase II study.

The agreement, also, provides for Tiziana a call option, which can be exercised in the event of failure of Phase II of the Hepatocellular or Breast clinical trial, or if, after 5 years from the signing of the agreement, no phase II has been launched or in the event that Tiziana decides to abandon the research project for just cause. The repurchase price agreed in the event that Tiziana exercises the option in contractually established in a pound Sterling. Any dividends and other economic rights pertaining to such shares remain with NMS S.r.l. but give rise to the temporary deposit of the amounts in a restricted deposit that can only be exercised when the aforementioned call option is no longer valid.

The decision of the management of Nerviano Medical Sciences S.r.l. to accept Tiziana shares as upfront fees comes from the will to directly monitor the molecule development process, whilst maintaining a possibility of influencing the decision-making process and the intention to forge a strategic alliance with the Company, in addition to the belief that the development process may have a positive outcome.

As shareholder of Tiziana Life Sciences, the Company maintains the right to be constantly informed about the progress of the product development and marketing activities. It also maintains its right to vote in the Shareholders' Meetings in relation to the shares held and is a regular member (with at least two participants) of the Joint Development Committee, a committee with the purpose of overseeing, reviewing and coordinating the product development plan, including any amendment and/or change that should be decided upon for its clinical development and patent strategies The combination of these instruments allows the Company to protect its interests and safeguard the value of its shares.



It should be reminded that, a Phase II clinical trial refers to an assessment study of the drug on selected patient populations, in order to assess its efficacy and tolerability and to define its dosage. Phase II studies can also be divided into phase IIA (pilot study, often open-label with various doses, but with measurable results) and phase IIB (randomized parallel-group studies with broader case studies and compared with placebo). It is therefore necessary to specify that there is a risk which phase II studies may be discontinued in the event that the drug proves to be excessively toxic or in the event that it is found to be ineffective. Therefore, there is a possibility of Tiziana exercising the aforementioned call option by purchasing the shares held by Nerviano for the symbolic value of a pound sterling.

Despite this, the Company deemed it appropriate to record this item in the financial statements, including for the part relating to the shares, for the following reasons:

- ✓ The nature of upfront fees of the shares received and the decision of the Company's Management to invest in these shares in lieu of accepting entirely monetary upfront fees;
- ✓ The contractual obligation of the licensee to develop at least one of the two main indications to which the right to sell the shares is related.

In the opinion of the Company's management, given the current progress of clinical trials, this item can be recognized in the financial statements. The book value of the shares at December 31, 2021 is lower than the market value at the same date.

### CI - INVENTORY AND WORK IN PROGRESS ON ORDER

At December 31, 2021 the item amounts to 1.783 thousand Euros and referred to advances to national suppliers or its subsidiaries.

	31/12/2021	Changes for the period	31/12/2020
Finished products	-	-	-
Finished products	1.393	(12)	1.405
Provision for finished products	(1.393)	12	(1.405)
Semi finished products	-	-	` _
Semi finished products	154	(0)	154
Provision for semi finished products	(154)	O	(154)
Advances to suppliers	1.783	176	1.607
Advanced to national suppliers	80	29	51
Advanced to CEE suppliers	72	(34)	106
Advanced to EXTRA CEE suppliers	703	402	301
Advanced to subsidiaries	928	(221)	1.150
Total	1.783	176	1.607

Advances payments to the subsidiaries Nerpharma S.r.l. and Accelera S.r.l., equal to 928 thousand Euros re related to support activities on pipeline projects owned by Nerviano Medical Sciences S.r.l.



Advances to EU and extra-EU suppliers are related to support activities in clinical and pre-clinical activities.

### CII - RECEIVABLES

At December 31, 2021 this item amounts to 29.626 thousand Euros and it composed as follows:

	31/12/2021	Changes for the period	31/12/2020
Receivables due from clients	3.869	69	3.800
Receivables due from clients	22.353	69	22.284
Provision for receivables	(18.484)	-	(18.484)
Receivables due from subsidiaries	2.480	128	2.352
companies subject to the control of the parent companies	1.856	889	967
Receivables due from parent companies	9.853	4.640	5.213
Tax credits	10.259	2.321	7.938
IRAP receivable	342	(284)	626
IRES receivable	-	(21)	21
Other tax credits	9.917	2.626	7.291
Receivables due from others	1.310	23	1.287
Employee advances	7	(1)	8
Inps High employees severance indemnity Receivables	747	94	653
Others	556	(70)	626
Total	29.626	8.070	21.556

Receivables due from customers amount to 3.869 thousand Euros net of provisions for write-downs of 18.484 thousand Euros mainly relating to national customers.

