Grant Agreement no: 829157

TopSpec

Project Deliverable Report

D8.6 TopSpec Exploitation Plan and Business Strategy

Version: 1.0

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Contributors: -

Internal reviewers: -

Deliverable due date: 2022-12-31

Actual submission date:

Work package: WP8

Task: T8.3, T8.7

Dissemination level: Confidential (CO)*

Lead beneficiary: MS

Status: Final

VERSION AND CONTROLS

Version	Date	Reason	Editor/ Author/ Reviewer
1.0	13 Dec 2022	First release	Jan Commandeur

Acknowledgement:

The research leading to these results has received funding from the European Union's Horizon 2020 research programme under grant agreement No. 829157

* This Deliverable is Confidential (CO) and subject to Section 10 of the TopSpec Project Grant Agreement

EXECUTIVE SUMMARY

This document provides an Exploitation Plan and Business Strategy for the TopSpec project, funded by the European Commission under Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020), Grant Agreement number: 829157

TopSpec is a project that started in January 2019. Its aim was to develop a ground-breaking TOP-down tandem mass SPECtrometry (MS/MS) platform to solve the challenge of unraveling the sequence repertoire of human antibodies and their respective antigens.

The TopSpec consortium comprises eight participants from seven countries that bring together a mix of stakeholder organisations and corresponding expertise. The participants include instrument manufacturers, technology SME's, universities, and research institutes.

In this document, which is a Deliverable in WP8 titled 'Dissemination, Communication & Exploitation', the Exploitation Plan and Business Strategy for the results of the TopSpec project is outlined.

CONTENTS

1 Background

TopSpec is a project that started in January 2019. A major and growing challenge in the EU health system is the cost of drugs and targeted therapies. Reducing time taken to develop novel therapies will reduce costs to the health system. To address this grand challenge, it is imperative to better understand how the human organism defends itself against diseases. The biggest mystery is the human immune system; and, understanding this ultimately requires knowledge of the sequence repertoire of human antibodies and their respective antigens.

The purpose of the TopSpec project is to be the first in the world aiming to solve this challenge, opening up opportunities in medical research and drug development that are today only dreamt about. We will create a breakthrough technology that will revolutionize academic, clinical and industrial proteomics and dramatically advance the development of new generation antibody- and protein-based therapeutics.

This complex and ambitious project brings together eight participants from seven countries and funded by the European Commission under Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020), Grant Agreement number: 829157.

This document outlines the exploitation plan and business strategy for the results of the project.

2 Introduction

The objective of the TopSpec project is to develop a ground-breaking top-down tandem mass spectrometry platform to solve the challenge of unravelling the sequence repertoire of human antibodies and their respective antigens. Thus, the activities within the project require tools to be developed by the participants and integrate these into a comprehensive and customised platform. TopSpec will greatly expand our knowledge of the human immune system, which may have a dramatic impact on the field of personalized, precision medicine. TopSpec may facilitate the development of new diagnostics and treatments for infectious diseases including global diseases and the problem of treatment resistance, ageing related diseases (e.g., AD) and other big killer diseases. Another significant impact will be in the field of MS instrument design. Specific impacts:

- Increase in the speed of diagnosis and in the speed of drug development
- Increase knowledge on an individual´s antibody response to disease
- Contribute to the growth and expansion of 4 European SMEs
- Expand scientific research around proteomics
- Create new business opportunities within and outside the project

The eight partners that make up the TopSpec consortium include instrument manufacturers, technology SME's, universities and research institutes. Their details and roles can be found in the table below.

Partner	Type	Primary role	Short name
Karolinska Institutet	Institute	Application development	KI
Fasmatech	SME	Hardware development	FASM
Thermo Fisher Scientific	Corporation	Hardware development	TF
Spectroswiss	SME	Hardware development	SPS
BioMotif	SME	Hardware development	BM
Nottingham Trent University	University	Software development	NTU

Institut Pasteur	Institute	Application development	IP
MS Vision	SME	Exploitation	MS

Expected results from the TopSpec project, as specified in the project proposal, were summarized as follows:

