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Oggetto : DiaSorin - North America business growth

drives Group revenues and profitability in

the first half of 2020

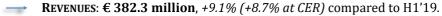
### Testo del comunicato

Vedi allegato.



# NORTH AMERICA BUSINESS GROWTH DRIVES GROUP REVENUES AND PROFITABILITY IN THE FIRST HALF OF 2020

### H1 2020 RESULTS



Growth in revenues driven, in part, by the contribution of SARS-CoV-2 molecular diagnostic and immunodiagnostic tests. Over 85% of the SARS-CoV-2 revenues have been generated in the Americas (especially in the U.S.) and in certain European countries.

It should be noted the award of important government contracts in Canada, United Kingdom, Belgium and Israel to carry out epidemiological studies on the population of these countries.

Ex-COVID business was -17.3% at CER.

- **EBITDA:** € **153.6 million**, +10.3% (+10.1% at CER) compared to H1'19, equal to 40.2% of Group revenues. The result was driven by the increase in sales and the operating leverage which reduced the ratio of expenses to revenues.
- **EBIT**: **€ 123.6 million**, +12.2%, equal to 32.3% of Group revenues.
- **NET Profit**: **€ 94.7 million**, +12.8%, equal to 24.8% of Group revenues.
- NET FINANCIAL POSITION: +€ 190.4 million at June 30, 2020 (+€ 172.9 million at December 31, 2019). The increase, equal to € 17.5 million, includes the dividend distribution, amounting to € 52.0 million, as resolved by the Shareholders' Meeting on June 10, 2020.
- **FREE CASH FLOW**: **€ 73.9 million** (**€** 69.5 million in H1'19).
- IMMUNODIAGNOSTIC ANALYZERS INSTALLED: net placements equal to +241 units, for an overall total of 8,530 units at June 30, 2020. Strong performance of LIAISON XL placements, equal to +282 units.
- GUIDANCE: in light of the current uncertainty and unpredictability about the global post-COVID-19 macroeconomic scenario, DiaSorin has deemed it appropriate to confirm the decision made during the publication of its Q1'20 financial results and refrain from providing its business outlook for 2020.
  - Nevertheless, following a solid H1'20 business performance and considering the industry in which DiaSorin operates, Management does not expect negative effects on the Group financial results in H2'20 and will provide updates to the market should the economic situation permit greater visibility on business outlook.
- IMPACT OF THE COVID-19 PANDEMIC ON BUSINESS: H1'20 was impacted by the spread of the COVID-19 pandemic in all the geographies where the Group operates. Each country has applied different restrictions imposed by local government authorities, especially as regards people mobility, transportation, goods production and distribution and services supply. This situation caused a global and unprecedented macroeconomic shock; in this context, the sector in which DiaSorin operates has been acknowledged to be strategic in providing all the necessary diagnostic tools to control and contain the spread of the infection. For these reasons, DiaSorin has not been subject to any restrictive measure and has continued its research, manufacturing and distribution activities without disruptions in all the Group sites, in compliance with the

provisions intended to ensure its workers safety. The Company has not identified significant COVID-19-related risks which may threaten its business continuity.



### **H1 2020 HIGHLIGHTS**



#### **BUSINESS DEVELOPMENT:**

• Exclusive licensing and technology transfer agreement signed with TTP plc, under which DiaSorin will gain access to PuckdxTM platform for the automation of sample-to-answer diagnostic assays. The agreement follows the Group's strategy to make molecular diagnostic tests available on a Point-of-Care platform.



#### **DEVELOPMENT OF IMMUNODIAGNOSTIC TESTS:**

 Launch of two serology tests in response to the COVID-19 pandemic: LIAISON® SARS-CoV-2 S1/S2 IgG and LIAISON® SARS-CoV-2 IgM.