Receivables from subsidiaries are equal to 2.480 thousand Euros and are broken down as follows:

- receivables from security deposits paid to Simis S.r.l. for 2.240 thousand Euros, for the lease agreement outstanding as of December 31, 2021.,
- receivables due from Simis S.r.l., amounting to 240 thousand Euros, related to the charge-back of technical costs attributable to the subsidiary.

Receivables from companies subject to the control of the parent companies amount to 1.856 thousand Euros and are composed of:

- receivables due from Nerpharma S.r.l., for 1.028 thousand Euros and Accelera S.r.l. for 795 thousand Euros, relating to invoices to be issued for for chargeback of technical costs that oncology activities to support market studies,
- receivables due from Consorzio Infra in Liquidation for 33 thousand Euros related to the consortium share held in the latter.

Receivables from the parent company NMS Group S.p.A., amounting to 9.853 thousand Euros, of which 151 thousand Euros of invoices to be issued, mainly related to the consolidated VAT and IRES transfer for joining the National Tax Consolidation.



The item Tax receivables, amounting to 10.259 thousand Euro, mainly refers for 5.743 thousand Euros to the withholding tax on receipts applied by foreign customers in the United States, for 4.174 thousand Euro related to the tax credit for R&D 2020 and 2021 expenses (as provided for by Article 2 of the MISE Decree of May 26, 2020, publication No. 182 in the Official Gazette of 21/07/2020) and 342 thousand Euros in IRAP receivables.

The item Receivables from others, amounting to 1.310 thousand Euros, , is mainly composed by 747 thousand Euros of receivables from Inps (Italian National Social Welfare Institute for TFR treasury (Employee Severance Indemnity), and by 556 thousand Euros of Other receivables mainly consisting of 555 thousand Euro of security deposits (of which 550 thousand euro from Engie Italia S.p.A.)..

Pursuant to Article 2427, paragraph 1, p.6 of the Italian Civil Code, it should be noted that there were no receivables due after five year.

### CIII) FINANCIAL ASSETS

Ammounting to 59 thousand Euros and is made up of the purchase of 14.750 shares of Banca Popolare di Sondrio of which 4.750 were assigned with option rights during 2014. Over the 2021 financial year, they were revalued by approximately 24 thousand Euros.

### C IV - CASH AND CASH EQUIVALENTS

These amounted to 2.089 thousand Euros and consisted of cash and cash equivalents and short-term bank accounts.

	31/12/2021 Change	es for the period	31/12/2020
Bank and post office deposits	2.087	(16.070)	18.156
Cash on hand	2	(1)	3
Total	2.089	(16.070)	18.159

### D - ACCRUED INCOME AND PREPAID EXPENSES

The item, at December 31, 2021, is equal to 542 thousand Euros. The composition and changes of the period are the following:



	31/12/2021	Changes for the period	31/12/2020
Accrued income	0	(0)	1
Prepaid expenses	542	122	420
Loans	-	(0)	0
Insurance	17	(39)	55
Licenses, maintenance and IT outsourced services	<del></del>	-	-
Various	522	161	361
Vs subsidiaries	3	(0)	3
Vs subsidiaries	-	-	-
Total	542	122	420

The amount of 542 thousand Euros is mainly composed of prepaid expenses, of which 17 thousand Euros refer to insurance costs and 522 thousand Euros to costs mainly related to patent nature.

### A - NET EQUITY

At December 31, 2021, Net Equity amounts to 35.239 The quota capital is equals to 1.040 thousand Euros and is entirely held by the parent company, NMS Group S.p.A. The change compared with the previous year is due to the recording of the loss for the year amounting to 13.901 thousand Euros. The table below shows the changes during the year in the amount of shareholders' equity over the last three financial years:

