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Diffusione presunta

Oggetto : DiaSorin: North America growth drives up

revenues and profitability in the first 9

months of 2020

Testo del comunicato

Vedi allegato.

NORTH AMERICA GROWTH DRIVES UP REVENUES AND PROFITABILITY IN THE FIRST 9 MONTHS OF 2020, WITH STRONG BUSINESS ACCELERATION IN THE THIRD QUARTER

FIRST 9 MONTHS 2020 RESULTS

- **REVENUES:** \in **610.1 million**, +16.2% (+17.2% at CER) compared to the first 9 months of 2019. Growth in revenues driven by the contribution of SARS-CoV-2 molecular diagnostic and immunodiagnostic tests and generated primarily in North America and Europe. Ex-COVID business was -14.3% at CER, showing a gradual recovery compared to Q2'20.
- **EBITDA**: € 257.7 million, +23.4% (+24.8% at CER) compared to the first 9 months of 2019, equal to 42.2%of Group revenues. The result reflects the sales growth, the operating leverage generated by high volumes of tests for SARS-CoV-2 and the containment of operating expenses.
- **EBIT**: **€ 213.5 million**, +28.9%, equal to 35.0% of Group revenues.
- **NET Profit**: € **162.5 million**, +28.3%, equal to 26.6% of Group revenues.
- **NET FINANCIAL POSITION:** +€ **256.1 million** at September 30, 2020 (+€ 172.9 million at December 31, 2019).
- FREE CASH FLOW: € 152.5 million in the first 9 months of 2020 (€ 138.3 million in the first 9 months of 2019).
- IMMUNODIAGNOSTIC ANALYZERS INSTALLED: 8,603 units at September 30, 2020. Strong performance of LIAISON® XL placements in the first 9 months of 2020, equal to +416 units.
- 2020 GUIDANCE: notwithstanding the current uncertainty caused by the introduction of new lockdown measures in countries where the Group operates, DiaSorin provides the following guidance for 2020:
 - REVENUES equal to around +25% at CER compared to 2019
 - **EBITDA MARGIN** equal to *around 43% at CER* compared to 2019
- IMPACT OF THE COVID-19 PANDEMIC ON BUSINESS: the first 9 months of 2020 have been 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 has 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 employees' safety.

The Company has not identified significant COVID-19-related risks which may threaten its business continuity.



9M 2020 HIGHLIGHTS



BUSINESS DEVELOPMENT:

- Exclusive licensing and technology transfer agreement signed with TTP plc, under which DiaSorin will gain access to Puckdx™ platform to make molecular diagnostic tests available in the Point-of-Care segment.
- Strategic partnership with MeMed, under which DiaSorin and MeMed will make the MeMed BV™ a pioneering test for distinguishing bacterial from viral infections available on LIAISON® XL and LIAISON® XS analyzers.
- Extension of the **Joint-Venture with the Chinese Government** to open a new manufacturing and research site in China. Through the strategic partnership with FuYuan and the extension to Shanghai Baoshan District Government, DiaSorin will furtherly increase its positioning in the country as a high quality China based diagnostic manufacturer.



DEVELOPMENT OF IMMUNODIAGNOSTIC TESTS:

- Launch of two serology tests in response to COVID-19 pandemic: LIAISON® SARS-CoV-2 S1/S2 IgG and LIAISON® SARS-CoV-2 IgM to identify IgG and IgM antibodies presence against SARS-CoV-2. Both tests are CE marked and have been approved by the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) in the USA.
- Launch of CE marked **LIAISON® Testosterone xt test**, a novel diagnostic solution for the dosage of testosterone, available on LIAISON® XL analyzer.
- FDA approval to **6 tests** that make up the **Hepatitis B panel**, completing the Hepatitis A, B and C menu offering in the US.
- Launch of CE marked LIAISON® SARS-CoV-2 Ag for COVID-19 detection, for use on LIAISON® family
 analyzers. The test allows high-throughput quantitative detection of SARS-CoV-2 viral load through
 nasal and nasopharyngeal swabs and will be offered as an alternative solution in cases where molecular
 PCR testing availability is lacking.