Expected Result	Target Industry	Use within the project	Use outside the project
Novel MS/MS platform	MS instrumentation	Adopted by TF	Adopted by other MS manufacturers
Top-down Ab sequencing assay	Biotechnology, Clinical diagnostics	Proof of principle, biomarkers of AD and bacterial infection	Quality control in mAb production, biosimilars and biobetters, clinical diagnostics
Library of Ab repertoire as immune system response to challenge	Immunology, Bioinformatics	Proof of principle	Large EU projects to collect Ab sequence libraries for specific diseases
Top-down data analysis software	Analytical, biotechnology, pharmaceutical	Proof of principle	Open source and commercial versions for industrial and academic analytical scientists
Novel data acquisition and realtime data processing system	MS instrumentation	Adopted by Spectroswiss	Adopted by other MS manufacturers, including TF

The novel MS/MS platform developed in the project consists of a combination of the Fasmatech Omnitrap™ platform and two different Thermo Scientific™ Orbitrap™ instruments, a Q Exactive™ HF and an Exploris™ 480 mass spectrometer. This platform in particular has seen considerable maturation during the course of the project and it has attracted quite some attention in the structural biochemistry community. The novel data acquisition and realtime data processing system also showed significant development, along with top-down data analysis software. The project partners are keen to bring all these technologies to the market. This can be as a complete LC-MS platform for antibody sequencing including hardware, software and consumables. However possibilities to further commercialize parts of the developed technology are certainly present, making these available to a much wider field of application thereby vastly increasing the market potential. With this in mind, in the following sections business development considerations for the individual technologies will be addressed.

3 Omnitrap

The Omnitrap in its current form is the culmination of eight years of development at FT, and based on the results of the TopSpec project is has now reached Technology Readiness Level (TRL) 4 to 5, a laboratory-scale instrument validated in a relevant environment. Efforts are now being made to take the Omnitrap to TRL 6, pilot scale production, with technology demonstrated in customer site. The key requirements for this process have been identified, and these can be classified as follows:

- generation of a TRL6 instrument
- establishment of a scalable development infrastructure to improve manufacturability and quality of the product

- creation of an extended service, marketing and sales network supported by technical documentation and certified procedures

All aspects related to the activities necessary to achieve these requirements will be addressed in the next paragraphs.

3.1 Research activities

These efforts will be limited in scope and focus on tuning the energy of the hydrogen activation source, the first of its kind in the field of MS. Efforts will also focus on testing the electron source at a higher kinetic energy (~1 keV) to explore meta-ionization effects where fragmentation is suppressed and radical ion formation is enhanced. The ability to generate super-radical ions will offer yet another unique analytical feature. Optimization of the VUV diffuse light source will also be undertaken to minimize background ions. These techniques, additional to the basic version of the Omnitrap platform, will extend the ion processing network considerably and establish its superior versatility. All additional techniques have been already partially validated in experiments with intact monoclonal antibodies (mAbs) and will be tested further to maximize sequence coverage. A patent application has been filed for the hydrogen source (see section 3.10) and several publications are being prepared to promote the Omnitrap. Since these research activities are associated with additional functionality they have no impact on the performance of the basic version of the Omnitrap platforms thus carry no considerable risks.

3.2 Technology development

Advances in software follow two directions. The number of options available in designing analytical workflows is exceptionally high but increasingly complex as new methods are integrated in the fragmentation toolbox. New control software is therefore necessary to support such advanced workflows through a friendly graphical user interface (GUI). An extended library of optimized workflows will be created, tailored to specific applications. The second direction is the development of a new de novo sequencing algorithm to process highly congested top-down spectra. Current state-of-the-art de novo algorithms are limited to bottom-up and the few attempts to process top-down spectra are severely hampered by deconvolution algorithms introducing errors. The extensive data processing performed in TopSpec has generated essential information that can be exploited for the comprehensive evaluation of a de novo algorithm. A new de novo sequencing tool is a very significant competitive advantage over state-of-the-art platforms supported by other software suites, particularly when the algorithm is extended to other classes of biologically relevant molecules. Functional data analysis software is an important requirement for market uptake of the Omnitrap platform, and considerable efforts have already gone into this. A new patent application is currently being prepared to protect the algorithm architecture.

