M@DE IN DIESSE

Nr. 6, April 2016

DIESSE IS AN ISO CERTIFIED COMPANY: UNI EN ISO 9001:2008 - UNI CEI EN ISO 13485:2012 - ISO 13485:2003, DIRECTIVE 98/79 CE

EBITDA MULTIPLES

Stefano Marchese, C.E.O.

The market valuation of business is quite often linked to the so-called "EBITDA Multiples".

The calculation of the Enterprise Value, *i.e.* the value of the business gross of financial liabilities, is made as a multiple of EBITDA. Usually, such multiple range from 5 to 8, but in some industries they may be higher or lower. The multiple is identified using the listed "comparables", *i.e.* the listed companies in the industry, and making an average value of them. However, it is difficult to justify such multiples because it is very difficult to find a real "comparable" of the company which is the target of the valuation.

Therefore, financial scholars have identified an algorithm which provides some foundation to these multiples.

Here is:

Enterprise Value/EBITDA = (1- t)/(WACC-g) + Depr*t/EBITDA/(WACC-g) - (CAPEX/EBITDA)/(WACC-g) - (Δ Working Capital/EBITDA)/(WACC - g)

In simple words such formula links the Free cash flow produced by a business to the EBITDA multiple. Such multiple is positively correlated to the growth rate and the level of depreciations, and is negatively correlated to the tax rate, the increase of working capital, the amount of capital expenditures.

This means that a conscious management of working capital and capital expenditure, as well as of the tax burden, can generate value as the increase of the growth rate; but this means also that, in some cases, growth at the expenses of huge increase in WC and CAPEX destroys value instead of generating a new one.

In other words, cash is king!

DIESSE's check-up *Catia Perazzolo, Finance Department*

Every three months, DIESSE makes a check -up in order to see if it is financially and economically healthy.

Here are the results of its last check-up, referred to the period Jan. 1, 2015 - December 31, 2015 compared to Jan. 1 – Dec. 31, 2014:

Consolidated figures (€ k)	2015	2014	2015/2014
Value of production	€ 88.830	€ 87.002	101%
EBITDA	€ 3.967	€ 3.566	111%
EBIT	€ 1.722	€ 1.614	107%
Profit from ordinary activity before tax	€ 1.016	€ 813	125%
Net financial position at the end of the period	€ 14.448	€ 15.578	93%

A NEW REGULATORY FUTURE

Chiara Muzzi, Regulatory Affairs Head

The main goal for all the manufacturers of Medical Devices (MD) and In Vitro Diagnostic Medical Devices (IVD) is to guarantee the safety of the patient, guaranteeing the placing on the market of always safer and performing products.For this reason, starting from the last 2009, a lot of activities for the revision of the current European Directives began. In 2012 the European Commission issued the first proposal of the New European Regulation for IVD; a new updated version of the proposal, issued on the last September 2015, is currently under the final analysis of the Trilogue (European Commission, European Parliament and Council), and its official emission is foreseen soon (probably within the next June).

The new IVD European Regulation will bring some important changes if compared with the current 98/79 EC Directive. The main changes will be:

Classification System and Conformity Assessment

IVD products will be classified, in accordance with the risk they pose to the individual and with the risk they pose to public health, into four classes (following seven rules): Class A (lowest risk), B, C and D (highest risk). According to this new classification, it has been estimated that over 80% of IVD products will be classified in the medium and higher risk categories (Class B, C, and D) and will require Notified Body involvement in the conformity assessment procedure. Another significant change from the current directive is that all devices that do not fit any of the classification rules are automatically classified as Class B and a notified body will be required for conformity assessment.

Clinical Evidence

It is proposed that clinical evidence will be required to support the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device. A performance evaluation report that includes the scientific validity report, the analytical performance report, the clinical performance report and an assessment of these reports will be required. The report will need to be updated throughout the product lifecycle, and will be part of the technical documentation.

Traceability

IVD products will be identified by an Unique Device Identification (UDI), present on the device label. The UDI will be used for reporting incidents and field safety corrective actions. UDI will consist of a production identifier and device identifier. A database, where the UDI of each device will be input, will be established.