Both tests are CE marked and have been approved by the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) in the country. The LIAISON® SARS-CoV-2 S1/S2 IgG test has also been approved for commercialization in Brazil and Canada and has been adopted by 4 governments (Israel, Belgium, Canada and UK), to carry out epidemiological studies on their population.



#### **DEVELOPMENT OF MOLECULAR DIAGNOSTIC TESTS:**

- Launch of two tests in response to the COVID-19 pandemic: Simplexa<sup>™</sup> COVID-19 Direct Kit and Simplexa<sup>™</sup> Flu A/B & RSV Direct Gen II Assay.
  - The first, which is CE marked and has received Emergency Use Authorization in the U.S., is used for the detection of SARS-CoV-2 directly from nasopharyngeal swab specimens. The latter, which is CE marked, is used for the detection of Flu A, Flu B and RSV strains and can be run alone or alongside the Simplexa<sup>TM</sup> COVID-19 Direct Kit, allowing differential diagnosis of the abovementioned infections and SARS-CoV-2.
- Launch of Simplexa<sup>™</sup> Congenital CMV Direct Assay, the first and only CE marked assay to detect
  Cytomegalovirus DNA directly in both saliva swabs and urine specimens from newborns up to 21 days
  old.



**Saluggia (Italy), July 30, 2020** - The Board of Directors of DiaSorin S.p.A. (FTSE MIB: DIA), a global leader in the production of diagnostic tests, reviewed and approved H1 2020 consolidated economic and financial results.

	Н1		change		
Amounts in million of euros	2019	2020	am ount	% @ current	% @ CER
Revenues	350.3	382.3	+32.0	+9.1%	+8.7%
CLIA tests	236.6	229.8	-6.8	-2.9%	-2.8%
ELISA tests	48.2	35.0	-13.2	-27.4%	-27.5%
Molecular tests	30.8	81.1	+50.2	+162.9%	+158.0%
Instruments sales and other revenues	34.6	36.4	+1.8	+5.2%	+5.3%
EBITDA	139.3	153.6	+14.4	+10.3%	+10.1%
EBITDA margin	39.8%	40.2%	+400 bps		
EBIT	110.2	123.6	+13.4	+12.2%	
EBIT margin	31.5%	32.3%	+88 bps		
Net profit	84.0	94.7	+10.7	+12.8%	

	Q	2	change			
Amounts in million of euros	2019	2020	am ount	% @ current	% @ CER	
Revenues	179.5	207.7	+28.2	+15.7%	+15.4%	
CLIA tests	122.9	117.3	-5.6	-4.6%	-4.3%	
ELISA tests	25.2	14.1	-11.1	-44.0%	-43.7%	
Molecular tests	14.6	56.6	+41.9	+286.2%	+279.7%	
Instruments sales and other revenues	16.8	19.7	+3.0	+17.9%	+18.2%	
EBITDA	71.7	89.2	+17.4	+24.3%	+18.7%	
EBITDA margin	40.0%	42.9%	+298 bps			
EBIT	57.2	74.2	+17.0	+29.7%		
EBIT margin	31.9%	35.7%	+386 bps			
Net profit	43.6	57.0	+13.4	+30.8%		

### **COMMENT ON RESULTS**



**Revenues:** € **382.3 million** in **H1'20**, +9.1% (+8.7% at CER) compared to H1'19.

Significant business decline, net of SARS-CoV-2 tests (-17.3% at CER compared to H1'19), offset by the contribution of the abovementioned tests, equal to  $\in$  92.2 million.

Over 85% of the COVID-19 revenues have been generated in the Americas (especially in the U.S.) and in certain European countries. It should be noted the award of important government contracts in Canada, United Kingdom, Belgium and Israel to carry out epidemiological studies on the population of these countries.

CLIA sales, net of Vitamin D, were +7.6% at CER.

Molecular business sales, net of COVID contribution, were +9.9% (+7.6% at CER) compared to H1'19.