Other technological advancements will be concerned with the optimization of ExD by the superposition of magnetic fields to increase speed and instrument robustness. The Omnitrap platform is currently the only analytical system where EID can be performed with high efficiency on chromatographic time scales and the number of applications based on this re-discovered method is expected to grow very fast, particularly for low charge state ions where collisional activation produces limited information and UVPD is not broadly adopted. A new RF generator will be developed to improve the resolution of isolation in MSn, improving the analysis of intact mAbs further. None of the aforementioned activities related to ExD/RF developments pose real risks for successful commercialization and they are associated additional functionality.

DDA workflows will also be developed using the application programming interface (API), enabling real time decision making on both ends of the hybrid MS platform. Calibration/troubleshooting procedures will be automated improving instrument operation. A new transmission mode will be developed where ions are accumulated directly in the Omnitrap platform to maximize space charge capacity for selected charge states in the higher m/z range, like mAbs and antibody-drug conjugates (ADCs), and support the development of high-potential applications with strong marketing opportunities.

3.3 Validation activities

On-going validation activities for authenticating the unique features of the technology are focused on the analysis of standard protein digests (BSA & HeLa) used extensively in proteomics labs to benchmark instrument performance. Results will be compared to those produced by high-end commercial platforms available within the consortium and white papers generated to highlight enhanced sequence coverage and the increased number of protein identifications. To make these comparisons unequivocally robust and widely accepted, standardized software solutions (Proteome Discoverer) will be used for automated data analysis. A peer reviewed open-access article will be published summarizing these efforts. Validation activities will be further extended to high-potential applications with intact mAbs, ADCs and 4th generation biopharmaceuticals (protein/RNA drugs). Enhanced sequence coverage and number of proteins identified will be demonstrated compared to other analytical platforms available at partner's sites (IP, KI). Validation activities will be supported by new developments in s/w that extend the depth of the analysis provided by standard software (Proteome Discoverer) to highlight the new level of information produced. For example, on-going activities already show that EID is performing better in terms of sequence coverage at peptide level compared to HCD /EThcD, the two most widely used fragmentation methods available on high-end platforms. As the vast majority of potential Omnitrap platform users are currently using comparable well-established and validated methods, these activities are pivotal for market acceptance.

3.4 Applications development

Another important activity in the maturation of the product is the development of Omnitrap applications. With the installation of the two TopSpec systems, partners IP and KI are fully equipped to harness the unique capabilities of the technology. IP will focus on intact mAbs/proteins (top-down), while KI will deploy ExD to peptides (bottom-up) and glycans. The wide range of samples to be investigated will lead to a series of high-profile publications raising the interest of the scientific community and validating the technology in different areas of MS-based bioanalytical research. New applications will be developed by FT. Tagworks is a European SME developing Herceptin-based radio-immunoconjugates for PET scanning applications in cancer diagnosis and therapy. Top-down characterization of these agents will provide unique insights into the development process and quality control by identifying the degree, the efficiency and position of conjugation.These experiments are ideally suited considering that Herceptin has been analyzed extensively by top-down MSn. The rationale behind choosing such a diverse range of samples to validate and promote the Omnitrap platform as a cutting edge tool is to enable a dynamic marketing strategy to be adopted and eliminate the risk associated with focusing on a single niche application. This approach will secure different routes to market and protect the future of the technology.

3.5 Marketing & sales strategy

The strategic goal is to inform future customers via communicating excellent science and practical solutions to analytical challenges through an extensive range of dissemination activities (articles, workshops,

conferences, tradeshows, marketing activities and customer visits), while providing ample access to the technology (application- and demolabs).

A number of articles has been pusblished in peer-reveiwed scientific journals, and further publications are in preparation. During the TopSpec project, a workshop with 200 participants featuring the Omnitrap platform was organized in Madeira. The Omnitrap platform has been promoted to the scientific community at the two major mass spectrometry conferences of 2022, ASMS (June 5-9, Minneapolis, US) and IMSC (August 27 – September 2, Maastricht, the Netherlands). FT and MV will continue to do so at mass spectrometry and proteomics related conferences and congresses. MV and partner ZefSci have included the Omnitrap platfrom to their product portfolios on their respective websites, and they execute marketing campaigns amongst their customer base.