DEVELOPMENT OF MOLECULAR DIAGNOSTIC TESTS:

- Launch of two tests in response to COVID-19 pandemic: **Simplexa[™] COVID-19 Direct Kit** and **Simplexa[™] Flu A/B & RSV Direct Gen II Assay**.
 - Both tests have been approved in markets accepting CE mark and have received FDA Emergency Use Authorization in the U.S.
 - The first is used for SARS-CoV-2 detection directly from nasal and nasopharyngeal swabs, as well as saliva specimens (only in markets accepting CE mark). The second is used for Flu A, B and RSV strains detection, allowing differential diagnosis of these infections and SARS-CoV-2.
- Launch of **Simplexa[™] Congenital CMV Direct Assay** in countries accepting CE mark. The test is the only available on the market to detect Cytomegalovirus DNA directly in both saliva swabs and urine specimens from newborns up to 21 days old.





Saluggia (Italy), November 11, 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 9M 2020 consolidated economic and financial results.

9 months		change		
2019	2020	amount	% @ current	% @ CER
525.1	610.1	+85.0	+16.2%	+17.2%
354.1	344.1	-10.0	-2.8%	-1.7%
72.3	51.3	-21.1	-29.1%	-28.4%
46.2	158.6	+112.4	+243.1%	+243.6%
52.5	56.1	+3.7	+7.0%	+8.2%
208.9	257.7	+48.8	+23.4%	+24.8%
39.8%	42.2%	+245 bps		
165.6	213.5	+47.8	+28.9%	
31.5%	35.0%	+344 bps		
126.7	162.5	+35.9	+28.3%	
	525.1 354.1 72.3 46.2 52.5 208.9 39.8% 165.6 31.5%	525.1 610.1 354.1 344.1 72.3 51.3 46.2 158.6 52.5 56.1 208.9 257.7 39.8% 42.2% 165.6 213.5 31.5% 35.0%	525.1 610.1 +85.0 354.1 344.1 -10.0 72.3 51.3 -21.1 46.2 158.6 +112.4 52.5 56.1 +3.7 208.9 257.7 +48.8 39.8% 42.2% +245 bps 165.6 213.5 +47.8 31.5% 35.0% +344 bps	2019 2020 amount @ current 525.1 610.1 +85.0 +16.2% 354.1 344.1 -10.0 -2.8% 72.3 51.3 -21.1 -29.1% 46.2 158.6 +112.4 +243.1% 52.5 56.1 +3.7 +7.0% 208.9 257.7 +48.8 +23.4% 39.8% 42.2% +245 bps 165.6 213.5 +47.8 +28.9% 31.5% 35.0% +344 bps

Amounts in million of euros	Q:	3	change		
Amounts in million of euros	2019	2020	amount	% @ current	% @ CER
Revenues	174.8	227.9	+53.0	+30.3%	+34.3%
CLIA tests	117.4	114.2	-3.2	-2.7%	+0.7%
ELISA tests	24.1	16.3	-7.9	-32.6%	-30.1%
Molecular tests	15.4	77.6	+62.2	+403.7%	+415.1%
Instruments sales and other revenues	17.9	19.8	+1.9	+10.6%	+13.8%
EBITDA	69.7	104.1	+34.4	+49.4%	+54.2%
EBITDA margin	39.9%	45.7%	+583 bps		
EBIT	55.4	89.8	+34.4	+62.0%	
EBIT margin	31.7%	39.4%	+772 bps		
Net profit	42.7	67.8	+25.1	+58.9%	

COMMENT ON RESULTS



Revenues: € 610.1 million in the first 9 months of 2020, +16.2% (+17.2% at CER) compared to the first 9 months of 2019.

The decrease in ex-COVID sales (-14.3% at CER compared to the first 9 months of 2019) was largely offset by revenues contribution of SARS-CoV-2 tests, equal to € 165.8 million, mainly in the U.S. and Europe.

Molecular diagnostic sales, which largely drove total revenues upward trend, increased by triple digits (+243.6% at CER), due to the strong contribution from COVID-19 tests.

Upward trend in CLIA sales, net of Vitamin D, and in instruments sales, driven by a marked increase in molecular and immunodiagnostic installed base.

It should be noted the expected negative trend of Vitamin D and ELISA sales.

Sales trend as follows:

- CLIA tests, net of Vitamin D: +5.4% (+6.7% at CER)
- Vitamin D (CLIA test): -29.3% (-28.6% at CER)
- **ELISA tests**: -29.1% (-28.4% at CER)
- **Molecular tests**: +243.1% (+243.6% at CER)
- Instruments sales and other revenues: +7.0% (+8.2% at CER)





At September 30, 2020, total units of installed immunodiagnostic instruments was 8,603. It is worth mentioning the strong performance of LIAISON® XL installed base in the first 9 months of 2020, equal to +416 units.

In **Q3'20**, **revenues** were **€ 227.9 million**, +30.3% (+34.3% at CER) compared to Q3'19.

