Ulisse BioMed

Sector: Health Care

"Thanks" to Covid, beyond Covid

VALUETRACK

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Fair Value (€) (*)	**4.50**
Market Price (€)	**3.45**
Market Cap. (€m)	**25.9**

Ulisse BioMed S.p.A. (UBM) is an Italian Diagnostic company active in the development of i) RT-PCR molecular diagnostic assays/reagents; ii) nano-switches based assays for therapeutic drug monitoring; and iii) antiviral aptamers for therapeutic or diagnostic purposes. It should hit the market via a licensing agreement with Menarini Diagnostics in 4Q 2021.

Revenues to take-off in 2022E (€4.1mn by 2024E)

Ulisse BioMed reached economic break-even in FY2020, it should generate positive free cash flow in FY2021E and from 2022E we envisage top line to accelerate and to post a 10x growth by 2024E. We expect Gross margin above 80%, EBITDA one above 60% and strong FCF despite €2.2mn cumulated R&D costs over 2021E-2024E. Proceeds from recent IPO should accelerate development of high potential technologies, yet more aggressive R&D plans will also lower short term earnings compared to our forecasts.

What could go wrong?

Risks faced by UBM are very typical of small players in its sector: 1) execution risk on commercial side and partnerships; 2) concentration of revenues (with Menarini Diagnostics and relative to Sars-CoV-2); 3) risk of R&D failure, regulation change and certification delays. We believe major hick-ups by Menarini Diagnostics, failures in R&D or in execution on the "go to market" strategy might seriously affect earnings outlook and value of the company.

What could go beyond expectations?

UBM's investment case also includes a few upside risks, namely: 1) slower than expected normalization of Covid-19 testing /genotyping; 2) more favourable co-development agreements and new grants awarded; 3) better and faster outcomes from R&D (on Sagitta and NanoHybrid); 4) M&A appeal, unlocked by listing and by positive R&D outcomes. All these events would be value enhancing compared to our assumptions.

€4.50 fair Equity value per share

We start coverage on UBM with a €4.50 fair value p/s (€37mn equity value), calculated as average of peers analysis and DCF valuation, based on outstanding number of shares and diluted for "Short Run Warrants 2021". At fair value, the stock would trade at 17.2x-15.6x EV/EBITDA and 26.9x-29.5x P/E based on our 2022E-23E estimates and warrants' dilution. Out of this value we estimate €2.62 p/s are due to Menarini Diagnostics Agreement and €0.76 p/s to cash (2021E adj. for "Short Run Warrants").

KEY FINANCIALS (€mn)	2020A	2021E	2022E
TOTAL REVENUES	0.8	0.8	2.7
EBITDA	0.3	0.3	1.7
EBIT	0.2	0.1	1.4
NET PROFIT	0.2	0.1	1.4
OPFCF a.t.	-0.7	0.4	0.9
NET INV. CAP.	1.5	1.2	1.6
EQUITY	1.6	5.8	7.1
NET FIN. POS.	0.0	4.6	5.5

Source: Ulisse BioMed SpA (historical figures), Value Track (2021E-22E estimates)

KEY RATIOS	2020A	2021E	2022E
GROSS MARGIN (%)	81.6	97.1	93.3
EBITDA MARGIN (%)	36.1	43.2	64.6
EBIT MARGIN (%)	29.4	8.7	52.3
NET PROFIT MARGIN (%)	29.1	6.6	51.0
EV/SALES (x)	nm	nm	9.1
EV/EBITDA (x)	nm	nm	11.8
P/E (x)	nm	nm	20.9

Source: Ulisse BioMed SpA (historical figures), Value Track (2021E-22E estimates)

STOCK DATA	
FAIR VALUE (€) (*)	4.50
MARKET PRICE (€)	3.45
SHS. OUT. (m), primary	7.5
MARKET CAP. (€m)	25.9
FREE FLOAT (%) (**)	79.3
AVG. -20D VOL. (#)	32,700
RIC / BBG	UBM.MI / UBM IM
52 WK RANGE	3.22-6.29

Source: Stock Market Data (*) based on outstanding number of shares and including the exercise of the "Short Run Warrants" (**) 46% of capital is free float but subject to a 2yrs lock-up

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Executive Summary

Ulisse Biomed and IPO rationale

Ulisse Biomed (UBM) is an **Italian healthcare biotech company** specialized in the development of innovative, cost-effective and rapid in-vitro diagnostics (**Molecular Diagnostics**), personalized medicine products (**Therapeutic Drug Monitoring**) and innovative therapeutic solutions (aptamers). The company's products should hit the market in Q4 2021, thanks to a licensing agreement relative to Sars-CoV-2 detection and genotyping. The company has strong R&D pipeline and prestigious Scientific Advisory Board, and a BoD strengthened by new members with diversified backgrounds. The recent IPO on AIM Italia (€5mn gross proceeds) should enable management to: a) strengthen UBM visibility and appeal; b) speed-up the development of more recent platforms and potentially consider selective M&A; c) provide marketability to existing shareholders (beyond usual lock-up period).

Competitive hedge of products and technologies

Ulisse Biomed has developed **three technology platforms** capable of generating innovative and competitive products (assays, reagent and molecules). Of these platforms **Sagitta is the most consolidated** one, with a few products for RT-PCR technology due to **start commercialization over 2021-2022**. Sagitta assays claim **strong competitive hedge** relative to products on the market, due to flexibility (multiplexing capacity), accuracy, higher speed/lower complexity of workflow and competitive cost. Management expects these advantages to be replicated in a number of new test menus to be developed in next quarters.

The "younger" technologies - **NanoHybrid** based on *nano-switches* and **Aptavir** based on *aptamers* - **will need more time and development** efforts; however, they represent **cutting-edge technologies**, with strong potential advantages relative to currently available technologies and applications. For these ones, management intends to pursue independent development and in-house production - and proceeds of the recent IPO may speed-up development schedule.

In FY 2020 first revenues, in FY2021 positive FCF, in FY2022 the inflection point

Until 2019 UBM was **a "pre-revenues" company** – reporting only revenues from grants and R&D tax credits, while consistently investing in research to patent its proprietary technology platforms. **In 2020,** UBM reported **some revenues thanks to the licensing agreement** signed with Menarini Diagnostics Srl, on the production and commercialization of Covid-related tests. This, combined with the streamlining of the cost structure following the focusing of R&D efforts and go to market strategy, led the company to positive bottom line. We expect **FY2021** to be a similar year, as commercialization of products should start only in Q4, but the company should start **generating free cash flow for the first time** since inception.

From FY2022 we expect the **top line to significantly accelerate** (€2.7mn) with a material improvement also for margins and bottom line. We forecast revenues from sales to grow by almost 10x between FY2020E and FY2024E.

Our forecasts factor only "visible" business

UBM business model strongly relies on partnerships and **our forecasts are based on two main partnerships**: 1) the existing licensing agreement with Menarini Diagnostics for the sale of CoronaMelt, CoronaMelt Var and the Syndromic Respiratory test; 2) a future potential agreement related to Sexually Transmitted Diseases (STD) and, in particular, HPV Selfy/LadyMed. In addition, we assume other co-development agreements to contribute to R&D costs (for 80% of total) for the new Sagitta's panels to be developed from 2022 onwards. Yet, the remaining products of UBM's potential

pipeline do not contribute to our revenues forecasts at all, as they are still far from commercialization and no negotiations to find a suitable partner have started yet. The rationale behind this choice is that of including **in** revenues from **sales only** those **products** that are ready to be marketed and **for which a licensing agreement has already been signed or, at least, is entering potential discussion**. As for R&D related revenues, beyond the collaboration revenues indicated above we assume revenues from grants limited to those already awarded and R&D tax credits equal to 20% of R&D expenses.

UBM fully funded, but IPO proceeds may accelerate R&D and dilute short-term earnings

UBM closed FY2020 in profit and with a small net cash position. We expect **the company to start generating free cash flow as of 2021** and see it as **fully funded**, based on: a) successful execution of license by Menarini Diagnostics and b) the current (pre-money) R&D pipeline. It is worth to add that our forecasts assume a) a cautious stance relative to Sars-CoV-2 test demand over 2022-2024E; b) new partnerships to fund only 80% of R&D costs and only for the Sagitta platform; c) partnerships to be limited to European markets over the forecast period, despite FDA 510(k) approval may be requested by partners and/or other markets accepting CE-IVD products may be targeted. Hence, assuming that despite the execution risk attached to UBM strategy, everything goes in line or better than our forecasts, the proceeds of the recent **IPO should either a) focus on speeding-up the development schedule of the high potential technologies** (in primis NanoHybrid), where management intends to pursue independent development and in-house production **or b) target other R&D hub(s)** involved in similar research areas. Pending clear indications from management we do not assume any o the two, yet the faster development and quicker path to market **may have the drawback of boosting R&D costs and hence lower earnings and FCF over 2022-23E**, compared to our current forecasts, based on pre-money R&D plans.

Good news may come from a few sides and enhance value

We see a few potential risks, as described below, but it is worth to add that **we also see many upside risks, as we start from a cautious stance** on a few elements, as: 1) Covid-19 outlook, 2) partnerships' timing and related collaboration revenues, 3) lack of revenues from new grants and 4) lack of revenues from new panels of Sagitta, 5) lack of revenues from new platforms Nanohybrid and Aptavir. For each of these factors we may have a more favourable outcome, which would materialize in higher revenues, margins and lead to additional value to the firm.

Last but not least, we have not mentioned the **potential M&A upside**, but the M&A appeal of UBM may be unlocked in the next couple of years by strengthened visibility and encouraging news on the development side.

Fair Equity Value at €4.50 p/s

We start coverage on UBM with a €4.50 fair equity value p/s (€37mn 100% equity value), calculated as average of Peers analysis and DCF valuation methodologies, based on outstanding number of shares and including the exercise of the "Short Run Warrants 2021". At fair value, the stock would trade at 17.2x-15.6x EV/EBITDA and 26.9x-29.5x P/E based on our 2022E-23E estimates and including the dilutive effect of mentioned warrants (to be exercised at €2.50 p/s). A fully diluted scenario, i.e. assuming the full-exercise of all outstanding 2021-26 warrants (exercise price €2.80 p/s), would imply a further minor dilution to €4.46 fair value per share.

In terms of "visibility" of such a value, we calculate that the business secured by the licence agreement with Menarini Diagnostics represents ca. 58% of our fair equity value (€2.62 p/s), while the remaining part is due to the potential value of other products already developed – where CE-IVD marking and/or licensing agreements are still missing – as well to the potential of the pipeline for products which still require development (€1.12 p/s), and lastly the Net Cash Position (2021E adj. for the "Short Run Warrants") accounts for €0.76 p/s.

Major elements of risk

High concentration of revenues for next three years

The drawback of the strategic licensing signed with **Menarini Diagnostics** is that, according to our forecasts, UBM will show in the next years a clear dependence on its partner. This partnership is expected **to bring the bulk of revenues over the whole forecast period** (average at ca. 75% including other revenues) and this also brings a strong dependence of the Company's business to Covid-related revenues. In the next few years (2021-2023E), we envisage a declining incidence of Covid-related revenues, with the expected contribution of **royalties and reagent's sale related to Sars-CoV-2** to UBM's total revenues to reduce from 67% in 2021E to 26% in 2023E.

Albeit Covid-19 is an unexpected and probably temporary business opportunity for UBM, as for many other MDx and IVD players, the development of CoronaMelt has allowed the company to sign a license with a major player in the industry, accelerate its path to profitability and fund its R&D pipeline relative to the other high potential technologies. **Should Menarini Diagnostics fail to achieve the targets implied by our forecasts** (they have not granted exclusivity to UBM and minimum guaranteed are not material beyond 2021 compared to our expectations), **UBM's financial outlook would be significantly impacted**.

Innovative products will take time, still high risk attached

NanoHybrid is Ulisse BioMed's most innovative and advanced technology platform and has also the highest potential, and management **intends to carry out development of NanoHybrid autonomously as well as in-house production, and to search a partner only for distribution.** This technology is based on **nano-switches**, i.e. synthetic nanotechnology structures capable of instantaneously detecting protein biomarkers (including biological drugs) in complex biological matrices: hence it can be implemented not only for diagnostic solutions but also in theranostics, in particular for drug monitoring – e.g. monoclonal antibodies, very expensive biological drugs particularly used in cancer therapy. NanoHybrid can represent a successful alternative to ELISA (Enzyme Linked Immuno-Sorbent Assay), currently considered the gold standard in immunological diagnostics, and to rapid lateral flow tests for portable diagnostics (POC). UBM wishes to develop through the use of NanoHybrid mainly **two products**: assay and POC. The latter **should take longer** and development will require a strategic partnership for the development of the hardware (fluo reader) and/or for the co-development of the underlying technology (electro reader).

Execution risk: No Patents & Partnerships, No Party

The company has a very lean structure and management team and, despite the efforts to strengthen it and to enrich the board with new valuable members, boasting also differentiated expertise and background, we still see some execution risk. The company will face **challenges on a few fronts**, namely: a) **development of new assays** based on different technologies and targeting different disease groups, as these are pre-requisite to offer appealing test menus to consolidate the presence of its platforms; b) **sign of a few strategic partnerships** to get support for the test menus' development and to secure effective commercialization; c) select partners for the development of the **hardware to support new POC systems**. All this will need a seamless and focused execution, already over the next 18 months, on both the R&D and the commercial/contractual sides.

Sector specific risk factors

The investment in stocks as UBM brings some risks that are not specific to the company itself, but rather to its sector and business model. Among these we name: the high competitiveness of diagnostics, the high risk related to R&D investments; regulatory changes and timing, risk of disruptive new technology, products or applications.

Valuation

We start coverage on UBM with a €4.50 fair equity value p/s (€37mn equity value), calculated as average of Peers analysis and DCF valuation methodologies, based on outstanding number of shares and including the (dilutive) "Short-Run Warrants" exercise. At fair value, the stock would trade at 17.2x-15.6x EV/EBITDA and 26.9x-29.5x P/E based on our 2022E-23E estimates and diluted for the exercise of the warrants mentioned above (whose exercise price is €2.50 p/s).

DCF model, assuming a 12.0% WACC and terminal value based on a 3.0% perpetuity growth rate, gives a value of €4.43 p/s. Peers' analysis which includes small European listed companies in MDx – as we believe these tend to factor the medium-term potential of pipelines, too – points to a fair equity value per share of €4.61, based on a fair multiple of 14x EV/Sales FY22 (peers' average).

As a crosscheck, we calculate that a) the business secured by the recent licence agreement with Menarini Diagnostics represents ca. 58% of our fair equity value (€2.62 p/s); b) Net Cash as of 2021E, adj. for "Short Term Warrants", accounts for €0.76 p/s; and finally c) the remaining part, due to the value of other products already developed and the potential of the pipeline of products which still require development, is worth €1.12 p/s.

Lastly, we highlight how similar peers (mostly pre-revenues companies) show on average equity values around €36mn with a high concentration in the €15-30mn bracket.

Valuation challenges

The key issues to be addressed to assess the valuation of Ulisse Biomed are the following:

- Evaluate the financials of the partnership with Menarini Diagnostics, which is the only business line with clear "go to market" strategy, terms, and timing;
- Evaluate the potential of the products (as HPV and other STD screenings) where UBM still has to find a partner(s) and seek CE-IVD certifications, but for which timing is more predictable and tests are all at least at RUO (Research Use Only) stage;
- Factor the potential of the pipeline for products which still require development and hence bear a certain risk of failure and a much lower visibility about timing of developments and certifications, financial requirements (R&D) and potential partnerships. This is the case for:
    1) the new panels by Sagitta - oncology and infectious diseases targeted are highly crowded and competitive diagnostic niches);
    2) the relatively younger and highly innovative technologies of NanoHyprid and Aptavir.

Valuation methodology

We set our valuation according to:

1. **DCF model that captures the whole business of UBM**, based on the partnerships we can envisage in this moment with **products already developed**, i.e. including Sagitta's CoronaMelt/Var and Respiratory Viral Panel (Menarini Diagnostics partnership), HPV and other STD by Sagitta (partnership(s) to be identified) and the reagent UlisseFaster;
2. **Relative market multiples** that embed a few elements of weaknesses - as setting an appropriate and accurate peers' group, dealing with high dispersion of multiples and often with lack of meaningful forecasts; yet market multiples of smaller players in the diagnostic sector do incorporate the expected growth and value related to their pipelines.

Cross checking our fair value for Menarini Diagnostic Agreement and peers' equity value range (mostly pre-revenues companies) validates our fair equity valuation.

Discounted Cash Flow Model

Here below we report our DCF model assumptions:

- a 2% risk-free rate in line with medium-term target inflation;
- a 4% specific risk factor (coupled with a 1.0 Beta), to incorporate the risk profile of a scale-up corporate in a highly competitive arena as diagnostics;
- WACC equals to Cost of Equity, as the company is cash positive, and new proceeds from IPO should accelerate product development without financial stress.

Ulisse BioMed: WACC Calculation

	(%,x)
Risk free	2.0%
Risk Premium	6.0%
Beta Unlevered	1.0
Small Cap Risk Premium	4.0%
Cost of Equity = WACC	**12.0%**

Source: Value Track Analysis

- 2021E as reference point for valuation and explicit 2022E-25E financial estimates;
- Terminal value at 2026E obtained applying a 3.0% PGR, as all the R&D investments are expected to bring additional long-term growth.

The model suggests a €34.4mn fair equity value (€4.60 p/s, primary) with a heavy bias to terminal value.

Ulisse BioMed: DCF model outcome

	€'000
PV of future Cash flow FY 2022E-25E	5,298
PV of TV 2026E	24,524
Enterprise Value	**29,821**
Implied EV/EBITDA 2022E(x)	17.4x
Implied EV/Sales 2022E(x)	14.5x
Net Cash Position 2021E	4,613
Equity Value	**34,434**
Outstanding number of shares (#mn)	7.5
Equity Value per share (€), primary	**4.60**

Source: Value Track Analysis

In order to clarify the implications of a higher/lower WACC/PGR combination, in the sensitivity below we indicate that a 100bp lower WACC corresponds to a 10% higher equity value, while a 50bp higher PGR corresponds to a 5% higher equity value.

Ulisse BioMed: DCF Model Sensitivity Analysis - Equity Value (€p/s), primary

		Perpetuity Growth Rate				
		2.0%	2.5%	3.0%	3.5%	4.0%
WACC	10.0%	5.00	5.26	5.56	5.90	6.30
	11.0%	4.58	4.78	5.02	5.28	5.58
	12.0%	4.24	4.40	**4.60**	4.80	5.03
	13.0%	3.96	4.09	4.25	4.42	4.61
	14.0%	3.72	3.84	3.96	4.11	4.26

Source: Value Track Analysis

Peers' Analysis

Market multiples within the IVD and MDx sector are extremely fragmented, with a clear cut between larger and consolidated players and small scale-up and pre-revenues names. We have built two separate groups of stocks:

- Larger global IVD/MDx players – including 8 names among those more exposed to assays, reagents and kits rather than hardware and machines;
- European scale-up names (mostly pre-revenues) – including 9 listed players we see as the most similar to UBM in terms of products, business model and life cycle (see table below).

The tables below summarise the current trading multiples of the stocks in the two groups, i.e. larger global players and smaller European scale up companies.