Positive contribution from instruments sales, driven by the significant increase in the molecular and immunodiagnostic installed base vis-à-vis the negative Vitamin D and ELISA sales trend.

Sales trend as follows:

- **CLIA tests, net of Vitamin D**: +7.4% (+7.6% at CER)
- Vitamin D (CLIA tests): -35.2% (-35.7% at CER)
- **ELISA tests**: -27.4% (-27.5% at CER)
- Molecular tests: +162.9% (+158.0% at CER)
- Instruments sales and other revenues: +5.2% (+5.3% at CER)



Net balance of CLIA platforms installed in H1'20 of +241 units. The total number of installed instruments was 8,530 units at June 30, 2020. Strong performance of LIAISON XL placements, most notably outside Italy, equal to +282 units.

In **Q2'20**, **revenues** were  $\in$  **207.7 million**, +15.7% (+15.4% at CER) compared to Q2'19. Sales trend impacted by the decline in ex-COVID business (-33.5% at CER), due to global lockdown measures, offset by the COVID-19 tests performance ( $\in$  89.1 million).

Sales trend as follows:

- CLIA tests, net of Vitamin D: +11.7% (+12.0% at CER)
- Vitamin D (CLIA tests): -56.7% (-56.6% at CER)
- **ELISA tests**: -44.0% (-43.7% at CER)
- **Molecular tests**: +286.2% (+279.7% at CER)
- Instruments sales and other revenues: +17.9% (+18.2% at CER)



REVENUES BY GEOGRAPHY H1'20 highlighted significant differences in revenues by geography, driven by the virulence and timing of the COVID-19 spread, along with the measures adopted by government authorities to handle the emergency.

It is worth mentioning the strong performance recorded in the U.S. and Canadian markets (*ca.* +75%), which moved the incidence of the region on Group revenues to *around* 40%.

From a general perspective, ex-COVID tests performance followed a trend which reflected the speed and scope of the virus; after an initial peak during which volumes dropped by 50%-60%, sales trend gradually improved even though it has not yet reached the pre-COVID-19 levels.

A breakdown of revenues by country is shown below:

	н	1	Change		
Amounts in millions of euros	2019	0000		%	
	2019	2020	am ount	@ current	@ CER
Europe and Africa	164.3	179.1	+14.8	+9.0%	+9.0%
% on total revenues	46.9%	46.9%			
USA and Canada	101.2	148.0	+46.8	+46.2%	+42.7%
% on total revenues	28.9%	38.7%			
Asia Pacific	64.7	41.6	-23.1	-35.7%	-34.9%
% on total revenues	18.5%	10.9%			
Latin America	20.0	13.6	-6.5	-32.3%	-24.3%
% on total revenues	5.7%	3.5%			
Total	350.3	382.3	+32.0	+9.1%	+8.7%

	C	2	Change		
Amounts in million of euros	2019	2020	amount	(	%
	2019	2020	amount	@ current	@ CER
Europe and Africa	82.3	89.6	+7.3	+8.9%	+9.0%
% on total revenues	45.9%	43.1%			
USA and Canada	52.4	92.5	+40.1	+76.6%	+72.9%
% on total revenues	29.2%	44.6%			
Asia Pacific	34.2	21.4	-12.8	-37.4%	-36.5%
% on total revenues	19.0%	10.3%			
Latin America	10.6	4.2	-6.4	-60.6%	-51.0%
% on total revenues	5.9%	2.0%			
Total	179.5	207.7	+28.2	+15.7%	+15.4%

### **Europe and Africa**

**Revenues** in **H1'20** were € **179.1** million, +9.0% (+9.0% at CER) compared to H1'19. It should be noted that most of the main countries of the area recorded increased revenues in the period.

In **Q2'20, revenues** were € **89.6 million**, +8.9% (+9.0% at CER). It should be noted the steady upturn in routine tests volumes, albeit at lower levels compared to Q2'19, with a more marked upward trend in the least hit-countries or in countries reporting early COVID-19 spread.