Regulatory Responsibilities within the Supply Chain

The proposed regulation outlines new responsibilities for importers and distributors. Before making the device available on the market, they will have to verify that the device is in compliance with the Regulation requirements. Moreover they will be obliged to ensure that while the product is under their responsibility it is stored and transported correctly, and ensure that product complaints they receive are logged and forwarded to the manufacturer for investigation where necessary. They will be also obliged to inform the competent authority if they have reason to believe that a device presents a serious risk or is falsified.

Notified Bodies

The proposed regulation contains detailed requirements for monitoring of the performance of notified bodies by national competent authorities.

Vigilance and Post-Market Surveillance

A reduction in the timeline for reporting of a serious incident to the national competent authority to no later than 15 days from when the manufacturer has become aware of the incident is proposed.

An obligation for manufacturers to produce a Periodic Safety Update Report (PSUR) on at least an annual basis is proposed. The PSUR will summarize the device's post-market surveillance data and risk-benefit information. An electronic system will be set up where incidents, field safety corrective actions, periodic summary reports, PSURs and trend reports are input.

This proposal constitutes an improvement in transparency, providing the users with the information to allow them to make more informed decisions about use of an IVD.

Companion Diagnostics

A definition for a companion diagnostic is provided in the proposed regulation. Companion diagnostic tests will be classified in Class C and will require notified body involvement in the conformity assessment.

All the changes proposed will have an important impact on the IVD industry considering:

- the increasing time, complexity, and resources required to launch a new product
- the increasing complexity of the post-market activities
- the significant investment, that will be necessary for the transitioning of the current products to comply with the increased regulatory requirements.

2015 Technical Support's Statistics - OVERSEAS

Mario Porciatti, Technical Support / CQS Manager

Despite the significant increase in installations , we noticed an important decrease in technical assistance requests in 2015, which means that the training sessions performed in our headquarters and at the customers' site were very helpful. This was not only due to the work of our technical support, but also to the quality of technicians made available by distributors. We would like to underline that trainings should be performed as much as possible at our premises: in our laboratory we can completely disassemble and e-assemble each instrument, we can show all spare parts and documentation, operations that obviously is almost impossible to perform at the Distributors' site on instruments that have to be installed in clinical laboratorie after the training has been completed. For this reason, we encourage all our Distributors to check the dates of the next training session in our web-site and to thoroughly fill-in the electronic form available in the web page.However, Cube 80 is the only instrument that reports an overall increase of 100% in technical assistance requests. What the sales analysis show is that the instruments were all sold to distributors that entered the Cube 80 market for the first time. As problems arose, we provided a dedicated technical support service. Finally, we would like to report an increase in the number of distributors that choose to contact our technical experts on Whatsapp, Viber, Skype or by phone to receive real time support.

INSTRUMENT	Mails Year 2014	Mails Year 2015	Sold Instruments Year 2015
Chorus	275	240	125
VesEasy	23	11	486
VesMatic20	49	30	122
VesMatic30	56	45	12
VesCube30	103	115	195
VesCube80	86	163	47
VesCube200	207	172	21
Robobact	3	4	0

2015 Technical Support's Statistics - ITALY

Mario Porciatti, Technical Support / CQS Manager

Analysing Chorus and Cube data, we noticed that although the number of newly installed instruments has increased compared to the previous year, the percentage of calls for assistance and interventions have pretty much remained the same.

However, we saw a slight increase of technical interventions for Chorus and Ves-Matic Cube 30: the first one was due to the new installations of refurbished instruments, in particular for the Calprotectin Test; the second one was due to the growth of the number of installed instruments.

We would like also to point out the improved reliability of Ves-Matic Cube 200 and Ves-Matic Cube 80, as a result of the changes in the software control of the motors (less jamming) and to the hardware changes implemented with the flat cables that prevent breakages in the wirings . On the other hand, we confirm the initial positive performances of Ves-Matic Cube 30, that is showing to be a rather robust machine.