Ulisse BioMed: Large Peers' trading multiples

Company	Listing market	Market Cap (€mn)	EV/Sales (x)		EV/EBITDA (x)	
			2021E	2022E	2021E	2022E
Seegene	South Korea	1,917	1.7	2.5	3.4	6.6
Meridian Bioscience	US	684	2.3	2.6	7.1	9.1
Biomerieux	France	12,715	3.8	3.8	13.4	15.4
Diasorin	Italy	10,025	9.2	8.3	21.9	21.4
Hologic	US	15,545	3.6	4.5	7.0	12.8
Co-diagnostics	US	208	2.1	2.4	5.1	4.8
Qiagen	US	10,510	6.0	6.2	15.1	17.2
Quidel	US	4,383	3.3	4.5	5.0	8.7
Average		**6,998**	**4.0**	**4.3**	**9.8**	**12.0**
Median		**7,204**	**3.4**	**4.1**	**7.1**	**10.9**

Source: Consensus Estimates, Value Track Analysis

Ulisse BioMed: Scale-up Peers' trading multiples

Company	Listing market	Market Cap (€mn)	Enterprise Value (€mn)	EV/Sales (x)	
				2021E	2022E
Spago Nanomedical AB	Sweden	23.9	18.3	26.2	25.9
SenzaGen AB	Sweden	30.0	24.0	24.0	9.6
BioMark Diagnostics Inc.	Germany	14.8	13.9	nm	nm
Genedrive PLC	UK	20.5	13.6	16.5	3.3
Epigenomics AG	Germany	11.4	9.3	1.6	17.2
Biovica International AB	Sweden	120.0	105.6	27.1	17.6
Lumito AB	Sweden	10.0	6.0	nm	nm
Aegirbio AB	Sweden	70.7	69.7	nm	nm
Attana AB	Sweden	18.8	16.7	12.0	10.5
Average		**35.6**	**30.8**	**17.9**	**14.0**
Median		**20.5**	**16.7**	**20.3**	**13.9**

Source: Consensus Estimates, Value Track Analysis

On the back of the multiples above we can highlight the following considerations:

a) the first group indicates for **larger players** trading multiples overall not so demanding (i.e. **EV/Sales of 4.0-4.3x** and EV/EBITDA of 9.8-12.0x for 2021-2022E average respectively), factoring also very strong balance-sheets and aggressive M&A strategies;

b) **smaller players** trade at much higher EV/Sales multiples – most of them are still loss-making: **17.9-14.0x** for 2021-2022E respectively (average values). Their **equity values range** is €10-70mn (€36mn average) – excluding Biovica, listed only 4 years ago with a pre-money equity value at the time of €16mn, and now well above the €100mn – with a high concentration **in the €15-30mn bracket**;

c) a few **recent M&A deals** made public in the MDx industry involved players positioned, in terms of size, in between the two groups above and multiples paid **averaged 6.9x EV/Sales** (see table). These imply a rich premium to large players (consolidator) but are well below those of scale-ups.

M&A deals - A few recent deals' multiples

Deals	Year	EV/Sales (x)	Target's revenues
Bidder > Target		FY0	($ mn)
Diasorin > Luminex	2021	4.2	417
Roche > GenMark	2020	10.3	172
Hologic > Biotheranostics	2020	7.0	33
Menarini Diagnostics > CellSearch	2017	na	na
Biomiereux > Biofire	2013	6.4	70
Agilent > Dako	2012	6.5	340
Average		**6.9**	**206.4**

Source: Value Track Analysis

This confirms that, as anticipated above, the rich trading multiples on EV/Sales for scale-up names do incorporate the material growth expected by these innovative and young companies and the value the stock market expects to come from their R&D pipeline. Hence, despite all the elements of cautiousness mentioned, we believe a relative valuation based on peers' multiples in the same market segment can provide a useful benchmark for a company with a strong R&D identity and relatively small presence on the market.

Hence, assuming a fair multiple in line with smaller peers, i.e. 14x EV/Sales 2022E **we get to an equity value of €35.9mn,** or €4.80 primary (i.e. based on outstanding shares). The 2022E revenues considered (€2.2mn) do not include the tax credits linked to the IPO charges (which are "one off" and not linked to the business, but have to be reported among revenues).

Menarini Diagnostic Agreement values some €21.3mn

The business related to the agreement already signed with **Menarini Diagnostics**, which includes i) the royalties coming from the sales of Covid-related assays and of the Respiratory Viral Panel and ii) the supply of the UlisseFaster reagent represents an unlevered value of €21.3mn.

Our valuation is made via a **DCF model** run over the licensing agreement horizon, i.e. 20 years, in line with the CoronaMelt/Var patent duration. The only cash costs associated to these revenue flows are the production costs of the reagent and taxes after 2024. The model 2021E-25E explicit financial estimates, while flat revenues and margins beyond 2025 for another 15 years until patent/license expiration.

On the contrary, this model does not include the rest of the business, related to:

- the planned partnership for HPV (HPV Selfy / LadyMed) and other STD tests, namely collaboration revenues and royalties;
- revenues from sales of UlisseFaster (reagent) to third parties, i.e. other than Menarini Diagnostics;
- collaboration revenues from partners to be identified as for the other Sagitta panels (Oncology, Infectious Diseases);
- grants already awarded but not cashed and expected R&D tax credits;
- R&D costs for all the planned developments, including NanoHyprid over 2021E-2024E as from our forecasts, and for 2025E R&D costs equal to 10% of revenues, invested for Aptavir and others.

Ulisse BioMed: Evaluating the Menarini Diagnostics license agreement – DCF model

	€'000
PV of cash flows 2021E-2025E	6,927
PV of cash flows 2026E-2040E	14,329
Menarini License Agreement – Unlevered Equity Value	**21,256**
Implied EV/EBITDA 2022E(x)	16.7x
Implied EV/Sales 2022E(x)	15.3x

Source: Value Track Analysis

Fair Equity Value at €4.50 p/s

We start coverage on UBM with a €4.50 fair equity value p/s, calculated as average of Peers analysis and DCF valuation methodologies and assuming the full exercise of "Short Run Warrants 2021" and the related diluted effect on value per share. At fair value, the stock would trade at 17.2x-15.6x EV/EBITDA and 26.9x-29.5x P/E based on 2022E-23E estimates. Our €4.50 fair value can be split as follows:

- €2.62 p/s (€21.3mn) refers to the agreement already signed with Menarini Diagnostics and dealing with i) the royalties coming from the sales of Covid-related assays and of the Respiratory Viral Panel and ii) the supply of the UlisseFaster reagent to Menarini;
- €1.12 p/s (€9.1mn) refers to the "rest of the pipeline" (i.e. not captured by Menarini Diagnostic license). This value would be backed by a cumulated level of R&D costs over 2021E-2025E (not covered by Menarini Diagnostics collaboration revenues) of ca €2.4mn, on top of the patents/investment already made over 2015-2020 as for NanoHybrid and Aptavir.
- €0.76 p/s for the 2021E year-end Net Cash Position (which clearly includes the net proceeds from recent IPO), adjusted for the proceeds of full "Short Run Warrants 2021" exercise (€1.56mn).

A fully diluted scenario, that is assuming also the dilutive effects coming from the exercise of deep in-the money "Warrants 2021-2026" (excluding those still to be assigned to BoD and management), would imply a further minor 1% reduction in fair value. It is worth to note that we do not consider at this stage the impact of the "Detachable Warrants" (whose estimated market value is €0.08 p/s), as they will be attached to UBM shares until January 2022.

Ulisse BioMed: Valuation Summary

	DCF	Peers	Average
Current situation – Primary (Outstanding Nosh)			
Fair Equity Value (€mn)	34.4	35.9	35.2
Number of Shares (mn)	7.50	7.50	7.50
Fair Equity p/s (€)	**4.60**	**4.80**	**4.70**
Base Case Scenario – Diluted for "Short-Run Warrants 2021"			
Proceeds (€mn)	1.56	1.56	1.56
New Shares from exercise of Short-Run Warrants (mn)	0.63	0.63	0.63
Fair Equity Value (€mn)	36.0	37.5	36.7
Fair Equity p/s (€)	**4.43**	**4.61**	**4.52**
Fully Diluted Scenario – Diluted for "Short-Run and 2021-26 Warrants" (*)			
Proceeds (€mn)	2.44	2.44	2.44
New Shares from exercise of Short-Run and 2021-26 Warrants (mn)	0.94	0.94	0.94
Fair Equity Value (€mn)	36.9	38.3	37.6
Fair Equity p/s (€)	**4.37**	**4.54**	**4.46**

Source: Value Track Analysis (*) Excluding the 0.34mn warrants to be assigned to BoD and company's management

Exercise price of "Short Run Warrants 2021" is €2.50, exercise price for "2021-2026 Warrants" is €2.80

Ulisse BioMed Scale-up Peers – Business Profile

Spago Nanomedical AB

Spago Nanomedical is a Swedish biotechnology company developing nanomaterials for cancer diagnostics and treatment. The company's main projects, SpagoPix and Tumorad, are based on nanoparticles that accumulate physiologically in tumors.

SenzaGen AB

SenzaGen AB is a Sweden-based company specialized in immunology and genomics. In particular, the company develops, performs and sells the in-vitro Genomic Allergen Rapid Detection (GARD) test to assess allergenicity of various substances.

BioMark Diagnostics

BioMark Diagnostics Inc. is an oncology-focused company that employs metabolites to develop cancer diagnostic solutions allowing for cancer detection, monitoring, and assessing treatment. The firm operates as a contract research organization.

Nanorepro AG

Nanorepro AG is a Germany-based biotechnology company engaged in the sale of medical rapid diagnostic products to allow for health planning and prevention in the fields of health care, food intolerance and allergies, as well as infectious diseases.

Genedrive PLC

Genedrive Plc is a UK-based company active in the MDx industry. The Company owns a patented molecular diagnostics platform able to diagnose and genotype infectious diseases, even without the need for nucleic acid isolation.

Epigenomics AG

Epigenomics AG is a German molecular diagnostics company focused on blood-based detection, prognosis and monitoring of multiple cancer indications using DNA methylation technology.

Biovica International AB

Biovica International AB is a Sweden-based biotechnology company which develops and commercializes blood-based biomarker assays for the monitoring of cancer therapies and for the prediction of patients' outcome.

Lumito AB

Lumito AB is a Swedish company focused on tissue diagnostics. In particular, the company is developing an instrument and reagents for digital pathology, where the analysis is carried out remotely and supported with computer-based tools.

Aegirbio AB

Aegirbio AB, a Sweden-based diagnostic company, offers tests to monitor and optimize the dosage of biological drugs via its patented technology platform, focusing neurology diseases, autoimmune diseases and cancer.

Attana AB

Attana AB is specializes in the development and sale of biosensors based on the Quartz Crystal Microbalance (QCM) technology, as well as consumables and services in biotechnology and drug development.

Source: Various, Value Track Analysis

The company at a glance

Ulisse Biomed (UBM) is a small healthcare biotech company, specialized in the development of innovative, cost-effective and rapid in-vitro diagnostics (Molecular Diagnostics), personalized medicine products (Therapeutic Drug Monitoring) and innovative therapeutic solutions (aptamers). The company's products will hit the market in second half 2021, thanks to a licensing agreement (Menarini Diagnostics) relative to Sars-CoV-2 detection and genotyping, and closed FY2020 in profit thanks to the related collaboration revenues and some cost streamlining. The company has strong R&D identity and prestigious Scientific Advisory Board, and a BoD strengthened by new members with diversified backgrounds; it is cash positive and fully funded, based on successful execution of license by Menarini and current R&D pipeline. Recent IPO should allow management to: a) strengthen UBM visibility and attractiveness; b) speed-up development of more recent platforms; c) provide marketability to existing shareholders (beyond 24 months lock-up period).

Ulisse BioMed

Ulisse BioMed (UBM) is specialized in the development of innovative, cost-effective and rapid **in-vitro diagnostics (Molecular Diagnostics), personalized medicine products (Therapeutic Drug Monitoring) and innovative therapeutic solutions (aptemers).** The company employs a team of scientists, scientific collaborators and advisors of the highest prestige.

The R&D and production labs of Ulisse BioMed are located in Trieste at the **Area Science Park**, which is the largest science park in Italy.

Key FY2020 and 1H2021 financials

UBM's products will hit the market in second half 2021 and so far the company has reported most of revenues as grants, R&D tax credits and collaboration revenues. In FY2020 UBM reported **Sales of €429k following the agreement with Menarini Diagnostics Srl** as it sold 25k tests to perform independent performance verification of CoronaMelt, for a total of €128k in sales revenue, and reported €300k related to the technology transfer of the Sagitta platform in favor of Menarini Diagnostics. In addition UBM reported research grants of €157k which, together with €178k due do change in intangibles and extraordinary items, pushed FY2020 Value of Production to €763k.

In 2020 the company was able to reach profitability for the first time since its incorporation generating a **Net Profit of €222k** and closed the year with a net cash position of **€43k.**

As for 1H2021, UBM reported a top line (Value of Production) of €152k and Net Loss of €88k, with net cash in the balance sheet of €199k (pre-IPO).

Key historical milestones

Ulisse BioMed was born thanks to the encounter of a motivated team of young scientists and experienced entrepreneurs, with the aim of making advanced diagnostic and personalized medicine an everyday reality. It is possible to identify the following milestones in the company's history:

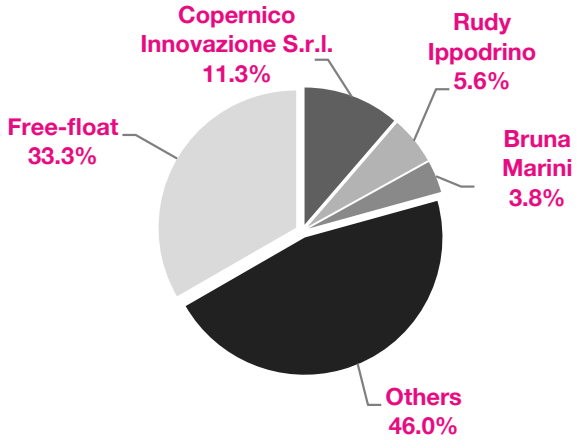
- **2014-2015.** Incorporation of the company and start of development of the two technology platforms Sagitta and NanoHybrid. The first patent on biosensors for antibodies was registered;
- **2016-2017.** Ulisse BioMed raised €1mn in a seed round led by Copernico Innovazione S.r.l. and was awarded grants for a total of €1.5mn. This allowed the company to open its laboratory n Trieste and file four patents related to Sagitta and NanoHybrid. It also raised €4mn among 1.154 retail shareholders by issuing preferred shares;

- **2018.** The company obtained the ISO13485 IVD certification - required to produce CE-IVD marked medical devices - and started a collaboration with the Institute for Human Virology. UBM filed two patents having as underlying technologies biomarkers and aptamers;
- **2019.** UBM obtained clinical validation of LadyMed, performed area tests to identify the most suitable distribution channel and found a lab partner and first private hospital customer (Campus BioMedico). It also raised €4mn among 1.154 retail shareholders by issuing preferred shares;
- **2020.** The company signed a technology transfer agreement with Menarini Diagnostics S.r.l., for production, distribution and commercialisation of Coronamelt and Coronamelt Var, two core products of UBM based on Real Time PCR aimed at the detection of Covid-19 and its variants;
- **April 2021.** Menarini Diagnostics Srl has started the production of Coronamelt and has announced the launch of Coronamelt Var by September 2021;
- **August 2021.** Listing on AIM Italia, the multilateral trading facility organized and managed by Borsa Italiana, by issuing 2.5mn ordinary shares (including 0.25 due to the fully exercised greenshoe option), and resulting in a capital injection of €5mn.

Shareholders and management team

As result of the successful IPO (over 5x oversubscription), UBM outstanding shares amount to ca. 7.5mn, resulting in a free float of ca. 33.3%. Copernico Innovazione S.r.l. is the majority shareholder, holding 11.7%, Bruna Marini and Rudy Ippodrino, i.e. the two founders, own a stake of 5.8% and 3.9% respectively, while the residual stake (46.0%) is in the hands of 1,154 minority shareholders, as reported in the chart below.

Ulisse Biomed: Shareholders Structure



Source: Ulisse BioMed SpA

Here below, it follows a brief profile of the current members of the Board of Directors:

- **Saverio Scelzo - Chairman**

  Co-founder of Ulisse BioMed in 2015, co-founder and CEO of Copernico Sim since 1999. After graduating in Political Science and Economics he gained managerial experience working for large corporations in North America and offered his services as a Financial Advisor.

- **Matteo Petti – CEO**

  Experienced manager and investment banking professional with over 15 years of experience, with focus on M&A and listings. He has managed over 20 IPOs and listings on exchanged regulated market throughout Europe, and has covered the role of CFO and Investor relator for several

companies. He has a strong background in strategic and financial analysis along with equity and debt fund raising. He is also in charge of financial and administrative functions as well as IR.

- **Bruna Marini - Executive Director**

  She obtained a PhD in Molecular Biology at the Scuola Normale Superiore of Pisa for her research carried out at the Laboratory of Molecular Medicine at the International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste. Her PhD thesis, focused on the influence of nuclear architecture on HIV integration, was published in Nature. After attending the master course "Complex Actions", she composed a scientific team that eventually evolved in the team currently present at Ulisse BioMed. Within the company Dr. Marini plays a key role in the general organization and regulatory affairs. Notably she has won Italian and European grants for a total value of € 1.5 million;

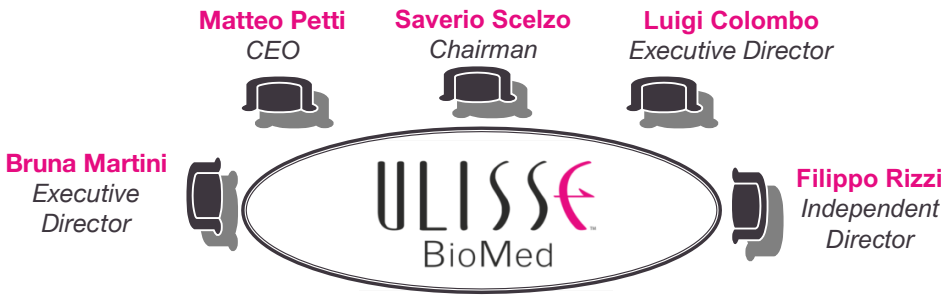
- **Luigi Colombo - Executive Director**

  Adjunct Professor at the Department of Pharmaceutical Sciences of the State University of Milan and author of numerous patents and publications, he is now an independent consultant. After graduating with honors in Chemistry and Pharmaceutical Technologies, he has held management positions in large pharmaceutical companies for more than 30 years: Marion Merrell Dow, Hoechst Marion Roussell, Boeringer Ingelheim, Biosearch Italia, Serono and Merck Group, that he left as vice president and CEO in 2018. In 1996 he co-founded Biosearch Italia, a biotech company then merged with Versicor, a company taken over for ca. $1.9 billion by Pfizer in 2005.

- **Filippo Rizzi - Independent Director**

  After having graduated in Economics at Ca'Foscari University in Venice, he obtained a Master in Business Organisation at CUOA Business School. He held the position of CEO of the largest Italian group of distribution of thermo-hydraulic material for several years, recently he took the role of chairman of the family holding company.

Ulisse Biomed: Board of Directors



Source: Ulisse BioMed SpA

The Scientific Advisory Board

Ulisse BioMed relies on the support, know-how and experience of its Scientific Advisory Board composed of 5 highly esteemed scientists and opinion leaders in the field of biotechnology research:

- **Joseph R. Kates**, a Princeton graduate, has had a distinguished career in the fields of Molecular Biology of Viruses and Cellular Biology. He has held the prestigious position of Director of Research for Bayer Pharmaceuticals and of Director of Research at the National Cancer Institute in Frederick, where he directed projects involving more than a thousand scientists;

- **Robert C. Gallo**, well-known for co-discovering HIV as a cause of AIDS and developing the HIV blood test, has hundreds of publications in the field of virology. Dr. Gallo has received 35 honorary Ph.D, he is a member of the National Academy of Sciences and Institute of Medicine of the United States and a member of the National of Fame of Inventors. He is also the Director of the Institute of Human Virology (IHV) in Baltimore;
- **Gordon Whiteley** has over 30 years of experience in medical diagnostics and has been involved in the design, development and FDA approval of over 75 diagnostic tests. Since 2008, he has directed the antibody characterization laboratory at the National Cancer Institute in Frederick;
- **Lawrence Banks** is considered one of the world's leading experts in the field of HPV and cervical cancer; he has recently become the General Director of the International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste, Italy. He is the official editor of Journal of Virology, FEBS Journal, Papillomavirus Research, PLoS One, and is member of the editorial board of Antiviral Therapy, Virology, Virus Research and Biological Chemistry;
- **Davide Zella** is an expert in cell biology and molecular oncology. He contributed to more than 50 publications and leads a research team at the Institute of Human Virology (IHV) and the School of Medicine of the University of Maryland, Baltimore.

R&D: lean but focused

UBM has been so far a pure research hub. The research team – supported by its Scientific Board and lead by Rudy Ippodrino– is currently composed by 4 senior people (March 2021) but in the last years it has been involving 8-10 researchers on average, in order to develop the technology platforms and finalize the specific research projects.