(value in Euros/1,000)	Quota capital	Legal reserve	Other reserves	Profits (losses) carried forward	Profits (losses) for the Year	Total
Balance at 31 December 2018	1.040	1.193	96.746	(67.717)	26.731	57.993
Report the result of 2018		5.346		21.385	(26.731)	-
Demerger operation Accelera S.r.l e Nerpharma S.r.l.			(2.735)			(2.735)
Report the result of 2019			Australia		4.234	4.234
Balance at 31 December 2019	1.040	6.539	94.011	(46.333)	4.234	59.491
Report the result of 2019		847		3.387	(4.234)	-
Demerger operation NMS Group SpA			(184)	)	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(184)
Report the result of 2020					(10.167)	(10.167)
Balance at 31 December 2020	1.040	7.386	93.827	(42.946)	(10.167)	49.140
Report the result of 2020				(10.167)	10.167	-
Report the result of 2021				,	(13.901)	(13.901)
Balance at 31 December 2021	1.040	7.386	93.827	(53.113)	(13.901)	35.239
of which:						
No-distributable share	1.040	1.477				2.517
Distributable share		5.909	93.827	(53.113)	(13.901)	32.722
	1.040	7.386	93.827	(53.113)	(13.901)	35.239

### **B - PROVISIONS FOR RISKS AND CHARGES**

Provisions for risks and charges amount to 2.045 thousand Euros. The table below shows the changes during the year:

HE STEEL STATE OF THE STATE OF	Changes for the period							
	31/12/2020	Provisions	Release	31/12/2021				
Provisions for risks on future costs	2.841	=	(796)	2.045				
Total	2.841	A SHARE	(796)	2.045				



is mainly composed of:

- > 1.955 thousand Euros relating to entries in the HR whose value has been adjusted to December 31, 2021 with a release of 796 thousand Euros,
- > 50 thousand Euros referring to costs estimated for the dismantling of the chemical synthesis fermentation pilot plant.

### C - EMPLOYEE SEVERANCE INDEMNITY (TFR)

The balance of the severance indemnity fund as of December 31, 2021 amounted to 2.056 thousand Euros gross of 747 thousand Euros receivables from Inps (Italian National Social Welfare Institute) for the amount paid to the institution in agreement with the Welfare regulations and represents the rights accrued as of December 31, 2021 by the employees, based on the provisions of the law in force, the National Collective Labour Agreement and the supplementary Company agreements:

	Provision value as at 31/12/120	Other charges	Transfer	Provision	Payment to welfare provisions	Tax Substitute	Amounts Equidated	Treasury AC	Provision value as at 31 / 12/21	Payment to INPS	Provision gross of payment to INPS
Tfr Executives	124	(6)		- 67	(44)	(0)		(14)	326	75	201
Tir Mangers	856	(22)		- 285	(203)	(2)	(28)	(29)	858	76	933
Tfr Employee	322	(13)		- 202	(136)		(9)	(40)	325	597	922
Total	1.302	775.		554	11 1	ia'	15		1,309		2.056

### D - PAYABLES

Payables at December 31, 2021 amount to 81.574 thousand Euros. The breakdown of items and related transactions are analyzed below in their most relevant parts:



	31/12/2021	Changes for the period	31/12/2020
Payables to shareholders for loans	5.318	-	5.318
Payables due to banks	17.824	(2.676)	20.500
Other short term loan	3.565	873	2.692
Other long term loan	14.259	(3.549)	17.808
Payables to other funders	0	(28)	28
Advances received from clients	392	-	392
Payables due to suppliers	6.153	(1.507)	7.660
National Suppliers	1.723	(642)	2.364
Foreign Suppliers	1.194	66	1.128
invoices to receive from national suppliers	2.818	(244)	3.062
Invoices to receive from national suppliers	418	(687)	1.105
Payables due to subsidiaries	1.188	(7.077)	8.265
Invoices to receive from subsidiaries	339	(75)	414
Receivables due from subsidiaries	850	(7.002)	7.851
Payables to companies controlled by parent companies	9.334	(15.104)	24.437
invoices to receive from companies controlled by parent companies	2.679	(777)	3.456
Receivables due from companies controlled by parent companies	6.655	(14.326)	20.981
Payables due to parent company	39.750	31.938	7.812
Invoices to receive from parent company	552	23	529
Other payables due to parent company	39.198	31.915	7.283
Tax payables	204	(51)	255
Irpef on employees	203	(47)	250
Irpef on professionals	1	(4)	5
Payables v/IRAP	0	1	_
Other tax payables	-	-	-
Payables due to social security institutions	592	13	578
INPS on wages of december	411	(1)	412
Contribution on allocation	60	2	58
Others	121	11	109
Others payables	818	(137)	955
Payables for unused vacation days	185	56	130
Other payables due to employees	468	(174)	642
Other	164	(18)	183
Total	81.574	5.373	76.201

Payables to shareholders for loans amounted to 5.318 thousand Euros are due to the parent company, NMS Group S.p.A., as a shareholder loan granted to support the financial needs of the Company and of its subsidiaries.