### **USA and Canada**

**Revenues** in **H1'20** were € **148.0 million**, +46.2% (+42.7% at CER) compared to H1'19.

In **Q2'20, revenues** were € **92.5 million**, +76.6% (+72.9% at CER) compared to Q2'19.

Business in the region was sustained by the positive contribution from LIAISON SARS-CoV-2 S1/S2 IgG and Simplexa<sup>TM</sup> COVID-19 Direct tests, in response to the COVID-19 pandemic, as against a sharp drop in CLIA sales, especially routine tests and Vitamin D.

Immunodiagnostic sales were +8.8% (+6.3% at CER), with a strong performance of Latent Tuberculosis and Gastrointestinal infections tests.

Molecular diagnostic business increased significantly by 129.8% (+124.2% at CER), on the back of



the Simplexa<sup>TM</sup> COVID-19 Direct Kit sales and increased sales of flu tests, following the SARS-CoV-2 spread.

As a consequence of abovementioned results, the impact of revenues generated in the Region on total Group revenues was around 40%.

#### **Asia Pacific**

**Revenues** in **H1'20** were € **41.6** million, -35.7% (-34.9% at CER).

In **Q2'20, revenues** were € **21.4 million**, -37.4% (-36.5% at CER).

The region recorded the sharpest drop in revenues due both to the early impact of the COVID-19 pandemic (as early as January 2020) and the unavailability of the LIAISON SARS-CoV-2 S1/S2 IgG and Simplexa™ COVID-19 Direct tests.

Downward trend in China, equal to -48.7% in local currency in H1'20.

### **Latin America**

**Revenues** in **H1'20** were € **13.6 million**, -32.3% (-24.3% at CER).

**Revenues** in **Q2'20** were € **4.2 million**, -60.6% (-51.0% at CER) compared to Q2'19.

The region, whose sales in Q1'20 had not yet been negatively impacted by the COVID-19, reported a sharp decline in sales volumes in Q2, concurrently with the pandemic spread in all the Countries of the area.

Positive contribution of LIAISON SARS-CoV-S1/S2 in Brazil starting from Q2'20.

REVENUES BY TECHNOLOGY

The following provides a breakdown of Group revenues by technology.

	F	1	
% of revenues contributed	2019	2020	Change
CLIA tests	67.6%	60.1%	-744 bps
ELISA tests	13.8%	9.2%	-461 bps
Molecular tests	8.8%	21.2%	+1,240 bps
Instruments sales and other revenues	9.8%	9.5%	-26 bps

	G	2	
% of revenues contributed	2019	2020	Change
CLIA tests	68.5%	56.5%	-1,200 bps
ELISA tests	14.0%	6.8%	-724 bps
Molecular tests	8.2%	27.2%	+1,908 bps
Instruments sales and other revenues	9.3%	9.5%	+16 bps

CLIA sales in H1'20 accounted for 60.1% of total Group revenues (67.6% in H1'19); the decrease is the net result of a downward trend in sales of routine CLIA tests and the growing percentage of revenues represented by molecular tests (equal to 21.2% of total revenues in H1'20 vs. 8.8% in H1'19).

The percentage of total revenues represented by ELISA sales in the periods under comparison decreased, as expected, from 13.8% to 9.2%.





Details of the Group operating performance in i) H1'20 and ii) Q2'20 are provided below.



#### **Gross Profit:**

- i) **€ 264.1 million**, +8.5%, equal to 69.1% of revenues (69.5% in H1'19).
- ii) € **143.4 million**, +15.0%, equal to 69.1% of revenues (69.4% in Q2'19).