UBM spent the first five years since inception in developing UBM technological platforms to produce assays in the infective and oncologic fields. It invested cumulated €3mn over 2015-2020 and was awarded grants for projects worth more than €1.5mn, with a success rate close to 100% in its applications to secure research funding. As of Dec 2020 only 60% of the funds granted have been cashed – the remaining amount due is ca. €310k and is going to be received over 2021-2022. On top of this UBM also reported R&D tax credits of around €280k as of Dec 2020.

The team obtained one EU patent relative to Nanohyprid (2016), applied for further 5 patents relative to the three platforms in 2017-2018 and for another in 2020 (CoronaMet and CoronaMelt Var).

The amount of capitalized R&D costs was virtually zero until 2020, when a €0.7mn revaluation of the Sagitta DNA platform was undertaken as of Dec 2020, according to the recent favorable fiscal legislation, and €71k costs (relative to Sagitta RNA) have been capitalized. As future R&D will be focused on specific products and assays developed with the technological platforms developed in past years, the company may opt for a partial capitalization of R&D costs, we believe.

Key reference markets

Ulisse BioMed operates within two main markets: In-Vitro Diagnostics and theranostics. More precisely UBM operates in three specific and fast growing segments:

- firstly, molecular diagnostics (MDx), which accounts for 25% of the Global In-Vitro Diagnostics market with a market value above $20bn in 2020, and within the MDx market **Ulisse's focus is on RT-PCR technology** which accounted to **$17bn in 2020** (83% of the overall MDx market). UBM's produces reagents and assays targeted at this market niche;
- secondly, UBM has addressed the market of theranostics, a combination of therapeutic and diagnostic, with focus on **therapeutic drug monitoring**, currently **valued at $1.4bn**;

- finally, in the longer term, UBM plans to expand in the field of therapeutics/medical devices, envisaging the development of products based on **aptamers**, still a **niche** and relatively young market valued around **$207mn** in 2020.

Ulisse BioMed Pipeline

Ulisse BioMed has three proprietary technology platforms able to generate innovative and competitive products: Sagitta (diagnostics), NanoHybrid (diagnostic/theranostics) and Aptavir (therapeutics):

#1 SAGITTA

Sagitta platform has developed 8 molecular assays (3 CE-IVD marked and 5 RUO), as well as a reagent, UlisseFaster (classified as RUO with pending CE-IVD). These assays and reagent are designed for the **RT-PCR** (Reverse Transcription - Polymerase Chain Reaction) technology.

The tests that obtained the **CE-IVD marking** and are **ready to be marketed** are the following:

- **Ladymed / HPV Selfy** for the detection of Human Papillomavirus (HPV), the agent responsible for cervical cancer, which allows the **identification and genotyping of 14 variants of HPV in a single analysis;**
- **CoronaMelt**, a **diagnostic test for Sars- CoV-2** characterized by high sensitivity (>95%) and high specificity (>99%) thanks to the double analysis performed by means of the melting curves, thus reducing the risk of false negatives and false positives;
- **CoronaMelt Var,** a diagnostic assay for the **detection and genotyping of Sars-CoV-2 variants** (whose approval for CE-IVD marking has arrived in mid-June 2021 and registration has just been completed).

The other products (tests, reagent) currently classified as **RUO** include:

- **Chlamydia + Gonorrhea, Syphilis and HPV**. At the moment, UBM has developed an assay for the concurrent detection of Chlamydia and Gonorrhea and one for identification of Syphilis. In addition, UBM has come up with two HPV diagnostic tests ("low-risk" HPV and "probably high-risk" HPV);
- **HPV for Oropharyngeal cancer,** a diagnostic test that allows the detection and genotyping of high-risk HPV present in paraffin-embedded samples of oropharyngeal cancer and in biopsies;
- **UlisseFaster** is a reagent developed by UBM for the pre-treatment of biological samples that allows avoiding the phase related to the extraction and purification of DNA/RNA, such saving costs and reducing workflow and time required (especially in processes not fully automated).

#2 NANOHYBRID

NanoHybrid leverages on a **cutting edge technology** with high potential and hence most of its pipeline is **still under development.** Management intends to target two applications in the **therapeutic drug monitoring,** based on nano-switches:

- within the next 12 months UBM intends to start clinical validation of a full menu of tests (so far only one test has been developed, for Trastuzumab), which will be developed by steps / disease groups, with a target of at least 10 biomarkers to be used for drug monitoring purposes After validation these tests should become a **revolutionary lab assays** alternative to ELISA (Enzyme Linked Immuno-Sorbent Assay), today considered the gold standard in immunoassay.
- as a further evolution nano-switches will be used to create **quantitative POC instruments** for drug monitoring. However, this should take longer as the development will require a further step on the technology (electrochemical vs fluo cartridge reader) and this in turn will require a strategic partnership for the manufacturing of the hardware.

#3 APTAVIR

Among UBM's platforms Aptavir is the one still **at very early stage of development** and consequently does not possess a detailed product pipeline yet. It has been created to develop and "produce" syntetic nucleic acid molecules, named aptamers, capable of limiting the infectivity of pathogens and that can be used for therapeutic or diagnostic purposes.

Aptamers are considered at the moment an undoubtedly **high potential technology**, as it should represent a) an effective and cheaper alternative to monoclonal antibodies in therapeutics; b) an innovative diagnostic tool; c) products with Simplify Regulatory Procedures, as no biologics are involved in production.

UBM applications will include:

- aptamers for **therapeutic** – inhibiting infection of viral pathogens (Sars-CoV-2); therapy and/or prevention of HPV infections, both genital and cutaneous;
- aptamers for **additives and components of medical devices** - skin creams, oils, lotion, topical creams, condom lubricants, genital gels for prevention or treatment of diseases.

UBM: Pipeline evolution

PLATFORM	2020	2021E	2022E	2023E
Sagitta	• **CoronaMelt:** CE-IVD marking • **Viral Respiratory Panel:** Exclusive technology transfer agreement with Menarini Diagnostics	• **UlisseFaster and CoronaMelt Var:** CE-IVD marking • **Syndromic assay (Flu + Covid):** RUO marking • **CoronaMelt and CoronaMelt Var:** Menarini Diagnostics starts the commercialization • **LadyMed / HPV Selfy:** Partnership(s) to be signed for distribution and commercialization	• **Oncology panel (Colon, melanoma, lung):** Development of a full oncologic panel • **Pneumonia:** Development of the assay • **Syndromic (Flu + Covid):** CE-IVD marking and commercialization under Menarini's agreement • **STD (Clamidia, Gonorrhea) and oncology:** Partnerships to be signed for CE-IVD marking and commercialization	• **Infectious Diseases (Herpes, Sepsis):** Start the development • **Full oncology panel:** Partner starts the commercialization
NANOHYBRID	• **Drug monitoring assays:** Development and RUO marking of the first oncology assay (Trastuzumab) based on NanoHybrid technology	• **Drug monitoring assays:** Start the development of three menus of assays (Oncology)	• **Drug monitoring assays:** Complete the development of the three menus (Inflammatory Bowel and Autoimmune Diseases) • **Drug monitoring assays:** Partnership to be signed to target laboratories (ELISA technology) • **POC system:** Development of electro technology	• **Drug monitoring assays:** Partner starts the distribution • **POC system:** Partnership to be signed (hardware portable Point of Care system)
APTAVIR				• **Aptamer-based products:** Partnership to be signed for the co-development

Source: Ulisse BioMed SpA

IPO structure

Ulisse BioMed (UBM) was listed back as of August 8th on AIM Italia – the multilateral trading platform organized and managed by Borsa Italiana – by issuing 2.5mn ordinary shares (including 0.25mn from greenshoe option), corresponding to a capital increase of €5.0mn

As result of the successful Initial Public Offering (5.3x oversubscription), UBM outstanding shares amount to ca. 7.5mn, resulting in a market float of ca. 33.3%. Pre-existing shareholders have signed a lock-up agreement of 24 months on their shares

More, the company has also issued additional financial instruments, as briefly described in the below table.

Ulisse BioMed: Additional financial instruments issued at IPO

Warrant Ulisse BioMed 2021-2026	1) **"Warrant" assigned** in the ratio of 1 warrant for every 8 ordinary shares subscribed in the context of the Offering and allocated on first day of trading. 2) Total 0.34mn **"Warrant" to be assigned to management / BoD** 3) "Detachable Warrants" attached in the ratio of 1 warrant for every 8 ordinary shares outstanding at first day of trading, to be stripped as of January 2022 - **Strike Period:** (i) June 1st - 30th 2022; (ii) October 1st - 31st 2022; (iii) June 1st - 30th 2023; (iv) October 1st - 31st 2023; (v) June 1st - 30th 2024; (vi) October 1st - 31st 2024; (vii) June 1st - 30th 2025; (viii) October 1st - 31st 2025; (ix) June 1st - 30th 2026; (x) October 1st - 31st 2026. - **Strike Ratio**: 1 newly issued **Ordinary Share** for every 1 **"Warrant"** - **Strike Price:** €2.80 - **Expiry:** End of the last Strike Period (**October 2026**)
Short Run Warrant Ulisse BioMed 2021	"**Short Run Warrant" assigned** in the ratio of 1 warrant for every 4 ordinary shares subscribed in the context of the Offering, allocated on the first day of trading - **Strike Period:** between December 5th 2021and December 17th 2021 - **Strike Ratio**: 1 newly issued **Ordinary Share** for every 1 **"Warrant"** - **Strike Price:** max between IPO price and the arithmetic average of the official share prices recorded in the 10 trading days between November 17th- November 30th 2021, reduced by 30% and subject to a min-max of € 2.00-2.50; - "Short-run warrants" not exercised within the strike period will be automatically converted into "Warrants" according to the conversion ratio established of 1 "Warrant" for every n. 2 "Short-run warrants".

Source: Ulisse Biomed, Value Track Analysis

Use of proceeds

Management intends to use the IPO proceeds to fund the **R&D costs** planned over 2021-2024 (€2.2mn) and potentially **accelerate on the development** of two areas with very high potential:

- the portable **POC technology** based on **Nanohybrid** for the Therapeutic Drug Monitoring segment;
- the **Aptavir platform** for both therapeutic and medical device applications, via partnership(s) in the pharma and medical devices/cosmetic industries).

Management may also **target other R&D hub(s)** involved in research areas closed to UBM.

The acceleration on the R&D front will hopefully lead to a) a faster and more effective time to market and b) stronger long term growth and M&A appeal. However, **this strategy in the short term**, namely in FY2022-2023E, **is more likely to dilute earnings and FCF** compared to our forecasts - which do not incorporate either M&A or any major new R&D project, pending more info by management.

Business Model

Ulisse Biomed has developed three technology platforms capable of generating innovative and competitive products (assays, reagent and molecules) in the fields of diagnostics, theranostics and therapeutics. Of these platforms Sagitta is the most consolidated, with a few assays for RT-PCR technology due to start commercialization over 2021-2022. UBM has a very lean corporate structure and management intends to seek partnership agreements for co-development and distribution, in order to share costs and hit the market earlier and more effectively. Sagitta assays claim strong competitive hedge due to flexibility (multiplexing capacity), accuracy, higher speed/lower complexity of workflow and competitive cost. So far UBM has signed its first license agreement with Menarini Diagnostics, but other should follow in next quarters, to widen the test menu offer, the target pathologies and the number of CE-IVD markings. The "younger" technologies (NanoHybrid and Aptavir) will need more time and development efforts and no revenues are expected over our forecast horizon. For these highly innovative technologies management intends to pursue independent development and inhouse production, while proceeds of the recent IPO may speed-up development schedule.

Technologies and products

Ulisse BioMed has three proprietary technology platforms capable of generating innovative and competitive products in the fields of diagnostics, theranostics and therapeutics:

- **Sagitta** (diagnostics);
- **NanoHybrid** (theranostics and diagnostics);
- **Aptavir** (therapeutics).

Since 2014 the company has spent around **€5.5mn** in the development of its technological platforms and most of costs were related to direct R&D (€3mn). These costs were funded for €5mn through capital increases subscribed by its shareholders (seed capital and a further capital injection) and for the remaining part by the grants awarded and cashed.

UBM owns a portfolio of intellectual properties consisting of 8 international patent applications: 3 related to Sagitta, 2 for NanoHybrid, 1 associated with Aptavir and 2 transversal to the three platforms. Up to now, only two patents have been granted in Italy and in Europe.

UBM: Intellectual properties portfolio

Patent	Filing (validity) Date	Technological Platform	Projects / Products	Status
Biosensore	2014	Biosensor	Biosensor for the detection of anti E6 antibodies associated with cervical and oropharyngeal cancer	Granted – Italy & Europe
Nanoswitch	2016	NanoHybrid fluo & electro	Nanoswitch for Trastuzumab	Granted – Italy & Europe
Sagitta DNA HRM + Sagitta DNA Direct	2017	Sagitta	LadyMed/ HPV Selfy low-risk and probable-risk testing; CT / NG test; paraffin test, Thin Prep test	2 Patents Pending
Tev proteasi	2017	NanoHybrid electro	Proof of concept	Patent Pending
P53	2018	All	Tumor biomarkers of bacterial origin	Suspended
Aptamers	2018	Preventive / therapeutic area	Proof of concept for the selection of molecules that inhibit HPV infection	Patent Pending
Sagitta RNA HRM	2020	Sagitta	CoronaMelt, CoronaMelt Var	Patent Pending

Source: Ulisse BioMed SpA

#1 - Sagitta

What is Sagitta?

It is a molecular diagnostics (MDx) technology platform based on **high multiplexing direct RT-PCR** (Reverse Transcription - Polymerase Chain Reaction), capable of detecting and characterizing nucleic acids of viral, bacterial and eukaryotic origin.

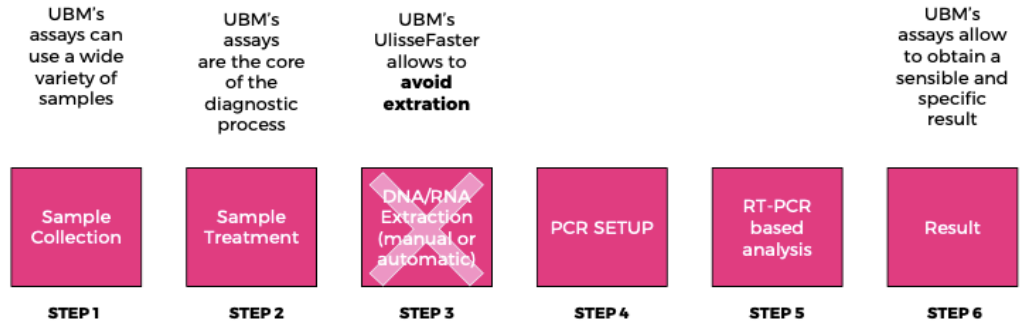
Ulisse BioMed employs Sagitta to develop assays for Respiratory Viral Panel, Sexually Transmitted Diseases, Infectious Diseases and Oncology.

What are Sagitta's competitive advantages?

With respect to competing technologies/products it has the following competitive hedges, according to the information provided by the company:

- **Much more informative**. The platform is able to identify multiple pathogens in the same analysis examining High Resolution Melting curves (HRM). While traditional PCR tests identify on average 1 to 6 targets per reaction, Sagitta discriminates simultaneously in a single reaction up to 20 different targets (**multiplexing**) using a single channel. In addition, Sagitta allows to develop assays able not only to detect but also to **genotype** up to 20 targets in one step, hence providing much more useful information within a single test;
- **Faster and cheaper diagnostic workflow**. The diagnostic analysis, using a specific reagent developed by UBM called UlisseFaster, can also be carried out directly **without** any pre-treatment aimed at the **extraction and purification of nucleic acids (DNA/RNA)**, which is a costly and time-consuming process (management estimates saving to range between €3 and €8/test). Additional savings come from the optimization of wells and therefore processing capacity;

RT-PCR workflow and UBM's assays



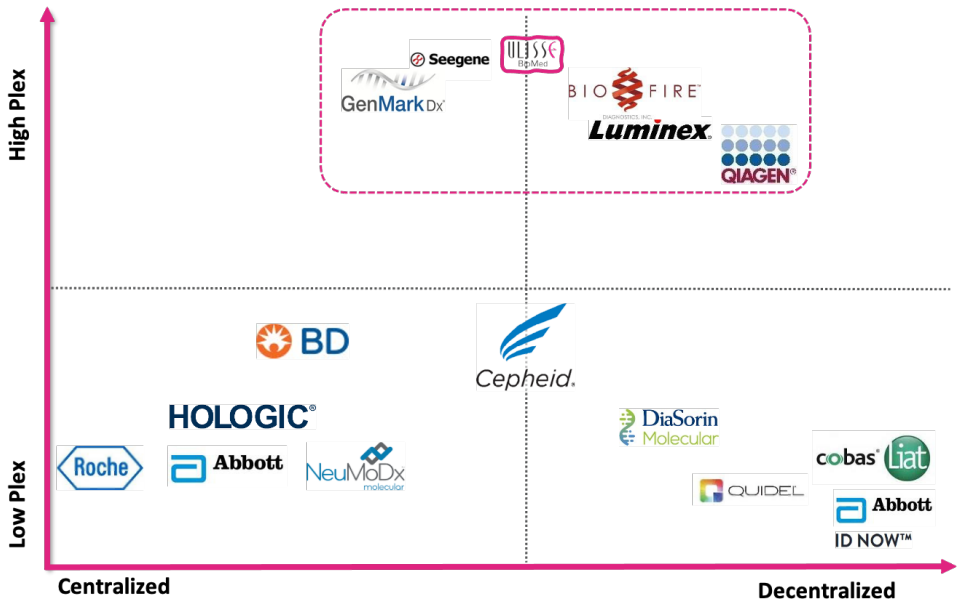
Source: Ulisse BioMed SpA

- **Flexibility of sample.** Sagitta works with a wide range of biological samples making their collection easier and facilitating self-collection. In particular, the platform can **perform analysis on any body fluid** including saliva, sputum, vaginal secretion, blood serum and urine;
- **High accuracy.** Sagitta's assays are characterized by **high sensitivity** i.e. lower risk of false negatives, thanks to its advanced multiplexing capabilities. At the same time, the melting curves' analysis grants **high specificity** i.e. lower risk of false positives;
- **Process/hardware flexibility.** Sagitta is suitable for all the most popular RT-PCR machines and for a wide range of labs, with different levels of throughput -albeit POC is currently not available.

Since 2017 Ulisse BioMed has filed 3 international patent applications to protect Sagitta technology, an additional international patent application related to UlisseFaster is in the process of being filed.

The chart below summarises Sagitta's competitive positioning relative to two key factors, i.e. multiplexing (where it is positioned at top) and throughput capacity (where Sagitta is in the middle of the pack). We believe such a **positioning is very well suited for a syndromic** approach, which is becoming a leading feature of diagnostics, also because this is coupled with its potentially competitive pricing.

Sagitta: competitive positioning



Source: Ulisse BioMed SpA

What is Sagitta current product pipeline?

For the market success of a diagnostic technology it is also key to offer an attractive test menu, in terms of quality, quantity and innovation level. This in turns implies the development of assays addressing, with a consistent quality standard - in primis accuracy and multiplexing but also registration - the right pathology (e.g. Sars-CoV-2 in 2020) and combination of biomarkers (e.g. Syndromic test). UBM is currently addressing this issue, as described below.

Up to now UBM has employed Sagitta platform to develop 8 molecular assays, 3 of which have already achieved CE-IVD marking and 5 are currently RUO, while many others are not developed yet and will require specific partnerships. In addition, the reagent UlisseFaster is still classified as RUO, but near completion for CE-IVD marking.

CE-IVD marked tests ready to hit market:

- **HPV Selfy/ Ladymed (Sexually transmitted diseases)**

  It is a diagnostic test for Human Papillomavirus (HPV), the agent responsible for cervical cancer. The HPV product has been developed in two configurations: 1) LadyMed, a B2C diagnostic kit to be sold directly to end-users, and 2) HPV Selfy, a B2B assays to be supplied to laboratories or doctors. It has three **distinctive features**:

  1. it **does not require sample purification** (faster, simpler, cheaper workflow);

2. it allows the **identification and genotyping** of 14 variants of HPV **in a single analysis.** This represents a step change compared to traditional HPV tests, which detect only the presence of the pathogen without providing the specific genotype;
3. these are the first CE-IVD labelled diagnostic tests for HPV in **self-collected vaginal mucus samples**, allowing women to benefit from a greater degree of privacy and/or a less annoying sampling – not to mention the potential cost savings.