Sales trend was impacted by the strong performance of COVID-19 molecular tests and the recovery of ex-COVID business in all the countries where the Group operates (-7.2% at CER).

Sales trend as follows:

- CLIA tests, net of Vitamin D: +1.3% (+4.8% at CER)
- **Vitamin D (CLIA test)**: -16.4% (-13.3% at CER)
- **ELISA tests**: -32.6% (-30.1% at CER)
- **Molecular tests**: +403.7% (+415.1% at CER)
- Instruments sales and other revenues: +10.6% (+13.8% at CER)







In the first 9 months of 2020 revenues by geography have not been homogeneous, due to the virulence and timing of the COVID-19 spread, along with the measures adopted by government authorities and the commercial availability of the Group's COVID-19 tests.

It is worth mentioning the strong performance in the North American market (+58.3% at CER), which increased the incidence of the region on Group revenues to 40%.

A breakdown of revenues by country is shown below.

	9 m o	nths	Change			
Amounts in millions of euros	0040	2022			%	
	2019	2020	amount	@ current	@ CER	
Europe and Africa	242.5	275.8	+33.3	+13.7%	+13.8%	
% on total revenues	46.2%	45.2%				
USA and Canada	154.5	244.1	+89.6	+58.0%	+58.3%	
% on total revenues	29.4%	40.0%				
Asia Pacific	97.9	68.3	-29.6	-30.2%	-28.9%	
% on total revenues	18.6%	11.2%				
Latin America	30.3	22.0	-8.3	-27.3%	-15.6%	
% on total revenues	5.8%	3.6%				
Total	525.1	610.1	+85.0	+16.2%	+17.2%	

	C	13	Change			
Amounts in million of euros	2019	2020		9	%	
	2019	2020	amount	@ current	@ CER	
Europe and Africa	78.1	96.6	+18.5	+23.7%	+23.9%	
% on total revenues	44.7%	42.4%				
USA and Canada	53.3	96.1	+42.8	+80.4%	+88.0%	
% on total revenues	30.5%	42.2%				
Asia Pacific	33.2	26.7	-6.5	-19.6%	-17.3%	
% on total revenues	19.0%	11.7%				
Latin America	10.2	8.4	-1.8	-17.7%	+1.5%	
% on total revenues	5.8%	3.7%				
Total	174.8	227.9	+53.1	+30.3%	+34.3%	

Europe and Africa

Revenues in the first **9 months of 2020** were € **275.8 million**, +13.7% (+13.8% at CER) compared to the first 9 months of 2019.

All the main countries of the area recorded increased revenues in the period, on the back of the contribution from COVID-19 tests and improved ex-COVID sales in Q3'20.

In **Q3'20**, revenues were € **96.6** million, +23.7% (+23.9% at CER). Positive contribution from SARS-CoV-2 tests and, particularly, molecular tests, in addition to strong business rebound, net of COVID-19.

USA and Canada

Revenues in the first **9 months of 2020** were € **244.1 million**, +58.0% (+58.3% at CER) compared to the first 9 months of 2019, on the back of immunodiagnostic products and, most notably, SARS-CoV-2 molecular tests. Net of these tests, business showed a gradual recovery with strong acceleration in Q3'20.

Molecular diagnostic sales were +189.7% (+190.2% at CER), driven by SARS-CoV-2 tests performed in hospital laboratories.

Immunodiagnostic sales were +1.6% (+1.8% at CER), as a result of robust COVID serology test sales in Q2'20 and a strong rebound in ex-COVID tests volumes in Q3'20 (primarily Latent Tuberculosis and Gastrointestinal infections).

As a consequence of the abovementioned results, the impact of revenues generated in the Region





on total Group revenues was equal to 40%.

In **Q3'20, revenues** were € **96.1 million**, +80.4% compared to the same period of 2019 (+88.0% at CER), reflecting the gradual recovery of ex-COVID business, along with the growing contribution from molecular tests in response to the pandemic.

Asia Pacific

Revenues in the first **9 months of 2020** were **€ 68.3 million**, -30.2% compared to the same period of 2019 (-28.9% at CER).

The performance of the region has been affected by sales decrease in China, the only market of the Group where DiaSorin's COVID-19 tests are not available.

The business trend is constantly and progressively improving due to ex-COVID sales recovery.

In Q3'20, revenues were € 26.7 million, -19.6% (-17.3% at CER), with business showing gradual recovery in all the Countries of the area. Particularly, Chinese market recorded a steady increase in sales volumes, although still below the sales delivered in Q3'19.