Payables to banks amounted to 17.824 thousand Euros. The change of 2.676 thousand Euros compared to the previous year is mainly due to the repayment of the installments pertaining to 2021 concerning the two loans signed with Banca Popolare di Sondrio during the previous year. In particular:

- loan agreement with Banca Popolare di Sondrio (Liquidity Decree) with a residual value as of December 31, 2021 of 5,3 million Euros;
- loan agreement with Banca Popolare di Sondrio that provides for the repayment of a further 5 annual installments of 2.500 thousand Euros each, gross of interest expense.

The amount to be paid by December 31, 2022 represents the short-term amount of the above-mentioned payables to Banca Popolare di Sondrio.

Payables due to suppliers amount to 6.153 thousand Euros and are broken down as follows:



- Payables due to national suppliers for 4.541 thousand Euros (of which 2.818 thousand Euros for invoices to be received).
- Payables due to UE suppliers for 707 thousand Euros (of which 327 thousand Euros for invoices to be received)
- Payables due to Extra- UE suppliers for 905 thousand Euros (of which 92 thousand Euros for invoices to be received).

Payables due to subsidiaries equal to 1.188 thousand Euros (of which 339 thousand Euros for invoices to be received) and refer mainly to payables due to Simis S.r.l. for site maintenance services and costs related to the lease agreement. The decrease in this item compared to the year ended December 31, 2020 is primarily attributable to the effect of the management of the centralized treasury as per the "zero balance" cash pooling contract signed with NMS Group S.p.A., Intesa San Paolo S.p.A. and the other companies of the NMS Group (NerPharMa S.r.l., Simis S.r.l. and Accelera S.r.l.) during the previous year.

Payables to companies controlled by parent companies are equal to 9.334 thousand Euros (of which 2.679 thousand Euros for invoices to be received) and are divided into:

- Payables due to Accelera S.r.l. for 6.413 thousand Euros (of which 932 thousand for invoices to be received) relating to services provided in support of projects in the pipeline of NMS S.r.l.,
- payables due to NerPharMa S.r.l. for 2.921 thousand Euros (of which 1.747 thousand Euros for invoices to be received) for activities of active ingredient and finished product development on projects in the NMS pipeline.

Payables due to parent company are equal to 39.750 thousand Euros and are composed by 552 thousand Euros invoices to be received relating to payables for personnel activities and 39.198 thousand Euros from the debt of Nerviano Medical Sciences S.r.l. to NMS Group S.p.A. arising from the integrated management of the Group treasury, as mentioned in the item Payables to subsidiaries.

Tax payables of 204 thousand Euros consist mainly of IRPEF (employees' tax direct taxation).

Items Other payables and Payables due to social security institutions for 1.410 thousand Euros, mainly include amounts due to INPS (Italian National Social Welfare Institute), payables for holidays not taken, the provision for employee bonuses, and fees payable to the Board of Statutory Auditors and the Independent Auditors for certification of the financial statements..

Finally, it should be note that the amount of payables expressed in currency other than the Euros at December 31, 2021 amount to 3 thousand CAD (Canadian Dollar),



5 thousand DKK (Danish Krone), 66 thousand GBP (British Pound), 87 thousand JPY (Japanese Yen), thousand SGD (Singapore dollar), 443 thousand USD (US Dollar), valued at the exchange rate at the end of the year, for an equivalent of approximately 475 thousand Euros.

There are no debts whose duration exceeds five years except for the debt against Banca Popolare di Sondrio.

### INFORMATION ON THE INCOME STATEMENT

### A - VALUE OF PRODUCTION

The value of production amounts to 20.628 thousand Euros at December 31, 2021. The composition of the items and relevant movements are analyzed here below for the most important items:

	31/12/2021	Changes for the period	31/12/2020
Revenue from sales and services	10.484	(12.632)	23.116
Revenue from sales and services	205	(533)	738
Revenue from services to subsidiaries	12	(36)	48
Revenue from research and development projects	250	(15.891)	16.141
Royalties	10.017	3.828	6.189
Other revenue	10.144	3.628	6.515
Grants on financed projects	-	(202)	202
Utilization of provision risk fund	796	777	19
Other revenue to subsidiaries	653	204	448
Other revenue to parent company	416	29	386
Recovery of R&D tax credit	3.035	1.122	1.913
Other revenue to subsidiaries	4.986	1.466	3.519
Various income	258	232	26
Total	20.628	(9.004)	29.631

The value of production includes both service activities performed in favour of customers, mainly in applied to pharmaceutical technology to support clinical trials both for oncology activities in support of market studies for the subsidiaries Accelera S.r.l. and Nerpharma S.r.l.