➢ **NEXT STEPS: In 2019 UBM sold LadyMed directly to test the market and new distribution channels (B2C) but later moved into a B2B strategy/licencing: the company has started to sound potential partners interested in the distribution of these two products both with B2B (and B2B2C) and B2C channels.**

HPV Selfy – Product positioning

Company	UBM	Qiagen	Hologic	Gen-Probe Incorporated	Becton Dickinson	Roche
Product name	HPV Selfy	HC2	Cervista	APTIMA HPV	Onclarity HPV	Cobas 4800
Skip DNA extraction	✓	✗	✗	✗	✗	✗
Genotyping 14 high risk HPVs	✓	✗	✗	✗	✓	✗
Suitable for any instrument	✓	✗	✗	✗	✗	✗
Fast (< 4 hours)	✓	✓	✓	✓	✓	✓
Rapid (< 80 minutes)	✓	✗	✗	✗	✗	✗

Source: Ulisse BioMed SpA

◆ **CoronaMelt - Sars-CoV-2 (Respiratory Viral Panel)**

Ulisse Biomed has taken advantage of the opportunities emerged in the molecular diagnostics sector because of the pandemic by developing CoronaMelt, a diagnostic test for Sars- CoV-2.

Among the many products now available in this rapidly crowded segment, CoronaMelt has the following **competitive advantages** relative to alternative molecular tests for Sars- CoV-2:

1. CoronaMelt resulted to be analytically **more sensitive** than the Perkin-Elmer test, the latter being the most sensitive test in a sample of 195 tests, according to a comparative study by the FDA published in Dec 2020 - these results are based on an independent trial carried out by Centro Diagnostico Italiano (CDI);
2. Despite its high sensitivity (>95%), CoronaMelt also ensures high specificity (>99%) thanks to the double analysis performed by means of the melting curves. As a result it offers an **extremely high level of accuracy**;
3. CoronaMelt can analyse **saliva samples and nasopharyngeal samples**; it is therefore more flexible and this is valuable entering a new phase of the pandemic management;
4. **It does not require RNA extraction, allowing an easier and faster workflow with less** workforce, reagents and equipment, i.e. with significant **costs and time savings**.

➢ **NEXT STEPS: UBM signed in June 2020 an exclusive technology transfer agreement with Menarini Diagnostics aimed at the production and distribution of CoronaMelt. Menarini Diagnostics started production in April 2021 and offers the kit alone or in reagent-rental contract (automatic workstation OmniaPRO). The agreement perimeter was then expanded (see below).**

- **CoronaMelt Var - Sars-CoV-2 Variants (Respiratory Viral Panel)**

  This is a diagnostic assay for the **detection and genotyping of Sars-CoV-2 variants.** Its **elements of differentiation** are:

  1. the test allows not only to identify the presence of the virus, but also to **discern the different variants in a single process**. It is currently able to identify English (B.1.1.7)/*Alpha*, South African (B.1.351)/*Beta*, Brazilian (P.1)/*Gamma* and recently the Indian (B.1.617.2)/*Delta* one (as RUO) and **can be easily upgraded to** extend the genotyping to **new variants of concern**, once sequenced, as the virus is constantly evolving;
  2.
  3. being labelled CE IVD, CoronaMelt Var can be used as a **Tier 1 test for screening purposes** (as majority of these tests are RUO and are used as a Tier 2 test for genotyping after tested positive for Covid);
  4. it also retains all the features of "plan vanilla" CoronaMelt, i.e. **high level of accuracy,** it is validated also with **saliva samples** and without RNA extraction, with significant **costs and time savings.**

➢ **<u>NEXT STEPS</u>: In May 2021 UBM has expanded the exclusive agreement with Menarini Diagnostics to CoronaMelt Var, with the same aim of production and worldwide distribution. Menarini Diagnostics intends to start commercialization of CoronaMelt Var in Q4 2021, following the CE-IVD approval and registration process completed in June.**

Sagitta CE-IVD marked products – Ready to hit the market

Source: Ulisse BioMed SpA

RUO (Research Use Only) tests/reagents:

- **Reagent UlisseFaster**

  This is a reagent developed by UBM for the pre-treatment of biological samples that allows avoiding the phase related to the extraction and purification of DNA/RNA for all the test menus of the Sagitta platform, but not only. Its **points of strength** are:

  1. while the extraction and purification step lasts between 45 to 180 minutes depending on the system, UlisseFaster takes just 13 minutes and does not require sophisticated equipment. This leads to significant time and costs savings: the company estimates the **saving per test between €3** (plus amortization in automatic processes) **and €8** (manual workflow);
  2. it is validated on a **wide range of matrices and** suitable also for **assays** different from Sagitta;

3. this reagent is **very flexible** in terms of machine/hardware, being suitable for assays produced by other technological platforms, in manual or automatic processes, opened or closed.

➢ **NEXT STEPS: The process for CE-IVD marking of UlisseFaster has been completed in July 2021. Menarini Diagnostic has signed a (non exclusive) supply agreement with a minimum guaranteed.**

- **Chlamydia + Gonorrhea, Syphilis, HPV (Sexually transmitted diseases Panel)**

  Sagitta technology is well suited for multiplex analysis of sexually transmitted diseases (STD), whose prevalence at worldwide level is growing at an alarming rate, as from the World Health Organization data. So far UBM has developed:

  1. an assay to concurrently detect Chlamydia and Gonorrhea;
  2. a test for the identification of Syphilis;
  3. HPV diagnostic tests: a) low-risk HPV, associated with benign skin lesions (warts) and ano-genital lesions (polyps); b) probable high-risk HPV, related to cervical cancer.

➢ **NEXT STEPS: UBM wants to proceed with the CE-IVD marking for all the aforementioned STD tests and plans to market them by September 2022. Thus, it has started to sound potential partners interested in a co-development of the test menu in this area, in order to share costs and speed up certification process and time to market, and this agreement may potentially include HPV Selfy.**

- **HPV for Oropharyngeal cancer (Oncologic Panel)**

  It is a diagnostic test that allows the detection and genotyping of high-risk HPV present in paraffin-embedded samples of oropharyngeal cancer and in biopsies. This test will also require the CE-IVD marking, but it is likely to be considered within an oncologic panel rather than as a standalone assay.

➢ **NEXT STEPS: Also for this panel UBM will start looking for a partner to obtain the CE-IVD marking, within a wider agreement for the overall oncologic panel, which may include all the pathologies still to be developed.**

… and future developments?

If we move into the products where development has still to start, the company has indicated a pipeline of tests to be developed over the next 12-18 months:

- **Respiratory Viral Panel: Syndromic Influenza + Sars-CoV-2, Pneumonia**

  UBM intends to complete this panel firstly with the syndromic test, meant for the detection and genotyping of influenza and Sars-CoV-2 viruses in a single assay (which is likely to become a standard in the post pandemic) and pneumonia. Thanks to its advanced multiplexing capabilities, Sagitta is suitable for the development of syndromic tests, i.e. tests aimed at identifying and discriminating pathogens with similar symptoms.

  1. **Syndromic Flus + Sars-CoV-2** (under the agreement with Menarini Diagnostics). Ulisse expects to be able to start development of the new test already in July 2021, obtaining RUO marking by December 2021 and CE-IVD by June 2022;

2. Pneumonia (depending on the biomarkers identified it may or may not be included under the agreement above); development should start in 2022.

➢ **<u>NEXT STEPS</u>: This panel is included in the agreement signed in 2020 for all the respiratory virus assays, while it has to be decided for other pathogens. Menarini Diagnostics intends to hit the market with this assay in mid-2022 and to launch also its new system (closed version of its automatic workstation).**

- **Oncology panel: colon cancer, melanoma and lung cancer**

The company intends to develop several diagnostic tests to detect panels of mutations associated with presence of different types of cancer - so as to improve diagnosis and therapy - in particular KRAS (colon cancer), NRAS (melanoma), BRAF (melanoma) and EGFR (lung cancer).

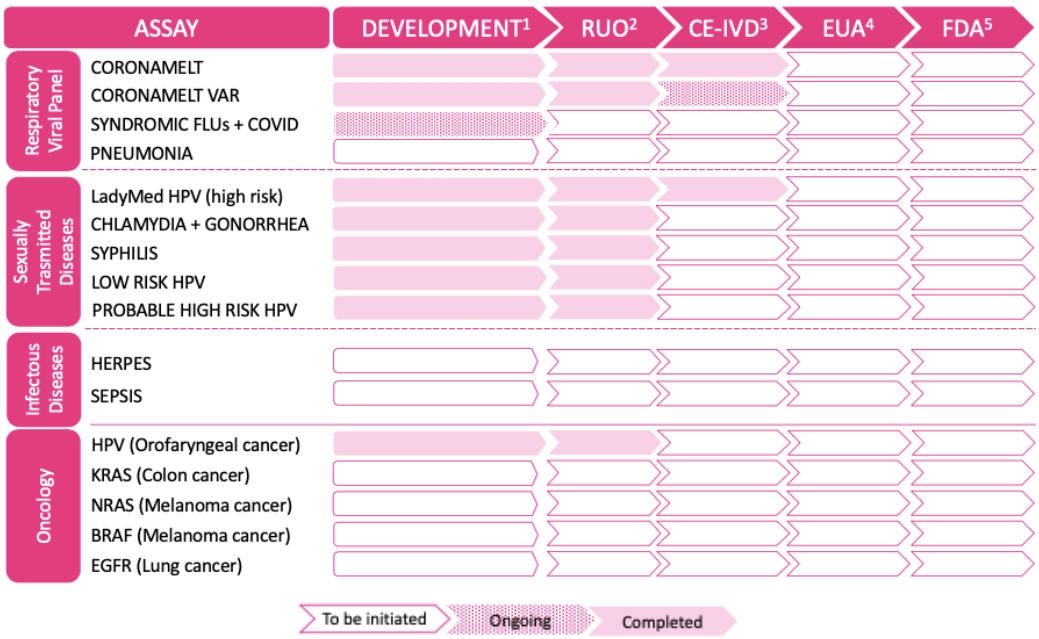
➢ **<u>NEXT STEPS</u>: The full oncology panel, once again subject to the identification of a specific partner, is expected to be developed by the end of 2022 with the aim of commercializing it in 2023.**

- **Infectious diseases: Herpes and Sepsis**

UBM plans to expand its menus with a diagnostic test that allows the detection and genotyping of the herpes virus and another one for the detection of the bacteria responsible for Sepsis.

➢ **<u>NEXT STEPS</u>: This segment appears at the moment with a lower priority for management and hence we have no indications about potential timing for development. However, we believe it will also require a specific partnership.**

Sagitta: assay menu development pipeline



Source: Ulisse BioMed SpA 1. Generally includes analytical validation; 2. Research Use Only, not for use in diagnostic procedures; 3. CE-marked IVD; 4. Emergency Use Authorization for commercialization in the US; 5. clearance from US FDA

#2 - NanoHybrid

What is Nanohybrid?

NanoHybrid constitutes Ulisse BioMed's most innovative and advanced technology platform. It is based on **nano-switches**, i.e. synthetic nanotechnology structures capable of instantaneously detecting protein biomarkers (including biological drugs) in complex biological matrices (blood serum, but whole blood sample and other matrices are under development). NanoHybrid platform can be implemented not only to develop diagnostic solutions but also in the field of theranostics - i.e. the integration of a diagnostic method with a specific therapeutic intervention aimed at maximizing the effectiveness of the drug, in particular for the drug monitoring - as well as vaccine/immunoterapies monitoring.

What are Nanohybrid's technology advantages?

NanoHybrid can represent an effective alternative to ELISA (Enzyme Linked Immuno-Sorbent Assay), currently considered the gold standard in immunological diagnostics, and to rapid lateral flow tests for portable diagnostics (POC). In fact, despite most of this technology applications are still under development, it seems to have a few **key advantages**:

- vs ELISA – ELISA success is due to its high sensitivity and to the fact that it provides a quantitative diagnosis of substances, including antibodies, antigens, proteins, glycoproteins, and hormones. However, ELISA is a multi-step technique that implies a long (2-3 hours) and complex workflow and this implies that very often it does not allow samples to be tested upon arrival but on week/half week batches, to gain cost efficiency. NanoHybrid can obtain the **same quantitative results of ELISA in 1-5 minutes (vs 120-180 minutes);**
- vs LFA (Lateral Flow Assays) - rapid tests have a competitive advantage with respect to ELISA in terms of rapidity and portability, but they provide only a qualitative and not **quantitative result**, as offered by nanoHybrid;
- vs innovative LFA (e.g. Monator by Aegirbio) – this innovative lateral flow test does offer a semi-quantitative results, but a) the test has to be carried in laboratory as the sample must be pre-treated by specialized personnel and b) the read-out requires a specific hardware. Hence it is not suitable for an **accurate results** and for a full **POC application**;

UBM has filed 1 European patent application (granted) and 1 international patent application covering NanoHybrid technology.

NanoHybrid vs competing technologies

Features	NanoHybrid	ELISA	Lateral Flow test
Rapid time of detection	✓	✗	✓
POC format	✓	✗	✓
Microplate format (96 samples)	✓	✓	✗
Raw sample analysis (whole blood)	✓	✓	✗
High sensitivity	✓	✗	✗
Quantitative analysis	✓	✓	✗

Source: Ulisse BioMed SpA

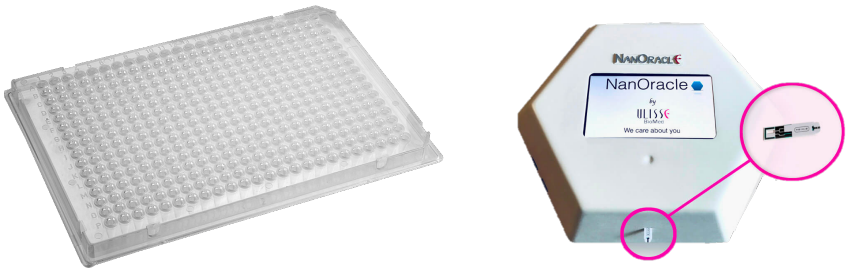
UBM development focus: theranostics

This technology potentially offers a high flexibility in terms of formats (labs assays, POC) and a wide range of applications in both diagnostics and drug, immunoterapies and vaccine monitoring. UBM has decided to **focus** its efforts in the theranostics, in particular nano-switches are used to monitor biological drugs such as monoclonal antibodies **(Biological Drug Monitoring).** Monoclonal antibodies are very expensive biological drugs particularly used in cancer therapy, whose correct dosage is key to administer an effective and safe therapy without wasting resources. In fact, overdosage can lead to serious side effects, while underdosage won't have any beneficial impact on the patient. This implies that drug monitoring is crucial for these therapies and lead to the development of "companion" and "complementary" diagnostics, core to personalised medicine.

UBM wishes to develop through the use of NanoHybrid mainly **two products**:

- **Assays,** i.e. laboratory tests for measurement of biological therapeutic drugs in blood samples. In particular, nano-switches will provide laboratories with a solution that simplifies and significantly speed up their workflow, while providing the same accuracy and quantitative results as ELISA. UBM aims at developing an assays menu of 10-12 biologic drugs and commercializing them through distributors already engaged in ELISA distribution in order to have quick access to end customers;
- **POC systems**. UBM also plans to create a Point of Care system to monitor biological drugs for physicians, hospitals and patients. The system will consist of a reader, i.e. a hardware component (with fluo or electrical reader) and disposable cartridges or strips. UBM is looking for a partner to co-develop the POC system, specifically for the development of the hardware component with fluo reader and/or electrochemical, potentially suitable for biomarkers detection in whole blood (akin to the glucometer used for blood glucose measurement).

NanoHybrid products: Assays and POC



Source: Ulisse BioMed SpA

NanoHybrid pipeline: most to be developed

In terms of products UBM so far has developed only one assay: a NanoHybrid prototype for the monitoring of Trastuzumab (monoclonal antibody for breast cancer) was tested in collaboration with the Istituto Nazionale Tumori of Milan. Now, thanks to the nano-switches technology, management intend to target the following steps

- **Step 1 - Clinical validation of a full menu of tests**

These tests for new biological drugs monitoring should include at least 10 biomarkers to be validated **within the next 18 months**, while between 18 and 36 months, these tests should gradually become drugs monitoring assays as an effective alternative to ELISA, according to management. More in

detail, UBM's goal is to develop three menus of assays focused on homogeneous disease groups (and related drugs):

- **Oncology – 3 tests**: Trastuzumab, Bevacizumab, Rituximab;
- **Chronic Inflammatory Bowel Diseases – 5 tests**: Infliximab, Adalimumab, Golimumab, Vedolizumab, Ustekinumab;
- **Autoimmune Diseases – 7 tests**: Infliximab, Adalimumab, Etanercept, Certolizumab, Golimumab, Rituximab, Tocilizumab (including 3 in common with inflammatory diseases).

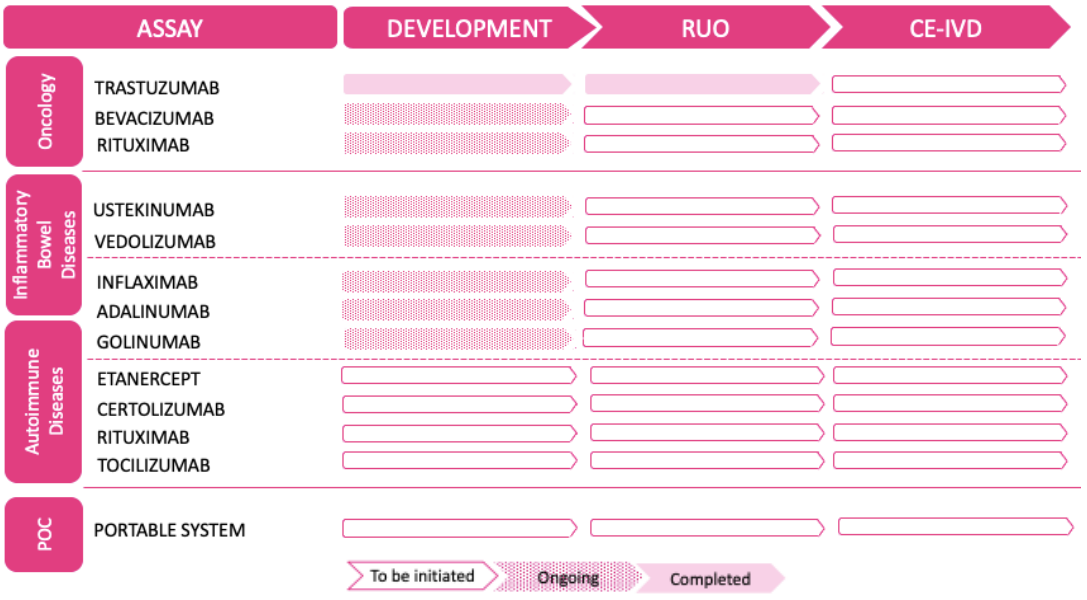
This kind of disease-focused approach in development is meant to facilitate the commercialization, by providing distributor a structured offer addressing a homogeneous set of diseases on the relevant markets. UBM foresees the commercialization of the first NanoHybrid products as soon as the first three oncology tests will be ready, then the offer will be expanded to inflammatory diseases, afterwards the firm will enter the autoimmune diseases market.

- **Step 2 - Therapeutic biological drug monitoring for point of care (POC)**

This version **should take much longer** and development will require a strategic partnership for the development of the hardware (flue reader) and/or for the co-development of the underlying technology (electro reader).

➢ **<u>NEXT STEPS</u>: UBM intends to carry out development of NanoHybrid autonomously and search a partner only for distribution. UBM could also exploit synergies of cross selling and costs by commercializing together Sagitta's and NanoHybrid's products related to oncology: this would suggest UBM may consider a unique partner for a) co-development and licensing of Sagitta oncologic panel and b) distribution of NanoHybrid.**

NanoHybrid: development pipeline



Source: Ulisse BioMed SpA

#3 - Aptavir

What is Aptavir?

UBM has also developed a technology platform for the identification and production of antiviral molecules, called aptamers, capable of limiting the infectivity of pathogens and that could be used for therapeutic or diagnostic purposes. Aptamers are one of only a few classes of molecules that, like antibodies, can be crafted to bind to multiple different targets: they are extremely versatile and bind targets with high selectivity and specificity.