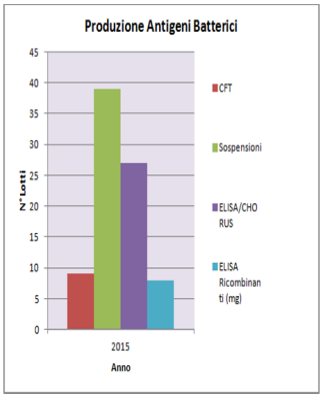
Instrument	Year	N. of Installations	N. of Calls	Average %	N. of Technical Interventions	Average %
Ves Cube 200	2011	105	365	3,5	215	2
	2012	129	356	2,8	219	1,7
	2013	131	351	2,7	232	1,8
	2014	145	381	2,6	258	1,8
	2015	**178**	**390**	**2,5**	**252**	**1,6**
Chorus	2012	628	905	1,4	538	0,9
	2013	647	872	1,3	629	1,0
	2014	680	913	1,3	663	1,0
	2015	**754**	**853**	**1,2**	**687**	**1,0**
cube 30	2012	82	63	0,8	40	0,5
	2013	108	55	0,5	38	0,3
	2014	124	57	0,5	37	0,3
	2015	**164**	**72**	**0,5**	**56**	**0,4**
cube 80	2012	12	25	0,8	15	1,3
	2013	14	27	1,9	18	1,3
	2014	15	34	2,3	24	1,6
	2015	**16**	**25**	**1,6**	**20**	**1,3**

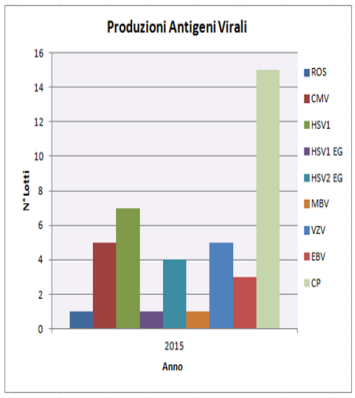
INSTRUMENT	MTBF
Ves-Matic Cube 200	228 days
Ves-Matic Cube 80	281 days
Ves-Matic Cube 30	912 days
Chorus	405 days

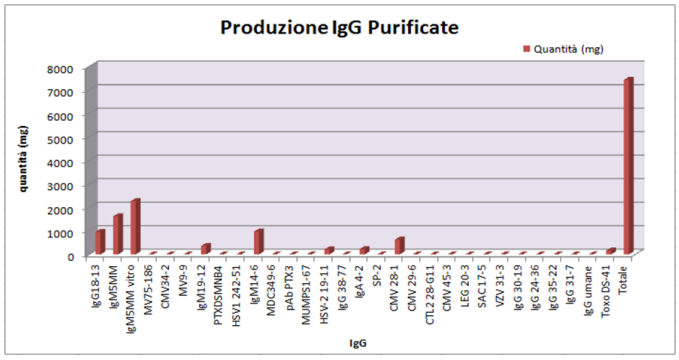
SIGNIFICANCE OF BIOREAGENTS PRODUCTION AREA IN DIESSE

Veronica Ricci, Responsible of Semifinished products department

One of key points of corporate strategy is the in-house production of the most of biological components employed on Diesse in vitro diagnostics systems. Diesse company have three rooms BSL-3 reserved for the production respectively of viral antigens, bacterial antigens and monoclonal antibodies. Bioreagents area in effect makes a substantial number of antibodies, specially monoclonal antibodies then used both in solid phase is marked in form of conjugates antibodies in diagnostics kits. Virology area produces more than forty viral antigens like primarily TORCH antigens but also Measles, Mumps, Adenovirus 2 and 7 and a lot of Echovirus, Coxsackievirus serotypes and other antigen. The Bacteriology department makes a large selection of bacterial suspensions like Salmonella Typhi and Paratyphi, Salmonella Enteritidis and Typhimurium but also Brucella and Proteus. The production also includes some bacterial antigens: Helicobacter Pylori, Bordetella Pertussis, Campylobacter Jejuni, Mycoplasma Pneumoniae and others. It's finally very important the recombinant proteins production specially P30 for Toxoplasma Gondii, 15k,17k and 42k for Treponema Pallidum and EBNA, EBA 74 for Epstein barr virus.