Revenue from sales and services amount to 205 thousand Euros and are determined by scientific services to third parties net of contingent assets recorded as a result of the closure of appropriations for invoices to be issued made in previous years. Revenue from research and development projects amount to 250 thousand Euros and mainly refer to to the milestone related to the license agreement signed in 2019 with Nanjing Hicin Pharmaceutical Co. Ltd. relating to an inhibitor of IDH and activities carried out under this agreement led to the identification of a candidate



molecule, which in 2021 was accepted by the customer as a Product Candidate (PC), which led to the payment of the corresponding milestone.

The decrease in 2021 in research project development revenues is due to the fact that in 2020 these revenues included 14.990 thousand Euros for the 3 milestones accrued during the year under the license agreement with Ignyta (Roche).

Royalties income from third parties, equal to 10.017 thousand Euros, represent the royalties from the licensing agreement for the two products currently on the market, Braftovi and Rozlytrek.

Other revenue, equal to 10.144 housand Euros, is mainly generated by other revenues from subsidiaries for 4.986 thousand Euros relating to the charge-back of costs to be recovered from NMS Group companies, primarily relating to technical costs and revenues relating to the recovery of R&D tax credits amounting to 3.035 thousand Euros (as provided for by Article 2 of the MISE Decree of May 123, 2020, publication No. 182 in the Official Gazette of 21/07/2020, for more details see the Directors' Report). In addition, the allowance for risks and charges mentioned in paragraph B - PROVISIONS FOR RISKS AND CHARGES of these Notes to the supplementary note was released.

### **B** – COSTS OF PRODUCTION

### B.6) Costs for primary, ancillary materials, consumables and goods

As December 31, 2021 these amounted to 1.290 thousand Euros. The breakdown of items and related transactions are analyzed below in their most relevant parts:

<b>经验证证明</b>	31/12/2021	Changes for the period	31/12/2020
Purchase of consumables not in stock	1.088	(349)	1.437
Purchase of stationary/paper	3	(15)	18
Others	199	(277)	476
Total	1.290	(641)	1.931

Purchases of non-stock material mainly refer to chemicals and pharmaceuticals products, reagents and laboratory supplies for in vitro and in vivo experiments.

### B.7) Costs for services

Cost of services are equal to 28.316 thousand Euros. The most significant components of the items and their movements are described below:



<b>外海水 6克米斯尔 4</b> 斯克尔	31/12/2021	Changes for the period	31/12/2020
R. & D. services from associated company	10.266	(1.637)	11.902
Energy utilities	8.351	2.473	5.878
R. & D. services	2.306	387	1.919
Services from parent company	1.977	328	1.649
R&S biostatistics / data management	1.133	822	311
Maintenances and repairs	999	343	656
Patent consultancy	740	(21)	760
Maintenances and repairs from parent company	731	(50)	780
Technical and IT consultancy	681	381	299
Others	621	(315)	936
Corporate costs	368	(22)	391
Other services outsourced	184	91	93
On line scientific subscriptions	154	(21)	175
Maintenances and repairs from subsidiaries	123	43	80
Insurances	119	8	111
Waste disposal	79	59	20
Catering	62	(6)	68
Telephonic expenses	54	(0)	55
Couries	52	7	46
Costs for staff recruitment	43	4	39
Administrative and tax consultancy	39	31	8
Professional training	33	(20)	53
Gardening expenses from parent company	24	(1)	25
Technical consultancy from parent company	21	(14)	35
Project contract wages	20	(90)	110
Reimbursement travel expenses and tickets	18	(4)	21
Partecipation in conferences and conventions	16	7	8
Legal advice	13	(21)	34
Notary sercives	6	(2)	8
Project contract contributions	3	(14)	18
Consultancy and medical-sanitary	3	1	2
Consultancy for research	3	1	2
Reimbursement of automotive	2	(0)	2
Trasporti per studi clinici da consociata	-	(4)	4
Non recurring costs for services	(930)	(113)	(817)
Total	28.136	2.634	25.682