The potential products that can be developed thanks to the Aptavir platform include, according to management plans, the following applications:

- **Aptamers for therapeutic purposes**. Ulisse BioMed has already developed aptamers for the treatment and prevention of cutaneous HPV, thus this technology can be used to produce aptamers aimed at the prevention and treatment of any pathogen. UBM plans to develop an aptamer to prevent and treat Sars-CoV-2, which could be integrated in a nasal spray;
- **Additives for pharmaceuticals, medical devices and cosmetics**. Aptamers could be additives for pharmaceutical or cosmetic products to enhance their therapeutic capabilities. For instance, they could be used in skin creams, oils, condom lubricants and genital gels in order to enhance their features for prevention or treatment of diseases.

UBM filed an international patent application in 2018 for aptamers for the prevention and treatment of HPV and is in the process of filing an international patent application related to aptamers for protection against Sars-CoV-2.

What are aptamers' advantages?

Aptamers might represent an effective and economical **alternative to monoclonal antibodies**. In fact, they have several advantages:

- They are **faster and cheaper to produce**, as once the optimal sequence has been selected, production of new batches of material is fast and inexpensive;
- can attack very **small molecules**, as aptamers are small and can penetrate tissues and cells and reach specific targets;
- **less burdensome approval processes** as aptamers' production does not involve the use of biological material.

Aptavir pipeline: still uncertain

Among all the UBM technologies Aptavir is the one with the lowest TRL (Technology Readiness Level) and we expect this line or research not to lead to any significant achievement in the short to medium term.

- **NEXT STEPS: Development horizon for aptamers is relatively long; however, should management sign a co-development agreement with a partner in the pharma, medical device or cosmetic segment, this may shorten development times.**

Go to market

Ulisse BioMed is fundamentally structured as a research hub with activities centered on research and development, thus management intend to leave to partners the tasks of distributing and commercializing final products. The company is characterized by a B2B-focused business model that is meant to provide kits and reagents to private laboratories and public hospitals, albeit the specific type of end customers will be dictated by the commercial strategies of the licensee partners.

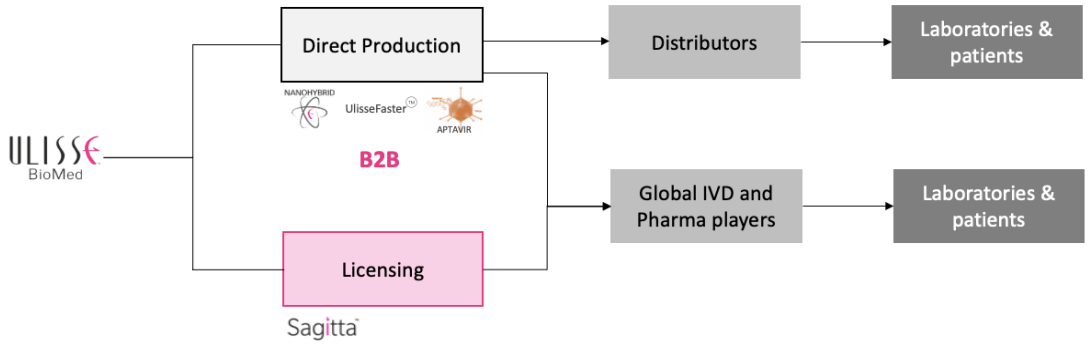
In particular, UBM's B2B consumable driven business model evolves along two main channels, as anticipated in previous section, depending on the specific technology and/or product:

- **Licensing agreements** with global IVD and pharma players aimed at co-developing products and potentially embedding UBM's technology in the partner's instruments (this is the main route for Sagitta assays);
- **Distribution agreements** to get direct access to existing and well-established distribution networks (this will likely be the case for NanoHybrid's panels).

At the same time, UBM will take advantage of the **production capacity** of its scientific site in Trieste to produce its highly innovative **UlisseFaster** and **nano-switches,** as well as for the production of prototypes and CE-IVD marking activities.

Here below we analyse in more details the "Go to market" strategy followed for the different platforms.

UBM's Business Model



Source: Ulisse BioMed SpA

#1 Sagitta: for MDx assays licensing agreements are key

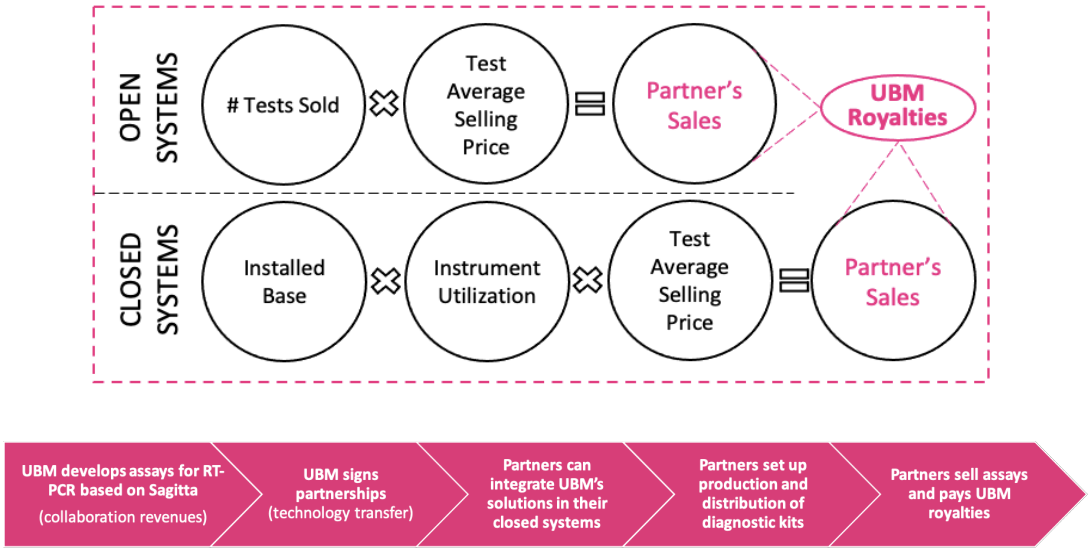
In order to commercialize Sagitta's molecular assays UBM will conclude licensing agreements with partners, which usually sell consumables together with their own PCR machines, with systems that may be closed or open. This is similar to what has been done with Menarini. At the same time, the company may also search for partners interested in creating a closed RT-PCR system based on Sagitta technology.

The key aspects to underline about open and closed systems are the following:

- In both circumstances Ulisse Biomed will only earn **royalties on the consumables' sales** made by the partner;
- By implementing Sagitta technology within the partner's **closed diagnostic system, UBM will benefit from higher royalties on kits sold.** In fact, in a closed system the partner often loans

its machinery to laboratories free of charge, but with a markup of reagents' prices. This would lead to an increase in unitary revenue of reagents, with a positive impact on UBM's royalties.

Licensing agreements' model: Open and Closed systems



Source: Ulisse BioMed SpA

Furthermore, partnerships with industry players allow UBM to rapidly expand testing, while reducing the cost of developing the product thanks to collaboration revenues received from the partners, something that is critical to the long-term success of the company.

Here below we analyze the state of the art in this respect for the Sagilla technology:

- the first **agreement secured with Menarini Diagnostics** on Covid-related and respiratory viral products;
- the strategy relative to **UlisseFaster**, as here management intends to follow a strategy of direct production and distribution partnership;
- the **new potential partnerships** with other players of the IVD industry in order to complete the development and/or marking of test menus relative to other pathology groups, namely **HPV** and other Sexually Transmitted Deseases (those envisaged in the shorter term).

First strategic agreement signed: Menarini Diagnostics on Sars-CoV-2

Up to now UBM has signed a technology transfer agreement with **Menarini Diagnostics S.r.l. aimed at the production and commercialization of two main products:**

- **CoronaMelt**. The agreement was signed in June 2020, with collaboration revenues recognized during 2020, and the partner started producing CoronaMelt in April 2021, officially launching it on April 30, 2021;
- The agreement was widened to **CoronaMelt Var** in May 2021 envisaging also future updates of the assay to detect new variants of Sar-CoV-2 that might emerge, as well as the inclusion of other respiratory viruses to create a **complete Respiratory Viral Panel.** The technology transfer related to CoronaMelt Var will be completed between May and June 2021 – with related

collaboration revenues - and the partner has already planned a marketing campaign aimed at promoting on the market the new kits for the detection and genotyping of Sars-CoV-2.

To support the launch of CoronaMelt and CoronaMelt Var, Menarini Diagnostics S.r.l. has set up a plant capable of producing **300k molecular diagnostic tests per month**, but plant's production capacity can be easily doubled by organizing the workflow in two shifts and could be further increased by introducing a robotic handling system.

Menarini Diagnostics proposes to its customers CoronaMelt and CoronaMelt Var also in combination with the automatic PCR workstation Menarini Omnia PRO, which is able to process 48 samples in less than 3 hours, including the step involving RNA extraction.

Furthermore, **using as a reagent UBM's UlisseFaster** – secured by Menarini with a supply agreement already in place - **no pre-treatment extraction step would be needed**, thus leading to a sensible reduction of process' duration (by 30/45 minutes) and costs (staff, reagents).

Licensing agreement with Menarini Diagnostics

A.MENARINI diagnostics	▪ Menarini Diagnostics is part of Menarini Group, one of Europe's leading pharmaceutical and healthcare companies, **present in 140 countries** ▪ Between March 2020 and March 2021 the company generated **around €100mn of revenues from the sale of kits and instruments to detect Sars-CoV-2** ▪ The company's **widespread distribution network** allows them to rapidly consolidate the products offered, as demonstrated by the sale of 4,000 units of the POC system "VITA-PCR" ▪ To support the launch of CoronaMelt and CoronaMelt Var, Menarini Diagnostics has set up a **plant capable of producing 300k molecular diagnostic tests per month**
Scope of the agreement	▪ The agreement encompasses the production and commercialization of all Sar-CoV-2 related assays, including **CoronaMelt**, **CoronaMelt Var** and a **Syndromic (Flu + Covid)** assay, thus creating a complete Respiratory Viral Panel ▪ The **production and commercialization of CoronaMelt** started in April 2021 ▪ The agreement envisages future **updates of CoronaMelt Var** to allow the detection of new Covid variants that might emerge ▪ UBM has also signed a **supply contract**, on a non-exclusive basis, with Menarini Diagnostics related to the reagent **UlisseFaster**, which will be supplied starting from July 2021

Source: Ulisse BioMed SpA

- **What about Menarini Diagnostics?**

The partnership signed with **Menarini Diagnostics is going to be the major source of revenues for UBM** over 2021-2022E, as CoronaMelt, CoronaMelt Var and Ulisse Faster will likely be the only products on the market until the second half of 2022.

Menarini Diagnostics represents the diagnostics division of the Menarini Group, one of Europe's leading pharmaceutical and healthcare companies, which consists of pharmaceutical, over the counter medicine and bio-medical divisions. It generated a total turnover in excess of €3.7 billion in 2020 and it is present in **140 countries.**

In 2020 Menarini Diagnostics reported Net Sales of €214mn and an EBITDA of €15.4mn with an EBITDA margin around 7.2%, reporting a 55% top line growth, thanks to the opportunities emerged during the pandemic. In fact, between March 2020 and March 2021 the company was able to generate around **€100mn of revenues related to** kits and instruments for **Sars-CoV-2 detection.**

More in detail, approximately 65% of these revenues were generated through the distribution of ca. **4,000 units of the POC system "VITA-PCR"** with a reagents rental mode. The ability to sell such a high number of units is even more remarkable considering that Biomerieux, one of the key players of the IVD industry, sold around 7,000 units of its BioFire PCR instrument in FY2020.

Menarini Diagnostics has only recently entered the field of molecular diagnostics and therefore aims at rapidly expanding its market share in this segment of the IVD industry: the significant commercial results obtained by Menarini Diagnostics with VITA-PCR in last quarter demonstrate that the company's **widespread distribution network** allows them to rapidly consolidate the products offered even in market sectors very crowded and where they were not present.

The reagent UlisseFaster: work in progress for a super versatile cost saver

This innovative reagent will not be part of a licensing agreement, according to current management position, but rather it will be provided on "plain vanilla" supply agreement.

In fact UlisseFaster is extremely versatile and will be supplied to **both small and large laboratories**, since it can be used **with or without automation** (in the former case with a liquid handler), with Sagitta technology but also with third parties' kits. In particular:

- For small/medium sized laboratories performing extraction manually, UlisseFaster can guarantee an easier workflow and a significant reduction in the time required to complete the process;
- At the same time, large laboratories can adopt UlisseFaster in their high-throughput systems by automatizing the process thanks to an ad-hoc liquid handing robot.

UBM has a supply contract signed with Menarini Diagnostics and it will start the **supply of the reagent to Menarini Diagnostics from July 2021 on a non-exclusive basis.**

In addition, Menarini Diagnostics has expressed interest in evaluating integration of UlisseFaster technology into its closed system to be launched in June 2022. Yet, the company is currently considering a few distribution options, for the time being on a non-exclusive basis.

Partnership(s) required for HPV related products

UBM has the objective to identify a **partner** interested in **selling the assay HPV Selfy to laboratories**, by leveraging on the distinctive features of the test, mainly the simpler and faster (i.e. cheaper) workflow, the ability to genotype in a single step and the sample self-collection opportunity.

- **Focus on private screening for HPV Selfy / LadyMed**

HPV Selfy will be sold **primarily to private laboratories (B2B)** or gynecologist (B2B2C), proposing HPV diagnosis to those women that do not participate in the national screenings offered at country level. These represent between 50% and 20% of total target population in Europe.

For this segment of the market, however, **the price/quality mix offered by HPV Selfy is compelling**, as:

1. it includes detection & genotyping in a single and less invasive test, which may also be priced competitively and
2. it comes much cheaper if compared to "tier 1 detection plus tier 2 genotyping tests".

Management intends to sign a partnership with a partner in the next quarters and expect the commercialization of HPV Selfy to start by September 2022, as they expect HPV test to be likely distributed together with the other assays of the STD panel. However, should the partner evaluate the launch of the HPV test as a standalone product, it may hit the market much earlier, as these are already CE-IVD marked.

As for **LadyMed**, UBM is also considering and testing potential agreements with partners with a specific **B2C** background to distribute its kit on different consumer channels, such as pharmacies and online.

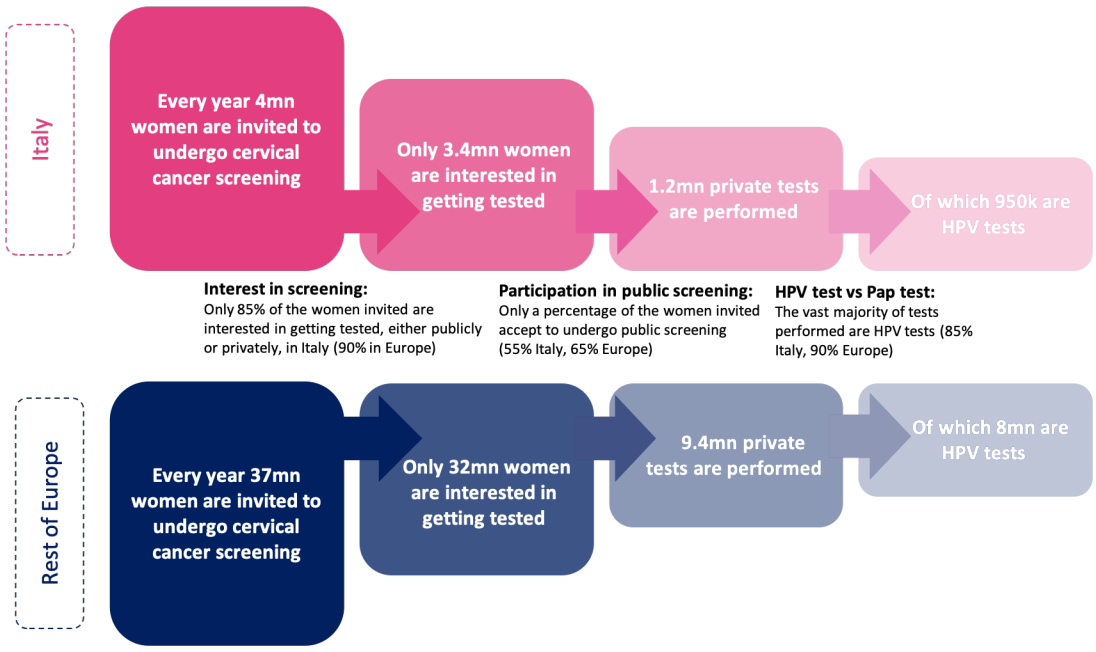
- **...while national screenings are a long term potential target**

The national screening segment appears today out of reach for UBM assays, as national HPV screening is still made using low-cost tests that only detect the presence of the virus without genotyping. Thus, until screening is solely focused on detection UBM test cannot be competitive on price.

However, there is a **new trend in HPV screening** campaigns - set in the USA - moving **towards** a greater importance of **genotyping**, as certain HPV strains are more correlated with the onset and progression of cervical cancer. If such trend consolidates, HPV Selfy would have a major competitive advantage over other tests currently on the market both in terms of proposition (multiplexing) and cost.

The chart below reports our model to identify the target market of UBM (at European level). The European cervical cancer screening has changed a lot over the past years due to a) the success of the national public screening campaigns and b) the move from a "pap-test driven" to a "HPV driven" model, following the WHO recommendation back in 2013. Both trends have been quite clear, albeit in Italy they have been slightly slower so far and differences remain among different countries. The picture described below represents an estimate of cervical cancer and HPV screening expected in 2022.

Cervical cancer and HPV screening model



Source: Value Track analysis

#2 NanoHybrid: UBM will require distribution partners, but not only

As far as NanoHybrid's products are concerned, UBM strategy can be summarized as follows:

1. **development** of an appropriate number of **test menus carried by UBM**. As indicated above the expected pipeline follows a disease-focused approach, that is also meant to facilitate the commercialization;
2. **manufacturing** process of nano-switches will be kept **in house**, at least initially and then potentially outsourced to meet future surges in demand;
3. applications and related **distribution** revolve around two main strategies:
   a) sale of nano-switches to laboratories as an alternative technology to ELISA in drug monitoring. The typical target for this new disruptive technology is the **high-throughput lab**, which may move from the current gold standard ELISA process (complex, multi-step process of ca 120-180 minutes) to Nanohybrid (much simpler and faster, 5-10 minutes, and consequently cheaper).
   b) sale of portable diagnostic devices **(POC)** based on nano-switches technology, albeit technology about these potential instruments has to be improved.

In fact, as for the POC version, the company is looking for a **partner to manufacture the hardware** required to provide a portable Point Of Care, quantitative system based on nano-switches and to be used in the field of biological drug monitoring.

In this respect the POC **Nanohybrid Fluo technology** is already available but needs the development of its POC system; while the development of the **Nanohybrid Electro version** - whole blood electrochemical detection and amplification system - has still to be started, but it has an enormous potential and could lead to an instrument similar to the glucometer.

#3 Aptamers: very innovative therapeutic / diagnostic tool seeking co-developers

The precise "Go to market' strategy of Aptavir's products has not been fully provided, as this technology is the most recent and innovative (and promising). We believe aptamers maight be commercialized following the same B2B business model of the Sagitta platform, i.e. by co-development agreements and hence applications and distribution will very much depend upon the partner identified for the **co-development**.

Aptamers technology could be used by partner firms to develop additives in pharmaceutical preparations and medical devices that will be commercialized in the form of skin creams, oils, lotions for mucous membranes, topical creams, condom lubricants and genital gels.

These will involve treatment and prevention of HPV, Sars-Cov-2 and other new viral pathogens, following the partners' needs.