A COFFEE WITH... MR. TINTON HERU SUSETIO

We are happy to start a new section expressly created to give voice to our Distributors. Rapid questions and answers, as if we were having a coffee time together!

Mr. Tinton Heru Susetio is Sales Manager at PT Abadinusa Usahasemesta, our **ESR Distributors** in Indonesia

1. What do you like most in working with Diesse?

We like work and coorperation with Diesse because Diesse has good product quality

- Delivery time is OK
- Stock always available and communication with Diesse is getting better.

Which new products would you like to have on your market?

Vesmatic 30 Tube, next future in Indonesia via EDTA Tube for reagent ESR, reduce cost and easy maintenance and operation.

Which will be the next appointments (exhibitions, congresses..) where you will promote Diesse products?

Our planning for promotion Vesmatic Diesse in this year :

- Indonesia Public Hospital Association / ARSADA Expo, 13 – 15 April 2016, Jakarta.
- Hospital Expo, in October 2016, Jakarta.

Which are the factors which lead your company to gain its position in the market?

A. We have good maintenance / sevice for our customer.

B. Reagent available, ready stock.

C. Product Diesse = Good Product.

D. Delivery time to our customer = Good.

Your country: how would you describe it to someone who never visited?

We have good distribution network with local dealers / sub dealers in all over Indonesia; we collaborate with 10 sub distributors in Java and with 4 sub distributors in Sumatera, with 2 sub distributors in Kalimantan and 1 sub distributor in Sulawesi.

NEWS FROM THE WORLD

CHINA

Come and visit us at

CMEF® China International Medical Equipment Fair

Shanghai, 17-20 April 2016, stand H3-K08

SINGAPORE

MEDLAB ASIA PACIFIC

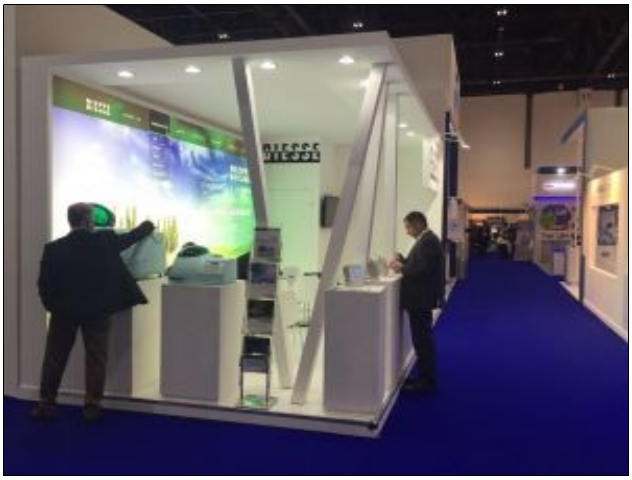
Diesse took part for the first time to the MEDLAB Asia Pacific exhibition in booth # M49 Hall A on 22 - 24 March 2016. We would like to thank Visitors who showed up at our stand during this event.

DUBAI ARAB HEALTH 2016

As announced in Nr. 5 issue, Diesse arranged a meeting on the first day of Arab Health Exhibition in the wonderful location of **The Address Hotel Downtown Dubai,** with the following main focuses:

AUTOMATIZED CHORUS NEW KITS UNDER DEVELOPMENT AUTOMATED SYSTEM FOR DIRECT AGGLUTINATION TESTS VES-MATIC CUBE 25

Thanks to our Distributor **Samir Digital Technology** for their valuable support in supporting us to arrange this important meeting.



DIESSE Diagnostica Senese SPA

Head Office: Via A. Solari 19, 20144 Milano, Italy

Secondary Seat: Via delle Rose 10, Loc. La Tognazza, 53035 Monteriggioni (Si), Italy,

email: madeindiesse@diesse.it website : www.diesse.it