### The main items are as follows:

- R&D services from associated company for 10.266 thousand Euros, particularly for 5.176 thousand Euros to Accelera S.r.l. and 5.090 thousand Euros to Nerpharma S.r.l. for services provided in support of pipeline projects;
- Energy utilities for 8.351 thousand Euros related to electricity and steam expenses of the whole site. The increase compared with the previous year is mainly due to the rise in the price of electricity and natural gas;
- R&D services 2.306 thousand Euros i.e. all costs incurred by the Company for collaborations with external laboratories to support the pre-clinical development of pipeline projects;
- Services from parent company for 1.977 thousand Euros relating to costs, recharged by NMS Group S.p.A. for central staff;



- R&D biostatistics/data management for 1.133 thousand Euros and refer to costs relating to services provided by the so-called CROs (Contract Research Organization) to which certain activities linked to the management of clinical trials in progress or about to start abroad are outsourced (e.g. monitoring, regulatory management, pharmacovigilance). The increase is due to the activities and contracts with CROs related to the management of foreign clinical trials already in progress in 2020 but also to regulatory and planning activities preparatory to the start of the studies started during 2021 or planned to start during 2022;
- Maintenance and repairs, amounting to 999 thousand Euros, mainly refer to annual costs for the maintenance of software used in both preclinical and clinical activities;
- Patent consultancy, equal to 740 thousand Euros including all costs incurred by the Company in connection with consultancy and patent registration;
- Maintenances and repairs from a subsidiary for 731 thousand Euros. This item includes costs incurred by the Company for maintenance activities carried out by Simis S.r.l.;
- Technical and IT consultancy amounting to 681 thousand Euros, mainly referring to consultancy costs for the implementation of software used both in preclinical activities and, above all, in the management of clinical studies and costs relating to technical-scientific consultancy, both relating to the clinical and preclinical areas (not directly attributable to specific pipeline projects).

In the item Others are mainly included costs for expenses of work wear, no recurring costs for services relating adjustment on allocations made in previous years, cleaning services, project and clinical research costs.

It should be noted that corporate costs equal to 368 thousand Euros, mainly refer to remuneration paid to the members of the Board of Directors for 2021 which amounts to 202 thousand Euros, remuneration paid to the members of the Board of Statutory Auditors which amounts to 73 thousand Euros, remuneration paid to audit firm amounted to 93 thousand Euros.

### B.8) Costs for use of third-party goods

This item breaks down as follows:



	31/12/2021	Changes for the period	31/12/2020
Vehicle rental	. 6	(11)	16
Rental of Office machinery	32	11	21
Software licenses	8	(52)	61
Rental from parent	105	3	103
Rental from subsidiaries	-	-	-
Rental from subsidiaries	1.682	(211)	1.893
Rental from parent company	19	_10	8
n de Maria de Carlos de Ca	1.851	(227)	2.102

and mainly includes 1.682 thousand Euros of rents payable related to the lease agreement signed on April 29, 2016 with Simis S.r.l. valid for six years renewable for another six upon expiry, 105 thousand Euros of rentals from subsidiary referring to the reversal of costs incurred by Simis S.r.l. for the rental of the thermal power plant and 32 thousand Euros related to the rental of plant and machinery, primarily regarding PCs and printers.

### B.9) Staff costs

Staff costs amount to 9.373 thousand Euros. The breakdown of these costs is provided in the Income Statement, which should be referred to.

The average number of employees and the breakdown by category are shown below:

	Number average employee 2021	_	Number average employee 2020
Executive	7	1	6
Manager	64	2	62
Employee	70	2	68
Total	141	5	136

### B.10) Amortization, depreciation and impairment

Amortization and depreciation of intangible assets for the current year amount to 410 thousand Euros, while amortization and depreciation of tangible assets amount to 1.629 thousand Euros.

The increase in this value at December 31, 2021 is attributable to new investments made during the year, details of which are provided in paragraph 7. INVESTMENTS in the Directors' Report.

The breakdown is as follows:



<b>有企为</b> 的基本的基本的	31/12/2021	Changes for the period	31/12/2020
Amortization of intangible fixed assets	410	37	373
Trademarks	4	4	1
Software licenses	34	-	34
Software projects	62	34	29
Amortization other intangible fixed assets	310	-	310
Amortization of tangible fixed assets	1.629	412	1.216
General machinery	15	(6)	22
Machinery for slightly and highly corrosive processing	0	(0)	0
Office furniture and machinery	30	1	28
Various equipments	1.583	418	1.165
Electrical equipments	0	(0)	0
Total	2.039	450	1.589

### B.14) Other operating costs

They have a negative value of 59 thousand Euros and are composed as follows:

<b>"是是我们的是我们的,我们</b>	31/12/2021	Changes for the period	31/12/2020
Taxes	17	(27)	44
Membership fee	23	3	20
Entertainment expenses	6	(0)	6
Subscription paper, magazine and periodical	0	(5)	5
Various	13	7	5
Total	59	(21)	80

Tax charges, amounting to 17 thousand Euros, mainly refer to customs duties for 9 24 thousand Euros and inter-group mortgage registration taxes for about 8 thousand Euros.