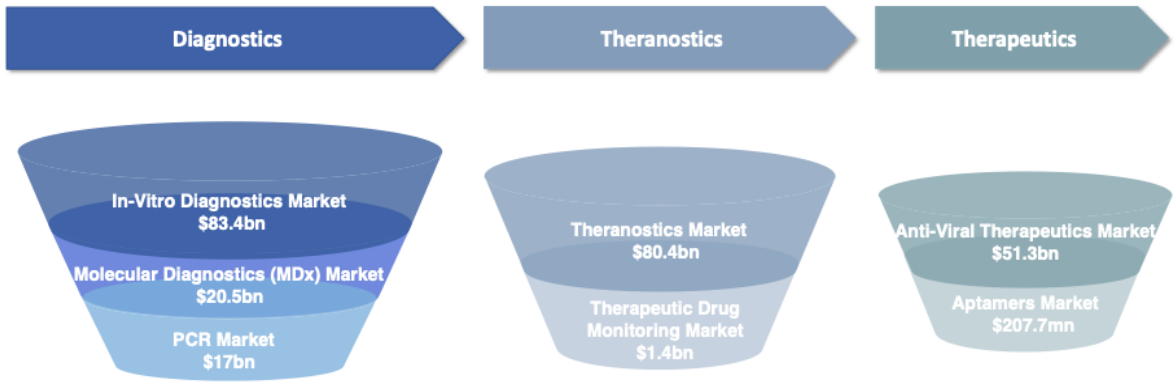
Reference markets and regulation

The key reference market for UBM is diagnostics via PCR (Polymerase Chain Reaction) technology, a segment of the larger MDx sector valued $17bn in 2020, following a major jump due to the molecular testing demand linked to Sars-CoV-2 pandemic. PCR market is expected to keep growing (17.5% 5-yrs CAGR), despite the expected normalization of the business related to Covid-19 testing, thanks to a few drivers, among which the recovery of screenings cannibalized by Covid-19, the much larger base of installed PCR machines and rising Point Of Care testing. We believe the new features of the PCR sector demand fits well with the UBP product offers (syndromic, multiplexing, faster, cheaper processes). The other two reference markets for UBM are much smaller than the $17bn of PCR diagnostics: the Therapeutic Drug Monitoring is valued $1.4bn (6.9% 5-yrs CAGR), while aptamers represent a niche of $200mn (16.7% 5-yrs CAGR). However, the technologies targeted by UBM for these segments (nano-switches and aptamers) are very innovative and markets less crowded, for the time being. In terms of regulation, the European IVD industry is facing the end of the transition period into the new regulation (official Date of Application is May 2022). This will tighten the requirements on clinical evidence and conformity assessment procedures and may initially cause longer than expected processes for the CE-IVD marking, higher costs for certifications and for post-sale traceability and obligations.

Ulisse BioMed's product pipeline spans over two main markets: 1) In-Vitro diagnostics and 2) theranostics, which together account for more than $160bn, but UBM operates in niche segments:

- the Molecular Diagnostics (MDx) market which has market value of $20.5bn in 2020, i.e. approximately 25% of Global In-Vitro Diagnostics market and in particular the **PCR technology,** which accounted for $17bn in 2020 (83% of the overall MDx market). **UBM's produces reagents and assays targeted at this specific market niche.**
- secondly, UBM has addressed the market of **theranostics** – mid way between therapeutic and diagnostic - with specific focus on the **drug monitoring** segment, highly strategic in a few key therapeutic classes (as oncology) and currently valued at $1.4bn. UBM in particular focuses on the Immonoassay technology within the Therapeutic Drug Monitoring.
- finally, in the long term, UBM plans to expand in the field of **Therapeutics**, envisaging the development of products based on **aptamers**, still a niche market valued around $207mn in 2020.

UBM's market scope



Source: Ulisse BioMed SpA, Value Track Analysis, Various

Within the In-Vitro Diagnostics (IVD) market…

The expression In-Vitro Diagnostics (IVD) refers to any medical device that is meant to be used "in vitro" to examine specimens derived from human body, including blood, serum, urine, and other tissues. The purpose being that of providing information concerning a physiological, pathological, congenital state or determining the compatibility and effectiveness on recipients. IVD tests are usually performed in private or public laboratories by qualified and trained staff with appropriate instrumentation.

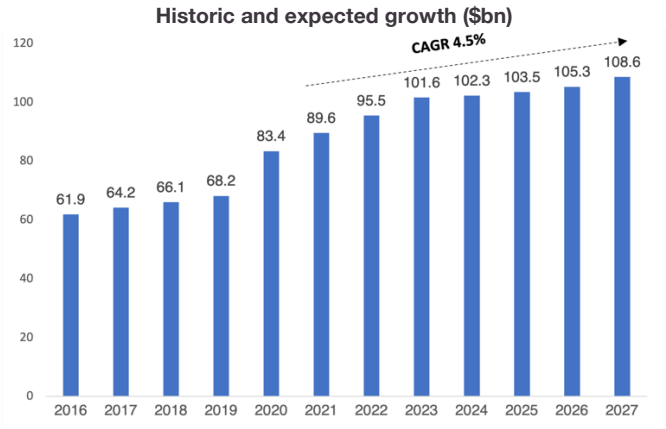
The IVD industry manufactures mainly three types of products:

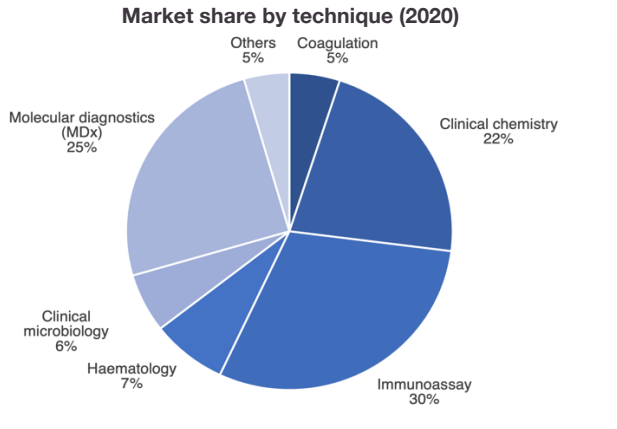
- **Reagents -** solutions of highly specific biological or chemical substances that are able to react with target substances collected in samples;
- **Instruments -** various machines and equipment that automate the analytic process and are used to bring samples and reagents together;
- Accessories and software programs used to run the instrumentation.

The global IVD market size is projected to reach **$108.6 billion by 2027** from $83.4bn in 2020, **growing at a CAGR (2021-27) of 4.5%: 6.8% p.a. in the period 2021-2023, due to the effects of the pandemic, and only 1.7% CAGR over 2024-2027.**

One factor that has positively impacted the growth of the global IVD market until 2019 (2009-2019 4% CAGR), has been the rising demand for POC IVD devices – i.e. devices that allow the IVD test to be performed in real time, not in laboratories but at Point Of Care and this phenomenon is expected to persist.

Global In-Vitro Diagnostics





Source: Grand view research

…Molecular diagnostics (MDx) market represents a large and growing segment

Within the different segment / diagnostic techniques of the IVD market, Ulisse BioMed's focus is on **Molecular diagnostics (MDx)**, which accounts for 25%.

Molecular Diagnostics (MDx) techniques entail the detection of DNA (Deoxyribonucleic Acid) and RNA (Ribonucleic Acid) sequences that are characteristic to specific cells.

The increasing prevalence in the global population of infectious diseases such as influenza, HPV, hepatitis, HIV and the recent Covid-19 pandemic are incentivizing the development of new

technologies able to detect infections and diseases in a quick and reliable manner. Thus in recent years MDx emerged as one of the fastest-growing segments in the IVD industry. This has been particularly the case in 2020, when molecular testing for Sars-CoV-2 boosted demand.

The global MDx market is projected to reach 27.9 billion by 2026 from $ 21.4 billion in 2021**, growing at a CAGR of 4.5% for the period 2021-2026.**

The primary drivers of such growth are expected to be: 1) greater prevalence of infectious diseases and cancer in the population; 2) increase in R&D funding; 3) development of POC testing devices and other technological advancements.

It is worth to highlight that these projections imply a very strong growth for all the diagnostics segments different from those related to Sars-CoV-2 detection and genotyping, as revenues related to Covid 19 -testing

1) represents probably two thirds of MDx revenues in 2020-2021E;
2) are expected to fall significantly from second half of 2021.

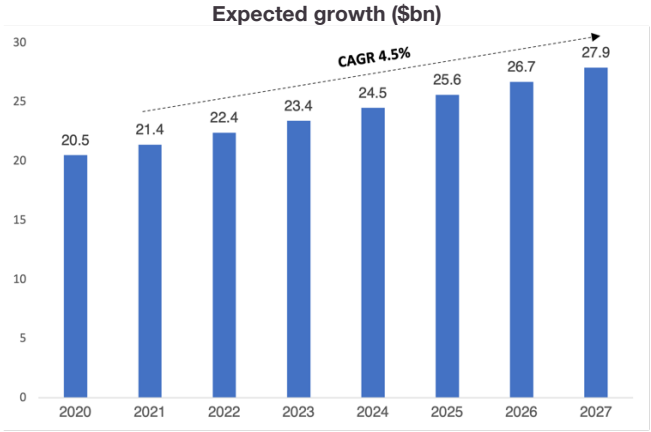
Nowadays the MDx market is dominated by Infectious Disease assays – these testing have certainly benefited from the spread of Covid-19 virus, but it was the largest market segment even before the pandemic - followed by Oncology testing and Blood Screening.

Several distinctive technologies are applied in molecular diagnostics analysis, among them it is worth mentioning most used and the most innovative, i.e. respectively:

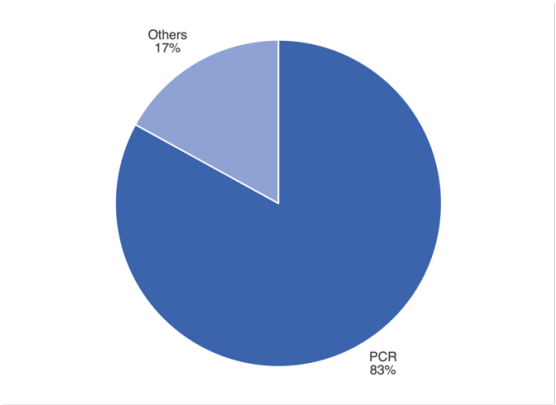
- **Polymerase Chain Reaction (PCR/RT-PCR)** involves the amplification of certain segments of DNA/RNA strands to detect the presence, or absence, of specific DNA/RNA segments. PCR was the most widely used technology within the industry in 2020, accounting for 83% of the total market revenues, mainly thanks to Covid-19-related diagnostics;
- DNA sequencing and in particular **Next Generation Sequencing (NGS)**, which allows the determination of the exact nucleic acid sequence of a DNA strand, albeit this, at the moment, is more focused on sequencing and research rather than diagnostics.

Molecular diagnostics market

Expected growth ($bn)



MDx market share by technology (2020)



Source: Grand view research

Polymerase Chain Reaction Market ($17bn in 2020, 17.5% CAGR into 2027E)

Polymerase chain reaction, or **PCR**, is a laboratory technique used to make multiple copies of a segment of DNA. PCR is very precise and can be used to amplify, or copy, a specific DNA target from a mixture of DNA molecules. These tests require a) the specimen of the patient (blood/serum/other tissue); b) the consumable kit including the reagent; c) a machine (thermal cycler).

Its variation **RT-PCR** adds an extra step involving the reverse transcription of RNA to DNA to allow for amplification and is used for those viruses (as SARS-CoV-2) and bacteria containing only RNA. Both techniques can be performed in **'real time'**, which means that the DNA amplification is measured as it occurs and results are visible almost immediately. Finally, a distinction can be made a) between single channel instruments (for detection of just one target sequence per channel) and **multiple channels machines**, which can identify different targets simultaneously and is more efficient as it lowers process time and reagent costs; b) between open or **closed systems** (the latter requires the use of specific reagents and kits, provided by the same manufacturer of the PCR machine itself).

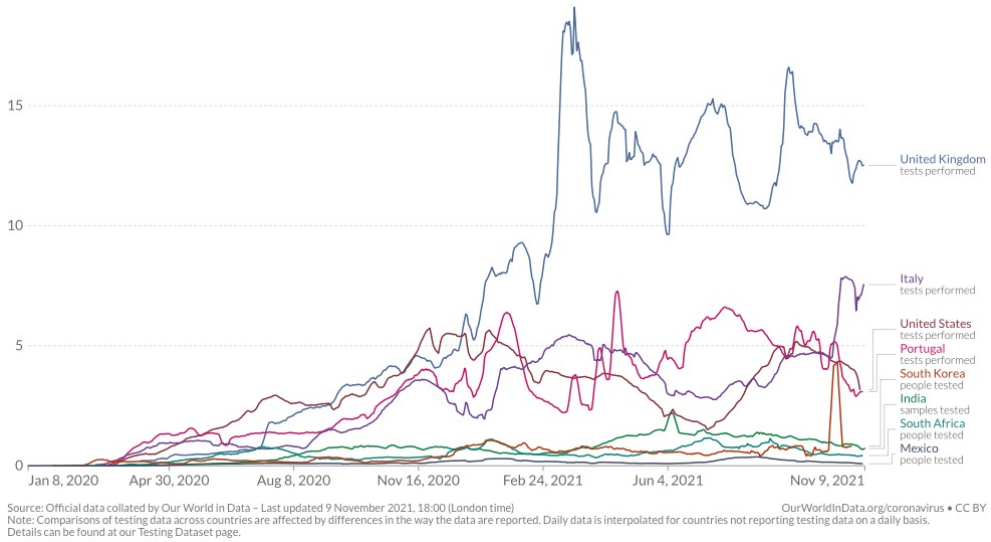
In 2020, the **overall PCR segment was valued $17bn** and accounted for **the largest share in the MDx market by technology (83%),** possibly owing to the accuracy, automation, precision, real-time quantification, and sensitivity of the technology, which offered the best answers to the Covid pandemic diagnostic needs. In fact, molecular testing is considered the gold standard testing for SARS-CoV-2 and we estimate this testing activity alone could account for $13-15bn of annual revenues over 2020-2021, also due to a widely reported cannibalization of other diagnostic activities, especially in 2020. Despite the major jump of 2020, the global PCR market **is expected to grow at a CAGR (2020-2027) of 17.5%** (Market & Market, Grand View Research). Among the major factors driving the market we find: 1) the increasing demand for advanced diagnostic techniques and prenatal genetic testing procedures; 2) the rising number of Clinical Research Organizations, forensic and research laboratories, but also 3) the normalization of the diagnostic and screening activities "cannibalized" by Covid-19 outbreak in 2020.

In Italy the number of laboratories that are allowed to perform molecular diagnosis on clinical respiratory specimens according to specific Real Time PCR protocols for SARS-CoV-2, as indicated by the World Health Organization**, are 389**. Each of them has more labs and in each lab there are many machines, as PCR is a "must have" of any MDx lab. These represent the potential clients, on the Italian territory, that will be targeted by UBM partner Menarini Diagnostics with its MDx assays for the SARS-CoV-2 detection and genotyping.

The Covid-19 "factor"

The impact of the pandemic on the IVD industry demand has been enormous: in Europe and US, demand for diagnostic tests increased more than twenty-fold between March and October 2020.

Daily Sars-CoV-2 tests per 1000 inhabitants



Source: Our World in Data

In the US the FDA has strongly recommended molecular tests as the gold standard for Sars-CoV-2 and also in Italy the molecular tests account for 50% market share, against 50% of the rapid antigenic test. As testing demand ease, vaccine campaign proceeds in developed countries (with increasing number of cases with light or no symptoms) and new variants of the virus are sequenced, it will be increasingly necessary to perform molecular tests rather than rapid tests. However, the key question remains the future trend of testing demand.

Demand for Covid-19 assays will normalize…

It is quite difficult to foresee how many Covid-19 tests will be performed. In order to gauge this trend as for the European market, we have put together the indications coming from different, independent sources:

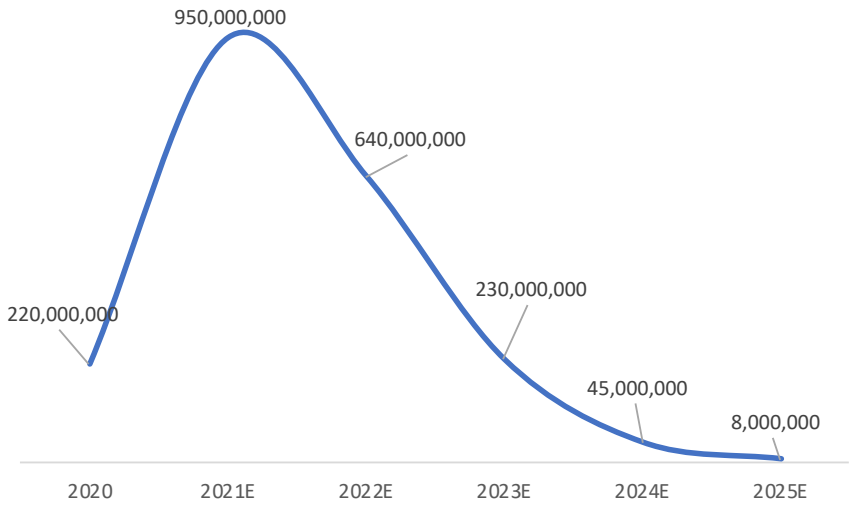
1) a Monte Carlo simulation analysis (conducted by *Madison Corporate Finance* in May 2021) to estimate the European diagnostic test market for Covid-19 over the time period from June 2021 to December 2022. A logarithmic function was used to describe the relation between the percentage of the population vaccinated and the number of swabs, combined with a few other key drivers of kits' demand: tourism, psychological divers, government policies and diffusion of new variants. The outcome is that over the period considered, **there is an 80% probability that the number of tests will be between 637mn and 941mn.** In particular, **the number of tests is expected to remain flattish over second half of 2021, but a decrease of approximately 32% is estimated in 2022**.

2) According to many sources the decrease will continue in following years as, once the pandemic have been eradicated, Covid-19 tests likely become a routine test, therefore Sars-Cov-2 will be detected together with other viruses with similar symptoms, such as flu;

3) Updated consensus relative to the leading 2020-1H 2021 players of the Covid-19 testing market imply average contraction rates for Sars-CoV-2 tests of 30%-60% YoY over 2022 and 2023, and further material reductions in the following years.

The combination of the above indications – combined with the global bounce of new cases and test run rate in the last weeks - has driven our model for Sars-CoV-2 tests to the shape reported below. This model still assumes the pandemic dies out despite variants and virus is gradually eradicated.

Sars-CoV-2 tests forecast (Europe 2020-2025E), n. of tests



Source: Value Track analysis (Includes RT-PCR and antigenic)

…but this tells only half of the story

However, the picture above is not enough to assess the opportunities that the pandemic will create for diagnostic companies in the years to come. In fact the pandemic has accelerated enormously the innovation process in the IVD industry, leading to developments that can structurally change the industry even in the long term.

In particular, four main trends can be highlighted:

- Significant **increase in MDx tests as well as immunoassays** meant to detect Sars-CoV-2. However, other segments of the IVD industry suffered because of the restrictions which reduced the number of people interested in other detections and participating in screening programs;
- **Higher adoption of PCR-based diagnostics.** The need for a very accurate detection of Sars-CoV-2 during the pandemic has incentivized laboratories to acquire a large number of PCR machines to carry out highly reliable molecular tests. In the post-pandemic world such a large base of installed machines are expected to be used by laboratories also for other pathologies;
- **Raising demand for POC testing.** The importance of these portable instruments has increased dramatically during the COVID-19 pandemic, as people/firms are opting for cheap and fast diagnostic tests that can be performed at Point of Care/ work/home, without the need of going to a hospital or laboratory;
- Adoption of new diagnostic technologies able to **reduce the response time** of laboratories and **overcome the shortage of reagents**;
- Last but not least, the enormous amount of money spent in diagnostics over 2020-2021, has provided the industry a **unique opportunity of funding its R&D and accelerating innovations**.

Hence, despite the expected normalization of the testing demand from 2022 onwards, according to major research hubs the global PCR and MDx segments are still seen to grow from 2020 levels, thanks to the drivers described above. On the one hand we acknowledge that consensus over MDx growth beyond 2021 may prove to be overly optimistic in terms of growth rates – if we consider that Covid-19 related business could be in the range of $13-15bn per year in 2020-2021 - but on the other hand we fully subscribe the trends described and expect them to offset the negative impact of the post Covid-19 normalization.

Implications for UBM

The outlook described perfectly fits UBM, as it will enter the market almost in a "post pandemic" phase (second half 2021) with an offer of Sars-CoV-2 and respiratory products that seems to suit perfectly the expected needs of the market and this will also support UBM pipeline in fields far from Covid-19.