Latin America

Revenues in the first **9 months of 2020** were $\mathbf{\in 22.0}$ million, -27.3% (-15.6% at CER).

Sales recorded an upward trend in Q1, followed by a sharp business decline in Q2 as a result of the pandemic. In Q3, the availability of COVID-19 serology tests and ex-COVID sales recovery led again to an upward trend.

In **Q3'20, revenues** were € **8.4 million**, -17.7% (+1.5% at CER) compared to Q3'19. The positive business trend in local currencies was strongly affected by foreign exchange rates, with a negative impact on Group results.







The following provides a breakdown of Group revenues by technology.

	9 m o	nths	
% of revenues contributed	2019	2020	Change
CLIA tests	67.4%	56.4%	-1,104 bps
ELISA tests	13.8%	8.4%	-537 bps
Molecular tests	8.8%	26.0%	+1,719 bps
Instruments sales and other revenues	10.0%	9.2%	-79 bps

	6	3	
% of revenues contributed	2019	2020	Change
CLIA tests	67.2%	50.1%	-1,702 bps
ELISA tests	13.8%	7.2%	-656 bps
Molecular tests	8.8%	34.0%	+2,523 bps
Instruments sales and other revenues	10.2%	8.7%	-155 bps

CLIA sales in the first 9 months of 2020 accounted for 56.4% of total Group revenues (67.4% in the first 9 months of 2019). The decrease is the net result of a robust upward trend in sales of molecular tests, with an incidence of 26.0% on total Group revenues (8.8% in the first 9 months of 2019). The percentage of total revenues represented by ELISA sales moved from 13.8% to 8.4%.

The contribution provided by instruments sales to total revenues slightly decreased, despite an increase in instruments turnover in the first 9 months of 2020.







The following provides the Group operating performance in:

- i) first 9 months of 2020
- ii) Q3'20.

GROSS PROFIT

Gross Profit:

- i) $\mathbf{\epsilon}$ **419.7 million**, +15.6%, equal to 68.8% of revenues (69.1% in the first 9 months of 2019).
- ii) € **155,7 million**, +29.9%, equal to 68.3% of revenues (68.5% in Q3'19).

EBITDA

EBITDA:

- i) € **257.7 million**, +23.4% (+24,8% at CER), equal to 42.2% of revenues (39.8% in the first 9 months of 2019).
- ii) € **104.1 million**, +49.4% (+54.2% at CER), equal to 45.7% of revenues (39.9% in Q3'19). The result was positively impacted by higher operating leverage generated by the increase in revenues and the corresponding decrease in the ratio of expenses to revenues, equal to 28.1% (36.5% in Q3'19). The result also benefited from increased absorption of fixed costs due to strong growth in molecular diagnostic volumes.

Евіт

EBIT:

- i) **€ 213.5 million**, +28.9%, equal to 35.0% of revenues (31.5% in the first 9 months of 2019).
- ii) € 89.8 million, +62.0%, equal to 39.4% of revenues (31.7% in Q3'19).



FINANCIAL PERFORMANCE:

- i) **Net financial expenses** were € **2.4 million**, as against € 1.1 million in the first 9 months of 2019.
- ii) **Net financial expenses** were **€ 1.0 million**, as against **€** 0.0 million in Q3'19.

INCOME TAXES

Income taxes were € **48.6 million**, with a *23.0%* tax rate, in line with the same period of 2019.



CONSOLIDATED NET PROFIT:

- i) $\mathbf{\epsilon}$ 162.5 million, +28.3%, equal to 26.6% of revenues (24.1% in the first 9 months of 2019).
- ii) € 67.8 million, +58.9%, equal to 29.8% of revenues (24.4% in Q3'19).

CONSOLIDATED

Consolidated Net Financial Position at **September 30, 2020** was positive at € **256.1 million**, an increase of € 83.2 million compared to the balance at December 31, 2019 (equal to € 172.9 million). Change includes dividend distribution, as resolved by the Shareholders' Meeting on June 10, 2020, for a total amount of € 52.0 million.

FCF

The Group Free Cash Flow in the first 9 months of 2020 was \in 152.5 million (\in 138.3 in the first 9 months of 2019).