Membership contributions, amounting to 20 thousand Euros, refer to the annual contributions paid to Federchimica and Farmindustria.

### C - FINANCIAL INCOME AND EXPENSES

### C.16) Other financial incomes

The amount of 268 thousand Euros refers to the following items:

	31/12/2021	Changes of the period	31/12/2020
Interest income on a bank account	-	(1)	1
Income from investment management	1	1	_
non-current financial income	267	267	_
Total	268	267	1

The item non-current financial income refers to the repayment of past interest expense recalculated by Banca Unicredit and re-credited on December 9, 2021.



### C.17) Interest and financial charges

The item Interest and financial charges has a positive value equal to 734 thousand Euros as shown in the table below:

THE SECOND SECOND SECOND	31/12/2021	Changes of the period	31/12/2020
Contingent assets financial charges	(867)	(867)	(0)
Interest expense	133	(164)	297
Default interests	0	(2)	2
Non recurring interest and financial charges	-	-	-
Others	-	(23)	23
Total	(734)	(189)	323

Interest expense mainly refer to interest on the debt to Banca Popolare di Sondrio for the year 2021, while contingent assets refer to the crediting of past interest expense recalculated by Banca Popolare di Sondrio and credited back to the current account on August 31, 2021.

### C.17 bis) Profits and losses of currency exchange

The positive item in the financial statements ended December 31, 2021 amounted to 1.015 thousand Euros. The composition and changes that occurred in the period are as follows:

<b>建筑设计区域</b> 社会经验	31/12/2021	Changes of the period	31/12/2020
Unrealized exchange rate losses	1.018	2.150	(1.132)
Unrealized exchange rate gains	40	875	(835)
Realized exchange rate gains	130	(940)	1.070
Realized exchange rate losses	(172)	115	(287)
Total	1.015	2.200	(1.185)

This item includes the profits and losses realized and recorded during the period at the time the receivables were collected and debts were paid. The item Unrealized exchange rate loss/gains results from the conversion, at the exchanges rate at December 31, 2021, of the receivables and payables expressed in foreign currency at the end of the year.

### D - VALUE ADJUSTMENTS TO FINANCIAL ASSETS

Value adjustments of financial assets, at December 31, 2021, amount to 24 thousand Euros.

<b>根据的现在分词</b>	31/12/2021	Changes for the period	31/12/2020
Investment on management write-downs	-	0	(0)
Revaluations assets	24	22	2
Total	24	22	2



The main difference can be attributed to the revaluation of shares in Banca Popolare di Sondrio mentioned in paragraph CIII) FINANCIAL ASSETS NOT INCLUDING FINANCIAL FIXED ASSETS of the Supplementary Notes.

### **INCOME TAX FOR THE YEAR**

### 20) Current, deferred and prepaid income taxes;

### Income tax for the year

As at December 31, 2021, the Company closed with a tax loss of 25.857 thousand Euros and therefore a tax consolidation income of 6.206 thousand Euros.

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### Other information

# Commitments, guarantees given and potential liabilities not shown on the balance sheet

Pursuant to Article 2427, subsection 9 of the Italian Civil Code, the following commitments, guarantees given and contingent liabilities not shown in the balance sheet are highlighted:

### Guarantees

The Company has no guarantees or other security in place as of the closing of the financial statements as of December 31, 2021.

### Commitments

The Company has assumed commitments for 75 thousand Euros concerning contracts for the rental of electronic machines.

### Potential liabilities

The Company has not assumed contingent liabilities that have not been recognized in the Financial Statement.

### Income or cost elements resulting from exceptional transactions

Pursuant to Article 2427, point 13 of the Italian Civil Code, it should be noted that no income or cost elements resulting from exceptional transactions.

### Fees of manager and statutory auditors

Below are reported information about fees of manager and statutory auditors pursuant to Article 2427, point 16 and 16-bis of the Italian Civil Code.

1) Position	2) Financial Year 2021	3) Financial Year 2020	
Directors	202.179 Euros	224.554 Euros	
Board of Auditors	72.800 Euros	72.800 Euros	
Audit firm	93.450 Euros	93.450 Euros	

### Transactions with related parties not concluded at market conditions

Transactions with related parties were concluded at normal market conditions, with the exception of non-interest-bearing loans received by the Shareholder and granted to subsidiaries.