In particular UBM products due to be launched via the licensing of Menarini Diagnostics seem to be well positioned as they:

1. **Provide cost-effective and time-saving tests**

Since the beginning of the pandemic all the big players of the IVD industry shifted the focus of their activities on the production of Covid-19 tests and many new players have entered the MDx market to exploit this opportunity. As a consequence, the MDx landscape appears to be characterized by a high level of competition and to make their products prevail incumbents are forced to offer tests that are efficient not only in terms of cost but also time.

UBM's CoronaMelt and CoronaVar are entering the market in second half of 2021 with exactly these characteristics:

- **No need for DNA/RNA extraction**, saving approximately 3-8€ per test and sensibly reducing the working time needed;
- **Detection and genotyping in one step** without the need to perform a re-examination which instead is required by competitors' tests (may cost up to 50€);
- **Very low cost of production**, thanks not only to the leaner and faster workflow, but also to the use of chemicals that are cheaper and less subject to scarcity, which in turn ensures flexibility in pricing.

2. **Take advantage of its syndromic capabilities**

As we mentioned before, after the end of the global pandemic Sars-CoV-2 testing will become routine and rather than identifying Covid-19 virus itself people will be interested in discriminating among many different viruses and variants with similar symptoms (flu), with a syndromic approach.

To take advantage of this opportunity, UBM can rely on the competitive advantage of Sagitta on syndromic testing. In fact, Sagitta's advanced **multiplexing capabilities**, allowing identifying up to 20 targets in a single reaction, are suitable for syndromic testing aimed at identifying simultaneously multiple pathogens with overlapping symptomology.

Theranostics Market

With the term theranostics we refer to the integration of a diagnostic method with a specific therapeutic intervention aimed at maximizing the effectiveness of a specific drug. Thus, theranostics

can be understood as a field in between diagnostics (MDx, immonoassays, etc. and increasingly in POC applications) and therapeutics.

The global theranostic market is expected to grow from $80.4bn in 2020 to **$129.8 billion by 2025, at a CAGR of 10.1% for the period 2020-2025.** According to the type of disease that is addressed it is possible to identify several market segments: neurological disorders, immunological, cardiovascular and oncology being the most relevant. More specifically, theranostics' market segment related to oncology, on which UBM is planning to focus, is the largest and is forecasted to grow from $73.1 billion in 2020 to $119.7 billion by 2025, at a CAGR of 10.4% over this period.

Therapeutic Drug Monitoring Market ($1.4bn in 2020, 6.9% CAGR into 2025E)

Therapeutic drug monitoring (TDM) is the clinical practice of measuring specific drugs at designated intervals to maintain a constant concentration in a patient's bloodstream, thereby optimizing individual dosage regimens.

TDM is employed to monitor drugs with narrow therapeutic ranges, drugs with marked pharmacokinetic variability, medications for which target concentrations are difficult to monitor, and drugs known to cause therapeutic and adverse effects. For instance, TDM is used to track monoclonal antibodies, very expensive biological drugs with serious side effects, mainly used in cancer therapy.

The global therapeutic drug monitoring market is **estimated to reach $ 2.0 billion by 2025** from $ 1.4 billion in 2020, **growing at a CAGR (2020–25) of 6.9%.**

Market growth can be attributed to the rise in the number of organ transplants, use of TDM across various therapeutic applications, adoption of precision medicine, and growing focus on R&D investments. Also, emerging economies such as India and China are expected to provide a wide range of growth opportunities, driven by rise in the cases of chronic diseases, such as cancer.

Therapeutics Market (Anti-Viral)

Antiviral drugs are a class of medication used to treat viral infections and can either target a specific virus, or a wide range of viruses (broad-spectrum antiviral). The global AVT market was valued at $51.26 billion in 2020, and it is expected to reach **$ 67.76 billion in 2026,** recording a **CAGR of 4.76%** during the forecast period**.** The future market's growth is expected to be driven by the increasing focus on the treatment of COVID-19 virus, but also increasing R&D investments for antiviral drugs, strong R&D pipelines and rising product launches.

Aptamers ($208mn in 2020, 16.7% CAGR into 2025E)

A niche within Anti-Viral Therapeutics is that of aptamers, i.e. short, single-stranded DNA or RNA molecules with defined structures that can specifically bind to a molecular target via three-dimensional structures. SELEX (systematic evolution of ligands by exponential enrichment) is the gold-standard methodology for generating aptamers, and it involves an iterative selection procedure to identify and expand binding aptamers.

The size of the aptamers market at a worldwide level is estimated to value $ 207.7 million in 2020 and is projected to grow to **$448.8 million by** the end of **2025**, at a **CAGR of 16.7%.** Such growth is expected to be backed by: 1) technological advancements; 2) increasing R&D investments in the pharma and biotech industries; 3) Low cost and high efficacy in binding to large molecules compared to antibodies.

Regulations: current practices and future developments

Steps for the approval of IVD devices

There are several stages related to development, regulatory approval and commercialization of molecular diagnostics assays:

- **Development -** Generally involves an analytical validation;
- **Research Use Only (RUO)** - Products that have only completed a scientific validation process, but not a full clinical validation. RUO products are marketable but the result of the analysis carried out is not certified for diagnostic purposes. This implies that the entity carrying out a diagnostic analysis with RUO products has to bear the responsibility for any inaccuracy.

A further step can be completed by diagnostic firms commercializing their products in the European Union and/or in other countries accepting EU certification:

- **CE-IVD marking** – this is the certification required for the marketing of diagnostic medical devices in the European Union in accordance with Directive 98/79/EC. Obtaining such certification is fundamental since only the results of assays with a CE-IVD mark are considered diagnostic. The CE-IVD marking process includes a pre-clinical technical-scientific validation, which verifies the analytical performance of the medical device. Subsequently, a clinical validation is performed on biological samples in order to ascertain the diagnostic performance of the device. Usually it takes between 1-9 months for a CE-IVD marking to be granted.

Companies willing to market assays in the United States must obtain the following authorizations:

- **Emergency Use Authorization (EUA)** – this is not a full FDA approval but an authorization for commercialization in the US provided in order to face emergency needs, as it is the case now with Covid-19 pandemic. Assays marketed under EUA will eventually have to undergo the FDA 510(k) procedure to remain on the market;
- **FDA 510(k) -** clearance from US Food & Drug Administration, which usually is released in a span of time that ranges between 3 and 9 months. More specifically, IVD assays go through a stringent 510(k) evaluation process to demonstrate that the device to be marketed is "as safe and effective" and "substantially equivalent" to a legally marketed device.

As for UBM, it initially plans to sell its reagents in Europe obtaining a CE-IVD mark and only at a later stage UBM, or its licensing partners, will request the FDA authorization to enter the US market.

UBM's products approval procedure

Source: Ulisse BioMed SpA

New IVDR regulation

Starting from May 2022 diagnostics companies will be required to comply with a new regulation of the European Union on in vitro diagnostic devices, namely the **IVD Regulation 2017/746/EU (IVDR).**

This new regulation entered into force in May 2017, marking the start of a five-year period of transition from the IVDD, i.e. the existing In Vitro Diagnostic Directive (98/79/EC).

The transitional period is meant to allow the IVDR to come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the IVDR. In addition, during the transition phase, products certified under the old directive and products certified under the new regulation will coexist on the market.

The main novelties of the IVDR consist in the risk classification of in vitro diagnostic (IVD) devices and the role of Notified Bodies (NBs). More specifically the new regulation encompasses:

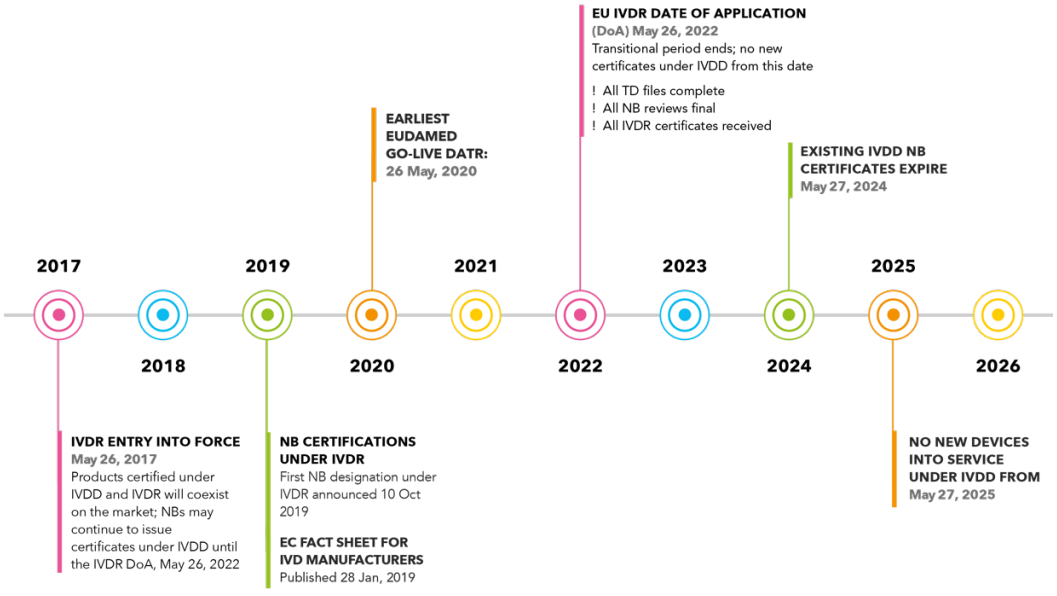
- More stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and the Commission;
- Wider array of IVD devices covered and a **more detailed classification based on risk class**, ranging from class A (lowest risk) to D (highest risk);
- **Tighter requirements on clinical evidence and conformity assessment procedures**. In particular, when dealing with companion diagnostics, the Notified Bodies are required to consult the competent authorities for medicinal products;
- Involvement of an **EU Reference Laboratory** in the conformity assessment procedure of the riskiest devices (class D) in order to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications;
- Introduction of a **unique device identifier (UDI)** for every IVD device to enhance traceability and support post-market safety activities.

As far as the timing of the regulation is concerned, Notified Bodies may continue to issue certificates under the old IVDD directive until the date of application of the Regulation, namely **May 26th 2022**.

Devices with valid certificates issued under IVDD before the aforementioned date may continue to be placed on the market until 26 May 2024 and they may be made available until 26 May 2025.

In any case, manufacturers can already place their products on the market under the IVDR as long as they comply with the Regulation.

Transition timeline from IVDD to IVDR



Source: European Commission, Tecan

SWOT Analysis

Strenghts

- **Partnership with Menarini Diagnostics**, a company with operations in more than 140 countries, a strong distribution network and a strategy focused on growth in MDx;
- Strong **R&D team** and prestigious **scientific committee,** which includes five renowned international scientists and opinion leaders in the biotech research sector;
- **Competitive products,** as assays developed offer a better value for money with respect to rival products available on the market (and are all in reimbursed categories);
- **Free cash flow break-even** and **fully funded R&D pipeline**, according to our estimates and also assuming delays in the planned partnerships to be signed;

Opportunities

- **Broad** portfolio of intellectual property rights and **scope of R&D;**
- **Diversification within diagnostics,** by developing technology platforms able to produce solutions, not only for the MDx industry, but also to be used in immunoassay (theranostics) and, eventually, in therapeutics/medical devices;
- **Highly innovative and fast growing technologies** (nano-switches, aptamers) and **applications** (POC, theranostics);
- Expected growth in the MDx industry is strongly linked to the **timing of the pandemic disappearance** and consensus now factors Sars-CoV-2 to be eradicated by 2022-2023, but this **might turn out as too optimistic**;
- Notwithstanding the final duration of Sars-CoV-2 pandemic and testing demand, the impressive **bounce in RT-PCR machine installed base** represents a solid growth driver for MDx in coming years, especially for multiplexing/syndromic diagnostics;

Weaknesses

- **UBM's technology platforms (even Sagitta, the more solid) are still to be tested on several different types of pathogens and matrices** and it is not granted that such assays have the same level of accuracy as those for Sars-CoV-2 and HPV or for matrices tested;
- **NanoHybrid and Aptavir technologies** enjoy a much **lower TRL** (Technology Readiness Level) than Sagitta, and this implies further sizeable investments (and time) to get ready;
- **Strong dependence on Menarini Diagnostics,** as this partnership is expected to bring the bulk of revenues over the whole forecast period (average at ca. 75% including other revenues);
- **Strong dependence on Covid-related revenues.** In the next few years (2021-2023E) the expected contribution of royalties and reagent's sale related to Sars-CoV-2 to UBM's revenues are material: from ca 56% in 2021E to ca 22% in 2023E of total revenues;
- The B2B consumable driven business model of the company will depend on the stipulation of **licensing and/or distribution agreements** with big pharma and IVD players;

Threats

- The **competitive pressure** within the IVD industry and, even more so in MDx, is quite high with many big players active, making firms seek a reduction of costs and economies of scale. The Post-Covid normalization of testing demand might add further pressure;
- **Change in regulations** can increase the costs faced by the firm with tighter requirements on clinical evidence and conformity assessment procedures and can require longer times;
- The company is still **very small** and has an extremely **lean corporate structure**.

Historical Financials

After 5 years of investments in R&D but very limited revenues, UBM has finally started to generate significant sales thanks to the licensing agreement signed with Menarini Diagnostics. Moreover, the simultaneous streamlining of the cost structure has allowed UBM to reach economic break-even in FY2020.

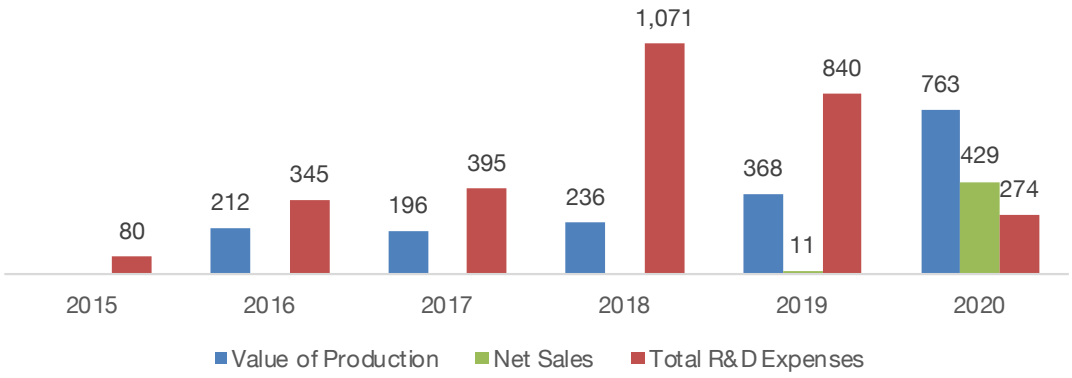
As for the Balance Sheet, the company has reported at the end of FY2020 a positive net cash position, despite the negative free cash flow generation of ca €733k.

Until 2019 little revenues and focus on R&D

Until 2019 UBM could still be considered a "pre-revenues" company, in fact up to that year it had only reported revenues from grants and R&D tax credits. In fact, despite earning some revenues from sales of HPV diagnostics kits in 2019, related to an initial test carried out on LadyMed to sound the B2C channel, Net Sales remained very limited at around €11k.

However, during the same period, the company invested consistently in research and development to allow for the creation and fine-tuning of its proprietary technology platforms. In particular, UBM has invested a cumulative amount of more than €3mn over the 6-year period between its incorporation and 2020.

UBM - VoP, Net Sales and R&D expenses over 2015-2020 (€'000)



Source: Ulisse BioMed SpA, Value Track Analysis

From 2020 monetization starts

In 2020, UBM reported some revenues thanks to the licensing agreement signed with Menarini Diagnostics Srl on the production and commercialization of Covid-related tests.

This opportunity was combined with the streamlining of the cost structure following the focusing of a) R&D efforts after years of wider scope and b) go to market strategy to a pure B2B strategy. This allowed UBM to reach economic break-even in FY2020.

More in detail, UBM reported:

- Revenues from sales of €128k in 2020, related to 25,000 tests produced by UBM and sold to Menarini Diagnostics to independently verify the performance of CoronaMelt;
- Collaboration revenues of €300k related to the technology transfer of a part of the Sagitta platform in favor of Menarini Diagnostics for the production and marketing of CoronaMelt;

- Grants and contributions of €157k relating to POR-FESR research projects;
- In addition, the 2020 Value of Production benefitted also from a number of one-off items, for a total of €177k, including R&D cost capitalization of €71k;
- EBIT and net profit benefitted from R&D capitalizations and extraordinary items (i.e. the €177k of "Other revenues"), adjusting operating profit and bottom line they would stand at €47k and €45k respectively, still a major jump relative to 2019.

UBM: Profit & Loss statement 2019A-2020A

(€'000)	2019A	2020A
Product sales revenues	10.8	128.6
Royalties	0.0	0.0
Collaboration revenue	0.0	300.0
Net sales	**10.8**	**428.6**
R&D tax credits	0.0	0.0
Grants	349.3	157.1
Other revenues	7.4	176.9
Value of production	**367.6**	**762.7**
COGS (incl. R&D)	-146.4	-140.7
Gross Profit	**221.2**	**622.0**
Research and development expenses	-724.4	-132.9
Sales and marketing expenses	-66.0	-3.0
General and Administrative expenses	-547.2	-261.9
EBIT	**-1,116.4**	**224.2**
Depreciation & Amortization	*-55.6*	*-50.9*
EBITDA	***-1,060.8***	***275.1***
Financial revenue (expense)	0.3	-0.1
EBT	**-1,116.1**	**224.2**
Income taxes	17.7	-2.3
Net Profit (loss)	**-1,098.5**	**221.8**

Source: Ulisse BioMed SpA, Value Track Analysis

Balance Sheet and Cash Flow Statement

UBM's Total Capital Employed in 2020 stood at €1.5mn, ca 200% of Sales, and was made up by:

- Net Working Capital at roughly €550k, significantly higher with respect to the previous year (negative for €176k), mainly because of a commercial debt of €582k, recorded in 2019 and relative to an investment which was afterwards withdrawn;
- Net Fixed Assets at ca. €977k compared to €173k in 2019, due to the reassessment of the value of intangible assets (see below);
- Provisions equal to ca. €11k.

It is worth to highlight that in 2020 UBM's management decided to reconsider the value attributed to the Sagitta DNA patent, following the implied validation coming from the exclusive agreement signed with Menarini Diagnostics. The revaluation of Sagitta DNA led to an increase in intangible assets of around €750k and will be amortized over a useful life of 3 years. At the end of FY2020, UBM was characterized by a positive financial position of approximately €43k (cash) and shareholders' equity equal to €1.6mn (vs ca 670k in 2019) due to the revaluation of Sagitta and the positive Net Result.

UBM: Balance Sheet 2019A-2020A

(€'000)	2019A	2020A
Net Working Capital	**-176.5**	**550.1**
Intangible Assets	17.1	862.1
Tangible Assets	152.3	111.5
Financial Assets	3.8	3.8
Net Fixed Assets	**173.2**	**977.4**
Funds and Provisions	-50.6	-3.8
TFR	-54.7	-7.4
Total Capital Employed	**-108.6**	**1,516.3**
Share capital	50.0	50.0
Reserves	4,950.9	5,620.6
Retained earnings	-3,234.7	-4,333.2
Profit (loss) for the year	-1,098.5	221.8
Shareholders' Equity	**667.7**	**1,559.3**
NFP [i.e. Net Debt (-) Cash (+)]	**776.2**	**43.0**

Source: Ulisse BioMed SpA, Value Track Analysis

In spite of the positive EBITDA reported, the 2020 free cash flow generation was still negative (for €733k) and further reduced the net cash position, due to

- the significant increase in Net Working Capital (also due to the fact that most of 2020 revenues were cashed in during early 2021);
- the high level of Capex;
- the "non cash" portion of gross profit (i.e. R&D capitalizations for €71k and extraordinary items for €106k).

UBM: Cash Flow Statement 2020A

(€'000)	2020A
EBITDA	275.1
Working Capital Needs	-726.6
Capex	-106.9
Change in Provisions & TFR	-94.0
OpFCF b.t.	**-652.4**
Cash Taxes	-2.3
OpFCF a.t.	**-654.8**
Other fiscal liabilities .	-20.7
Other Op. Items (incl. Fin. Inv.)	-57.7
CF available to serve debt/equity investors	**-733.2**
Net Financial Charges	-0.1
Net Cash generated (absorbed)	**-733.2**

Source: Ulisse BioMed SpA, Value Track Analysis

1H21 Update

UBM has recently released 1H21 financial figures, among which we highlight:

- **Sales at €145k** (almost zero in 1H20), related to the know-how transfer and licensing agreement signed with Menarini;
- **Value of Production at €152k**, decreasing by €50k y/y, linked to the lower amount of accounted grants – mainly due to some delay in the reporting of subsidized research projects – expected to be recorded within 2021 year-end;
- **EBITDA close to the break-even point** (-€27k), and substantially in line y/y, together with a Net Loss of €88k, almost doubled y/y;
- Favourable WC dynamics led to an **improving Net Financial Position** of €199k cash as of June'21 if compared to €43k cash reported at the end of FY20.