#### EBITDA

#### **EBITDA:**

- i)  $\mathbf{\epsilon}$  153.6 million, +10.3% (+10.1% at CER), equal to 40.2% of revenues (39.8% in H1'19).
- ii) € 89.2 million, +24.3% (+18.7% at CER), equal to 42.9% of revenues (40.0% in Q2'19). The result was positively impacted by the higher operating leverage generated by the increase in revenues and the corresponding decrease in the ratio of expenses to revenues, equal to 31.6% (36.0% in Q2'19).

#### Евіт

#### EBIT:

- i) € 123.6 million, +12.2%, equal to 32.3% of revenues (31.5% in H1'19).
- ii) **€ 74.2 million**, +29.7%, equal to 35.7% of revenues (31.9% in Q2'19).



#### FINANCIAL PERFORMANCE:

- i) **Net financial expenses** were € **1.4 million**, as against € 1.1 million in H1'19.
- ii) Net financial expenses were € 1.0 million, as against € 0.8 million in Q2'19.

INCOME TAXES

**Income taxes** in H1'20 were € 27.5 million, with a tax rate of 22.5%, in line with 2019 taxation.



### **CONSOLIDATED NET PROFIT:**

- i)  $\mathbf{\xi}$  94.7 million, +12.8%, equal to 24.8% of revenues (24.0% in H1'19).
- ii) € **57.0 million**, +30.8%, equal to 27.4% of revenues (24.3% in Q2'19).



**Consolidated Net Financial Position** at **June 30, 2020** was positive and equal to € **190.4** million, thus increasing € 17.5 million when compared with the balance at December 31, 2019 (equal to € 172.9 million). The change includes dividend distribution, as resolved by the Shareholders' Meeting on June 30, 2020, for a total amount of € 52.0 million.



The Group **Free Cash Flow** in **H1'20** was € **73.9 million** (€ 69.5 in H1'19).





BUSINESS OUTLOOK In light of the current uncertainty and unpredictability about the global post-COVID-19 macroeconomic scenario, DiaSorin has deemed it appropriate to confirm the decision made during the publication of its Q1'20 financial results and refrain from providing its business outlook for 2020. Nevertheless, following a solid H1'20 business performance and considering the sector in which DiaSorin operates, Management does not expect negative effects on the Group financial results in H2'20 and will provide updates to the market should the economic scenario permit greater visibility on business outlook.

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Mr. Piergiorgio Pedron, the officer in charge of preparing the corporate accounting documents of DiaSorin S.p.A. declares that, pursuant to paragraph 2, Art. 154 bis of the Consolidated Law on Finance, to the best of his knowledge, the accounting information contained in this Press Release corresponds to the documental results, accounting books and records.

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### CONSOLIDATED INCOME STATEMENT

(Amounta in million of ourse)	H1		Chai	nge
(Amounts in million of euros)	2019	2020	amount	%
Net Revenues	350.3	382.3	+32.0	+9.1%
Cost of sales	(107.0)	(118.2)	-11.2	+10.5%
Gross profit	243.3	264.1	+20.8	+8.5%
	69.5%	69.1%	-0.4%	
Sales and marketing expenses	(70.4)	(70.9)	-0.4	+0.6%
Research and development costs	(23.3)	(25.5)	-2.2	+9.5%
General and administrative expenses	(34.3)	(34.8)	-0.5	+1.3%
Total operating expenses	(128.1)	(131.2)	-3.1	+2.4%
	36.6%	34.3%	-2.2%	
Other operating income (expense)	(5.0)	(9.3)	-4.2	+84.3%
non recurring amount	(0.9)	(3.4)	-2.4	n.m.
EBIT	110.2	123.6	+13.4	+12.2%
	31.5%	32.3%	+0.9%	
Net financial income (expense)	(1.1)	(1.4)	-0.3	+24.2%
Profit before taxes	109.1	122.2	+13.2	+12.1%
Income taxes	(25.1)	(27.5)	-2.4	+9.7%
Net result	84.0	94.7	+10.7	+12.8%
EBITDA <sup>(1)</sup>	139.3	153.6	+14.4	+10.3%
	39.8%	40.2%	+0.4%	