### **Derivative financial instruments**

Pursuant to art. 2427-bis, first paragraph, n. 1 of the Italian Civil Code, the Company has not underwriter derivative financial instruments.

### Agreements not resulting from the Balance Sheet

There are no agreements not resulting from the Balance Sheet, which can significantly influence the equity and financial situation and the economic result of the Company, pursuant to art. 2427, point 22-ter of the Italian Civil Code.

### Information pursuant to art. 1, paragraph 125, of the law of 4 August 2017 n. 124

According to the art. 1, paragraph 125, of the Law of 4 August 2017, n. 124, in compliance with the obligation of transparency, it should be noted that, during the year, the following amount were received for subsidies, contributions, paid positions and in any case economic advantages of any kind from public administrations:

		amount collected 2021
		(value in Euros)
Fondazione Crui		9.105
	Total	9.105

# Name and registered office of the Company preparing the consolidated financial statements

With reference to the information required by article 2427, point 22-quinquies and sexies of the Italian Civil Code, the Company NMS Group S.p.A., with its registered office in Nerviano, street L.Pasteur 10, prepares the Group's consolidated financial statements.

### Significant events after the reporting period

On January 17, 2022, the Annual Shareholders' Meeting was held to approve the financial statements for the year ended December 31, 2020.

The Shareholders' Meeting, acknowledging that the term of office of the Board of Directors has expired, appointed the new administrative body with a three-year term of office until the approval of the financial statements as at December 31, 2023. The new Chairman of the Board of Directors is Dr. Hugues Dolgos, the CEO is Mr. Wu Guoxian and Dr. Barbara Marenco was appointed director.

Moreover, the Shareholders' Meeting approved the renewal of the Board of Statutory Auditors, confirming Mr. Mario Tagliaferri as Chairman, Mr. Stefano Sacchi



and Dr. Massimo Venuti as Statutory Auditors and nominating Mr. Salvatore Marco Fiorenza and Mr. Giovanni Ghelfi as new Substitute.

On March 17, 2022, the Board of Directors of the company appointed the new Supervisory Board for the three year 2022-2024. The new Supervisory Board is composed of an NMS Group S.p.A. employee, Dr.ssa Deborah Bolco, head of legal department, in quality of Chairperson and two external consultants, Dr. Ascensionato Raffaello Carnà and Dr. Massimo Fossati.

On March 17, 2022, CEO Dr. Guoxian Wu resigned effective April 01, 2022.

The Company's Board of Directors appointed Dr. Hugues Dolgos, in charge as Chairman of the Company, as Chief Executive Officer, assigning him all the powers of the previous CEO.

### Proposals for the allocation of profits or the hedging of losses

With reference to the information required by Article 2427, point 22-septies of the Italian Civil Code, it is proposed to the Shareholders' Meeting to allocate the profit for the year as follows:

Loss for the year at 31-12-2021	Euros	13.900.579,10
A profit/loss carried forward	Euros	13.900.579,10

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# Essential data regarding the Company exercising management and coordination activities

Pursuant to Article 2497-bis, paragraph 4 of the Italian Civil Code, below is a summary of the essential data resulting from the latest approved financial statements of the parent company, NMS Group S.p.A., at 31.12.2020.

Description	
	31/12/2020
Fixed assets	113.047
financial assets that are not fixed assets	3
Net working capital	2.614
Net invested capital	115.663
Provisions for risks and charges and Severance Indemnity	(926)
Net invested capital and funds	114.737
financed by:	
Net financial position	10.146
of which	1011-10
payables due to banks due beyond the next year	(20.000)
payables due to banks due within the next year	-
financial assets from cash pooling	10.584
financial liabilities from cash pooling	(1.371)
Current availability	14.202
Financial receivables and payables vs parent companies	6.730
Net Equity	124.883
Description	-
Description	24 # 2 # 200
Value of production	31/12/2020 4.234
Costs of production	(6.907)
Gross operating result (E.B.I.T.D.A.)	(2.673)
Amortisation depreciation and write-downs	(782)
Net operating result (E.B.IT.)	(3.455)
Net financial charges	(428)
Value adjustments of financial assets	(2.122)
Profit before tax	(6.006)

Net profit

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# Report Of the Board of Statutory Auditors On the financial statement 2021

# Report Of the Audit firm On the financial statement 2021