Business Outlook Notwithstanding the current uncertainty caused by the introduction of new lockdown measures in countries where the Group operates, DiaSorin provides the following guidance for 2020:

- **REVENUES** equal to *around +25% at CER* compared to 2019
- EBITDA MARGIN equal to around 43% at CER compared to 2019

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

(Amounts in million of sures)	9 months	S	Change	
(Amounts in million of euros)	2019	2020	amount	%
Net Revenues	525.1	610.1	+85.0	+16.2%
Cost of sales	(162.0)	(190.4)	-28.4	+17.5%
Gross profit	363.1	419.7	+56.6	+15.6%
	69.1%	68.8%	-0.4%	
Sales and marketing expenses	(105.8)	(105.0)	+0.8	-0.8%
Research and development costs	(34.4)	(38.0)	-3.5	+10.3%
General and administrative expenses	(51.7)	(52.3)	-0.6	+1.2%
Total operating expenses	(191.9)	(195.3)	-3.4	+1.7%
	36.5%	32.0%	-4.5%	
Other operating income (expense)	(5.6)	(11.0)	-5.4	+97.6%
non recurring amount	(1.2)	(3.5)	-2.4	n.m.
EBIT	165.6	213.5	+47.8	+28.9%
	31.5%	35.0%	+3.4%	
Net financial income (expense)	(1.1)	(2.4)	-1.3	n.m.
Profit before taxes	164.5	211.1	+46.6	+28.3%
Income taxes	(37.8)	(48.6)	-10.7	+28.3%
Net result	126.7	162.5	+35.9	+28.3%
·				
EBITDA (1)	208.9	257.7	+48.8	+23.4%
	39.8%	42.2%	+2.5%	

(Amounts in million of ourse)	Q3		Change	•
(Amounts in million of euros)	2019	2020	amount	%
Net Revenues	174.8	227.9	+53.0	+30.3%
Cost of sales	(55.0)	(72.2)	-17.2	+31.2%
Gross profit	119.8	155.7	+35.8	+29.9%
	68.5%	68.3%	-0.2%	
Sales and marketing expenses	(35.4)	(34.1)	+1.3	-3.6%
Research and development costs	(11.1)	(12.5)	-1.3	+12.1%
General and administrative expenses	(17.3)	(17.5)	-0.2	+0.9%
Total operating expenses	(63.9)	(64.1)	-0.2	+0.4%
	36.5%	28.1%	-8.4%	
Other operating income (expense)	(0.6)	(1.8)	-1.2	n.m.
non recurring amount	(0.2)	(0.1)	+0.1	-40.0%
EBIT	55.4	89.8	+34.4	+62.0%
	31.7%	39.4%	+7.7%	
Net financial income (expense)	0.0	(1.0)	-1.0	n.m.
Profit before taxes	55.4	88.8	+33.4	+60.3%
Income taxes	(12.7)	(21.0)	-8.3	+64.9%
Net result	42.7	67.8	+25.1	+58.9%
EBITDA (1)	69.7	104.1	+34.4	+49.4%
EBITUA	39.9%	45.7%	+5.8%	+43.4 /0

⁽¹⁾ 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.





(Amounts in million of euros)	12/31/2019	09/30/2020	Change
Goodwill and intangibles assets	370.3	361.0	-9.2
Property, plant and equipment	128.4	129.6	+1.2
Net working capital	211.0	218.3	+7.3
Other non-current assets / (liabilities)	(33.9)	(59.3)	-25.4
Net Invested Capital	675.7	649.6	-26.1
Net Financial Position	172.9	256.1	+83.2
Total shareholders' equity	848.6	905.7	+57.1

CONSOLIDATED STATEMENT OF CASH FLOWS

(Amounto in million of ourse)	9 months	5
(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	171.1	199.3
Cash used in investing activities	(34.6)	(47.1)
Cash provided/(used) in financing activities	(47.6)	(68.9)
Acquisitions of companies and business operations	(4.4)	-
Net change in cash and cash equivalents before investments in financial assets	84.5	83.3
Divestment/(Investment) in financial assets	(16.4)	42.7
Net change in cash and cash equivalents	68.1	126.0
Cash and cash equivalents at the end of the period	141.2	283.6

(Amounto in william of arms)	Q3		
(Amounts in million of euros)	2019	2020	
Cash and cash equivalents at the beginning of the period	90.1	138.7	
Cash provided by operating activities	81.8	93.9	
Cash used in investing activities	(10.2)	(15.7)	
Cash provided/(used) in financing activities	(24.4)	(9.6)	
Acquisitions of companies and business operations	-	-	
Net change in cash and cash equivalents before investments in financial assets	47.1	68.6	
Divestment/(Investment) in financial assets	4.0	76.2	
Net change in cash and cash equivalents	51.1	144.8	
Cash and cash equivalents at the end of the period	141.2	283.6	

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