(Amounta in million of ourse)	Q2		Chan	ge
(Amounts in million of euros)	2019	2020	amount	%
Net Revenues	179.5	207.7	+28.2	+15.7%
Cost of sales	(54.8)	(64.3)	-9.4	+17.2%
Gross profit	124.7	143.4	+18.8	+15.0%
	69.4%	69.1%	-0.4%	
Sales and marketing expenses	(35.9)	(34.5)	+1.4	-3.8%
Research and development costs	(11.6)	(13.1)	-1.4	+12.4%
General and administrative expenses	(17.2)	(17.9)	-0.8	+4.5%
Total operating expenses	(64.7)	(65.6)	-0.9	+1.3%
	36.0%	31.6%	-4.5%	
Other operating income (expense)	(2.7)	(3.6)	-0.9	+32.6%
non recurring amount	(0.3)	0.1	+0.4	n.m.
EBIT	57.2	74.2	+17.0	+29.7%
	31.9%	35.7%	+3.9%	
Net financial income (expense)	(0.8)	(1.0)	-0.3	+36.0%
Profit before taxes	56.5	73.2	+16.7	+29.6%
Income taxes	(12.9)	(16.2)	-3.3	+25.7%
Net result	43.6	57.0	+13.4	+30.8%
EBITDA (1)	71.7	89.2	+17.4	+24.3%
	40.0%	42.9%	+3.0%	

<sup>(1)</sup> EBITDA is defined as the "Operating Result", gross of amortization and depreciation of intangible and tangible assets. EBITDA is a measure used by the Company to monitor and evaluate the Group's operating performance and is not defined as an accounting measure in IFRS and therefore shall not be considered an alternative measure for assessing the Group's operating result performance. Since the composition of EBITDA is not regulated by the reference accounting standards, the criterion of determination applied by the Group may not be homogeneous with that adopted by other operators and/or groups and therefore may not be comparable.



### CONSOLIDATED BALANCE SHEET

(Amounts in million of euros)	12/31/2019	06/30/2020	Change
Goodwill and intangibles assets	370.3	372.2	+1.9
Property, plant and equipment	128.4	126.4	-2.0
Net working capital	211.0	230.1	+19.1
Other non-current assets (liabilities)	(33.9)	(32.0)	+2.3
Net Invested Capital	675.8	696.6	+20.9
Net Financial Position	172.9	190.4	+17.5
Total shareholders' equity	848.6	887.0	+38.4

### CONSOLIDATED STATEMENT OF CASH FLOWS

(Amounto in million of ourse)	Н	11
(Amounts in million of euros)	2019	2020
Cash and cash equivalents at the beginning of the period	73.1	157.6
Cash provided by operating activities	92.7	105.4
Cash used in investing activities	(24.3)	(31.4)
Cash provided/(used) in financing activities	(26.6)	(59.3)
Acquisitions of companies and business operations	(4.4)	-
Net change in cash and cash equivalents before investments in financial assets	37.4	14.7
Divestment/(Investment) in financial assets	(20.4)	(33.5)
Net change in cash and cash equivalents	17.0	(18.8)
Cash and cash equivalents at the end of the period	90.1	138.7

(Amounts in william of sums)	Q2	
(Amounts in million of euros)	2019	2020
Cash and cash equivalents at the beginning of the period	70.1	181.1
Cash provided by operating activities	44.7	49.6
Cash used in investing activities	(11.5)	(15.5)
Cash provided/(used) in financing activities	(16.6)	(58.6)
Acquisitions of companies and business operations	(3.4)	-
Net change in cash and cash equivalents before investments in financial assets	13.3	(24.5)
Divestment/(Investment) in financial assets	6.7	(17.8)
Net change in cash and cash equivalents	20.0	(42.4)
Cash and cash equivalents at the end of the period	90.1	138.7

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