The Company has also announced:

- the finalization of know-how transfer process on behalf of Menarini Diagnostics related to the CoronaMelt and CoronaMelt Var tests, in vitro diagnostic devices aimed, respectively, at the detection and genotyping of Sars-CoV-2.;
- the validation of the Coronamelt Var salivary test, that facilitates the collection process of biological samples while maintaining a high-test sensitivity.

UBM: Key P&L items (1H20,1H21)

(€'000)	1H20	1H21
Product Sales Revenue	**1.2**	**145.8**
Other Revenues	200.9	6.0
Value of Production	**202.1**	**151.9**
EBITDA	**-20.6**	**-27.0**
Net Profit (Loss)	-47.4	-88.4

Source: Ulisse BioMed SpA, Value Track Analysis

UBM: Balance Sheet (FY20,1H21)

(€'000)	FY20	1H21
Net Working Capital	550.1	130.2
Net Fixed Assets	977.4	1,141.7
Provisions	(11.3)	0.0
Equity	**1,559.3**	**1,470.9**
NFP [i.e. Net Debt (-) Cash (+)]	**43.0**	**199.1**

Source: Ulisse BioMed SpA, Value Track Analysis

Financial Forecasts 2021E-24E

According to Value Track estimates UBM's Net Sales are forecasted to grow almost ten-fold reaching €4.1mn in 2024E from €428k in 2020A. Over the same period EBITDA margin (on VoP) is expected to increase up to 71%: in absolute terms we foresee EBITDA to grow to ca. €3mn in 2024E. While Menarini's agreement should represent a significant portion (ca 75%) of UBM's value of production in the whole period, starting from 2022E we envisage a declining incidence of Covid-related revenues. At the same time, we expect the company to keep strengthening its financial structure due to the accelerating Free Cash Flow generation, thus achieving a net cash position of €8.5mn by 2024E, clearly benefitting from €4.2mn of IPO proceeds (net of related costs expected at ca. €0.8mn). Our forecasts do not factor any revenues from sales linked to products still far from entering the market and/or with no negotiations for co-development or distribution partnerships at sight (while we do include some collaboration revenues for Sagitta's new panels). Finally, our forecasts do not include the proceeds of "Short term Warrants 2021" and "2021-2026 Warrants", albeit their dilutive effect is factored in our Fair Equity Value assessment.

As far as 2021E-24E financial forecasts are concerned, we note that all our projections are:

- Post-money, i.e. including €5.0mn IPO proceeds;
- Based on a stand-alone scenario, no financial impact from future M&A is considered.

Revenues 2021E-2024E

Key assumptions for the top line

As explained in previous sections, UBM's business model strongly relies on partnerships in order to commercialize its products.

Thus, in forecasting revenues we have considered two main partnerships:

- the existing licensing agreement with Menarini Diagnostics for the sale of CoronaMelt, CoronaMelt Var and a full Viral Respiratory Panel;
- a future potential agreement related to Sexually Transmitted Diseases (STD) and, in particular, HPV Selfy/LadyMed;
- in addition, we assume other co-development agreements to contribute to R&D costs (for 80% of total) for the Sagitta's panels to be developed from 2022.

All the remaining products that make up UBM's potential pipeline were not incorporated into our revenues model. In fact, they are still quite far from being ready to enter the market and no negotiations to find a suitable partner have started yet. The rationale behind this choice is that of including only those products that are ready to be marketed and for which a licensing agreement has already been signed or, at least, is entering potential discussion.

While we have discussed in detail the agreement with Menarini Diagnostics in previous sections, as far as STD panels are concerned, we assume that

a) UBM signs a similar licensing agreement with a partner (or two, assuming a different player focused on B2C for LadyMed). In particular, such partner (or partners) is expected to commercialize HPV Selfy, LadyMed and other STD tests (Chlamydia, Gonorrhea and Syphilis) both in Italy (3% market share) and in the rest of Europe (1%-1.75% market share). See previous section for more details about our HPV screening model (for Italy and Rest of Europe).

b) Partnership is signed by 1Q 2022 and we assume one-off collaboration revenues of 60k in FY2022E;

c) we assume products to be commercialized from 4Q2022 and, starting from there, UBM is expected to earn 8% royalties on the partners' sales of STD assays every year.

As for the other Sagitta panels we only forecast collaboration revenues (for 80% of total R&D), while for NanoHybrid and Aptavire we have assumed no revenues.

UBM - Net Sales and VoP breakdown 2020A-2024E

€'000	2020A	2021E	2022E	2023E	2024E
Product sales revenue	128.6	66.3	542.1	1,066.8	1,636.1
Royalties	0.0	100.0	906.6	1,499.9	2,449.0
Collaboration revenue	300.0	393.0	610.0	136.0	0.0
Net sales	**428.6**	**559.3**	**2,058.7**	**2,702.7**	**4,085.1**
R&D tax credits	0.0	54.7	70.0	172.0	134.0
Grants	157.1	163.0	102.0	0.0	0.0
Other revenues (incl.R&D cost capit.) (*)	176.9	10.0	425.0	0.0	0.0
Value of production	**762.7**	**787.0**	**2,655.7**	**2,874.7**	**4,219.1**

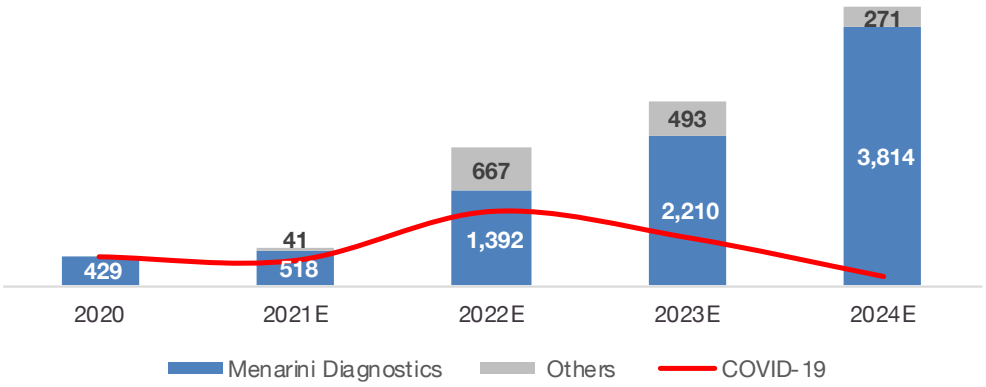
Source: Ulisse BioMed SpA, Value Track Analysis (*) The 2022E amount is due to the Tax Credits related to IPO costs.

Drivers of the Top line

UBM's Net Sales are expected to grow almost seven-fold and reach €4.1mn in 2024E from €560k in 2021E. Among the main drivers of UBM's top line we find:

- **Revenue from sales**, i.e. expected revenue from the sale of UBM's UlisseFaster reagent both to Menarini Diagnostics and directly to third parties. It is the component that is predicted to grow at the highest CAGR over the projection period, amounting to ca €1.6mn in 2024E;
- **Royalties,** forecasted to be earned on the sale of respiratory diseases and STD assays made by partners. They are expected to reach €2.4mn by 2024E and represent the main revenue stream for UBM;
- **Collaboration Revenues** related to the technology transfer of Sagitta with Menarini Diagnostics and other partners. UBM's management expects to earn enough collaboration revenues to cover the R&D costs related to the development of future Sagitta's assays, for a cumulative amount of €1.1mn over the next three years. However, we cautiously assume only 80% of costs to be covered by partnerships;
- Not surprisingly, the **revenues related** to the licensing agreement with **Menarini Diagnostics**, together with the supply agreement of UlisseFaster, are predicted to represent the vast majority of UBM's Net Sales in the years to come. As shown in the chart below Menarini Diagnostics should represent 84% of revenues from sales over 2021-2024E and 75% of VoP;
- As for the **Covid-19** driven business, the chart below reports also the contribution of CoronaMelt and CoronaMelt Var (and the corresponding reagent sales). This business segment is expected to fall quite rapidly - to virtually nil by the end of the forecast period - and to be replaced by the syndromic test (Covid+Flus), which is expected to become the new standard

UBM - Net Sales split: Menarini Diagnostics vs Others (€'000)

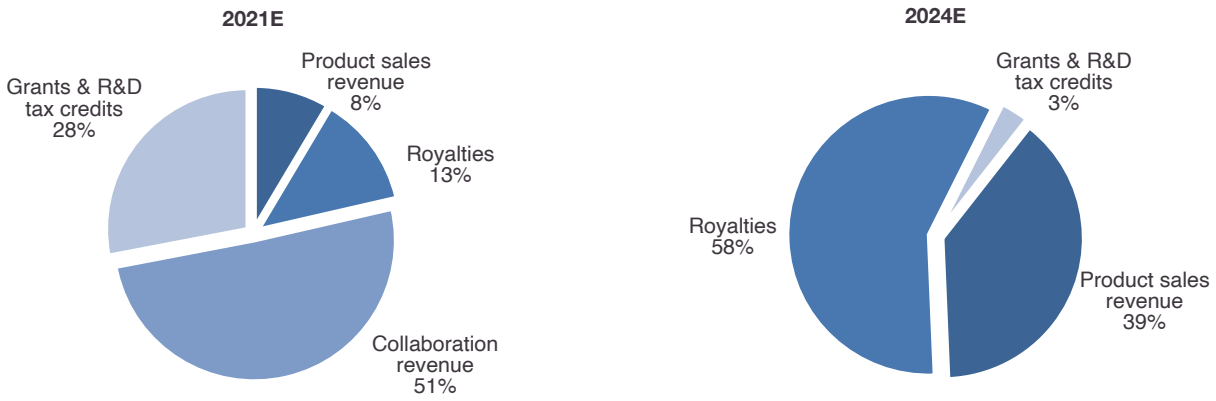


Source: Ulisse BioMed SpA, Value Track Analysis

On top of those key drivers, UBM's Value of Production is expected to benefit also from other sources of income, mostly related to the R&D activity:

- Private and public grants, which are conservatively assumed to be nil starting from 2023 and as for 2021-2022 only factor the formalization and cash-in of grants already awarded;
- R&D tax credit, amounting to 20% of total UBM R&D expenses;
- Finally we assume a €425k tax credit related to listing costs to be received in 2022E.

UBM - VoP breakdown 2021E vs 2024E



Source: Ulisse BioMed SpA, Value Track Analysis

Costs

On the costs side, we foresee:

- Direct costs to increase over time mainly due to the increasing output of UlisseFaster reagent that will be sold both to Menarini and third parties, being it very much a "platform" and "machine" neutral reagent. This would lead to a progressive shrinking of the gross margin, which however would remain above 80%. Note that prior to 2021 this item included the direct costs of the R&D activity (e.g. consumables), as this was the main activity carried out by the company;
- R&D costs are expected to remain a significant portion of costs in the next few years as the company will continue to expand the assays menu of Sagitta and NanoHybrid. However, it should be noted that we assume from 2021 a partial capitalization of R&D costs (50%), which are assumed to be capitalized straight to balance sheet (with no revenues recognition), see below;
- At the same time, G&A costs are forecasted to grow due to a reorganization of the managing structure of the firm and with the entrance of new components in the BoD;
- Finally, due to UBM's choice to pursue a B2B driven business model, Sales and Marketing expenses are estimated to be quite contained.

UBM - Cost structure and EBIT – 2020A-2024E

€'000	2020A	2021E	2022E	2023E	2024E
Value of Production	**762.7**	**787.0**	**2,655.7**	**2,874.7**	**4,219.1**
COGS (from 2021 excl. R&D)	-140.7	-23.2	-178.5	-399.3	-672.4
o/w D&A	*-31.6*	*-2.0*	*-5.0*	*-20.0*	*-26.0*
Gross Profit	**622.0**	**763.8**	**2,477.2**	**2,475.4**	**3,546.7**
Gross Margin (%)	*81.6%*	*97.1%*	*93.3%*	*86.1%*	*84.1%*
R&D expenses	-132.9	-424.7	-738.0	-786.4	-376.7
o/w D&A	*-10.0*	*-259.3*	*-314.3*	*-461.4*	*-216.7*
Sales and marketing expenses	-3.0	-3.6	-4.3	-5.2	-6.2
G&A expenses	-261.9	-267.1	-347.3	-364.6	-401.1
o/w D&A	*-9.3*	*-10.0*	*-10.0*	*-10.0*	*-10.0*
EBIT	**224.2**	**68.3**	**1,387.6**	**1,319.2**	**2,762.7**
EBIT Margin (%)	***29.4%***	***8.7%***	***52.3%***	***45.9%***	***65.5%***
Total D&A	*-50.9*	*-271.3*	*-329.3*	*-491.4*	*-252.7*
EBITDA	**275.1**	**339.6**	**1,716.9**	**1,810.6**	**3,015.4**
EBITDA Margin (%)	***36.1%***	***43.2%***	***64.6%***	***63.0%***	***71.5%***

Source: Ulisse BioMed SpA, Value Track Analysis

R&D costs and capitalization policy

The R&D budget represents the most significant cost item for UBM, and we expect it to remain relatively high also in coming years, as the Company plan to develop a few panels to offer full test menus for both Sagitta RT-PCR assays and Nanohybrid's Therapeutic Drug Monitoring assays and POC.

We assume cumulated R&D costs at around €2.2mn over 2021-2024E, albeit the impact on EBITDA will be slightly mitigated by a partial capitalization of costs. In fact we assume management to continue the policy of capitalization started in 2020, albeit we assume no revenues recognition for

these capitalizations, but a straight impact on intangible assets, and a 3-years amortization period. The table below provides a breakdown of this cost item and the related assumptions on accounting.

UBM – R&D expenses and accounting policy – 2020A-2024E

€'000	2020A	2021E	2022E	2023E	2024E
Sagitta		300.0	710.0	170.0	0.0
NanoHybrid		50.0	150.0	500.0	350.0
Aptavir		0.0	0.0	0.0	0.0
Total R&D expenses (excl. capitalizations/amort.)	**273.5**	**350.0**	**860.0**	**670.0**	**350.0**
o/w capitalized via P&L	71.1	0	0	0	0
o/w capitalized directly to B/S	690.5(*)	175.0	430.0	335.0	175.0

Source: Ulisse BioMed SpA, Value Track Analysis (*) Revaluation as of Dec 2020

UBM – Profit & Loss Statement – 2020A-2024E

€'000	2020A	2021E	2022E	2023E	2024E
Product sales revenues	128.6	66.3	542.1	1,066.8	1,636.1
Royalties	0.0	100.0	906.6	1,499.9	2,449.0
Collaboration revenues	300.0	393.0	610.0	136.0	0.0
Net sales	**428.6**	**559.3**	**2,058.7**	**2,702.7**	**4,085.1**
R&D tax credits	0.0	54.7	70.0	172.0	134.0
Grants	157.1	163.0	102.0	0.0	0.0
Other revenues	176.9	10.0	425.0	0.0	0.0
Value of production	**762.7**	**787.0**	**2,655.7**	**2,874.7**	**4,219.1**
COGS (from 2021 excl. R&D)	-140.7	-23.2	-178.5	-399.3	-672.4
Gross Profit	**622.0**	**763.8**	**2,477.2**	**2,475.4**	**3,546.7**
Gross Margin (%)	*81.6%*	*97.1%*	*93.3%*	*86.1%*	*84.1%*
R&D expenses	-132.9	-424.7	-738.0	-786.4	-488.3
Sales and marketing expenses	-3.0	-3.6	-4.3	-5.2	-6.2
General and Administrative expenses	-261.9	-267.1	-347.3	-364.6	-401.1
EBIT	**224.2**	**68.3**	**1,387.6**	**1,319.2**	**2,651.0**
EBIT Margin (%)	*29.4%*	*8.7%*	*52.3%*	*45.9%*	*62.8%*
Total D&A	*-50.9*	*-271.3*	*-329.3*	*-491.4*	*-252.7*
EBITDA	**275.1**	**339.6**	**1,716.9**	**1,810.6**	**3,015.4**
EBITDA Margin (%)	*36.1%*	*43.2%*	*64.6%*	*63.0%*	*71.5%*
Financial Income (Expense)	-0.1	0.2	23.1	27.7	33.8
EBT	**224.2**	**68.6**	**1,410.7**	**1,346.9**	**2,684.8**
Income taxes	-2.3	-16.5	-56.4	-107.8	-671.2
Net Profit (loss)	**221.8**	**52.1**	**1,354.3**	**1,239.2**	**2,013.6**

Source: Ulisse BioMed SpA, Value Track Analysis

Cash Flow and Balance Sheet

Leaving aside the €4.2mn net proceeds from the recent IPO, we expect UBM to start generating free cash flow from 2021, as reported in the cash flow model below. The key assumptions are the following:

- NWC is expected to absorb capital in the light of the strong top line growth;
- R&D as indicated above is expected to require more capital than suggested by P&L, following capitalization policy, and this will inflate the capex line;
- Capex (excl. capitalizations) are forecasted relatively low in 2021-2022E - as production capacity for UlisseFaster and equipment for R&D and certifications are sized for expected growth – and higher for 2023E, when Nanohybrid products launch will require capex for production;
- Our model does not factor the impact of "Short term Warrants" and "Warrant" exercise (albeit the assumptions for the Fair Equity Value assessment may differ).

Ulisse BioMed: Balance Sheet 2020A-2024E

€'000	2020A	2021E	2022E	2023E	2024E
Inventory	68.3	26.5	140.3	245.0	359.4
Receivables	774.4	274.9	513.7	540.5	817.0
Payables	-297.1	-47.1	-109.5	-158.5	-183.3
Accruals & deferrals	4.5	5.9	21.7	28.5	43.1
Net Working Capital	**550.1**	**260.2**	**566.3**	**655.6**	**1,036.3**
Intangible Assets	862.1	777.8	893.6	767.2	613.9
Tangible Assets	111.5	119.5	134.5	194.5	208.5
Financial Assets	3.8	3.8	3.8	3.8	3.8
Net Fixed Assets	**977.4**	**901.1**	**1,031.9**	**965.5**	**826.2**
Severance pay and other funds	-11.3	-12.6	-25.3	-20.6	-12.6
Total Capital Employed	**1,516.3**	**1,148.8**	**1,572.9**	**1,600.6**	**1,849.9**
Shareholders' Equity	**1,559.3**	**5,761.4**	**7,115.7**	**8,354.8**	**10,368.4**
NFP [i.e. Net Debt (-) Cash (+)]	**43.0**	**4,612.6**	**5,542.8**	**6,754.2**	**8,518.6**

Source: Ulisse BioMed SpA, Value Track Analysis

Ulisse BioMed: Cash Flow Statement 2020A-2024E

€	2020A	2021E	2022E	2023E	2024E
EBITDA	**275.1**	**339.6**	**1,716.9**	**1,810.6**	**3,015.4**
Change in Working Capital	-726.6	289.9	-306.1	-89.3	-380.5
Capex (incl.R&D cost capit.)	-106.9	-195.0	-460.0	-425.0	-225.0
Change in Provisions & TFR	-94.0	1.3	12.8	-4.8	-8.0
OpFCF b.t.	**-652.4**	**435.9**	**963.5**	**1,291.5**	**2,401.8**
Cash Taxes	-2.3	-16.5	-56.4	-107.8	-671.2
Capital Injection	0.0	4,150.0	0.0	0.0	0.0
Other Op. Items	-71.4	0.0	0.0	0.0	0.0
CF available to serve debt/equity	**-733.2**	**4,569.4**	**907.1**	**1,183.7**	**1,730.6**
Financial Income (Expense)	-0.1	0.2	23.1	27.7	33.8
Net Cash generated (absorbed)	**-733.2**	**4,569.6**	**930.1**	**1,211.4**	**1,764.3**

Source: Ulisse BioMed SpA, Value Track Analysis

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