A first demolab will be established at FT in Athens, Greece offering access to the latest Omnitrap version and to all newly developed fragmentation tools as the technology evolves. FT will deliver an Omnitrap to MV, where a second demolab will be established in Almere, the Netherlands. This new facility will also support field activities undertaken by MV engineers. The TopSpec systems at partners KI and IP will break new grounds in bottom-up and top-down proteomics, while providing essential feedback to FT for future developments. KI and IP will also provide controlled access to the technology where leading scientists from academia and biopharma will have the opportunity to analyze different classes of molecules, a critical step for growing a solid customer base. The advanced Omnitrap-based R&D facility in Athens will be further expanded with the latest Orbitrap Exploris 480 MS platform delivered by TF and all three platforms will be upgraded to TRL6. Continuous improvement of instrument control software by TF scientists will further work towards increasing TRL level of the whole instrument. The establishment of four active sites across the EU is essential for offering the necessary access to the technology while also supporting validation/applications and marketing activities.

Agreements for the Sales, Marketing and Support of the Omintrap platform have been signed between FT and MS for the European market, and with MV's partner ZefSci for North America. ZefSci is a well-established independent provider of MS support, active in the US, Canada and India.

All sales, marketing and support procedures will be incorporated in the existing ISO9001:2015 quality system of MV. Sales and marketing activities will be performed by MV's highly qualified sales force, which includes four sales people with scientific background and many years of experience in sales/marketing of analytical MS equipment. Sales and marketing in North America will be undertaken by ZefSci. MV already supports a large number of Orbitrap-based laboratories, which will be exploited via distribution of targeted white papers and application notes combined with direct communication activities. An example of how a potential customer database can be updated is a recent study published by the Consortium of Top-Down Proteomics (DOI: 10.1021/jasms.0c00036) co-authored by 60 researchers representing 19 top universities and 7 industrial companies in the field of mAb structural analysis, all being prime targets for collaboration and sales. Incorporating their insights in further development will help mitigate commercialization risks. Sales performance will be monitored and compared to forecasts and projections in order to ensure that remedial actions can be taken should sales do fall behind.

3.6 Infrastructure

In order to develop the Omnitrap platform to a pre-production beta device (TRL6) that can undergo all validation tests necessary for regulatory purposes, including all the end-of-development intellectual property

rights (IPR) filings, FT will recruit dedicated staff and create a scalable production environment. Operational improvements include the establishment of IT infrastructure to document/control all company activities, including a product lifecycle management (PLM) platform focused on quality control, risk-change management and post-market surveillance as well as an enterprise resource management (ERP) platform for the control of production activities of the TRL6 version. The focus will be on optimization of electromechanical assemblies for ease of manufacture and assembly, testing and servicing while also improving quality and communication protocols with key subcontractors. FT will expand its supplier network to increase the percentage of sub-assemblies manufactured and tested in specialist suppliers (electronics) and also improve prices of key OEM components based on upscaling of volume. Knowledge transfer from R&D to production will be enhanced through documentation to support manufacturing. Efficient warehousing, assembly and testing tools/methods will be established. FT and MV have extensive experience in operational aspects for the manufacturing, distribution and support of complex analytical instruments in the global market. The FT team shall seek advice from specialist consultants to adapt company practices to the latest ISO9001/ISO13485 standards. The chosen PLM system will be connected to the existing mechanical/electronic bill of material (BOM) management infrastructure (Solidworks, Altium) to provide design version control and change management. The device will also undergo all tests necessary for CE-marking. FT is in contact with a certified laboratory (www.labor.gr) for CE marking and several units are already being redesigned to pass electrical safety/emission tests. The infrastructural changes proposed will allow controlling critical aspects in the manufacturing process and minimize technological and innovation uncertainties related to performance and robustness of the product. Regulatory hurdles will be overcome by hiring experienced personnel to support the infrastructural transformation of FT and accreditation activities.

In parallel, MV will set up a new infrastructure, addressing all aspects of efficient technical and application support. An application chemist will be employed to manage the demolab at MV. Collating relevant information from the partners, MV will write support documentation (user manuals, maintenance procedures). For field service engineers (FSE's), documentation for installation, maintenance and troubleshooting is currently generated covering both Q Exactive and Exploris platforms as several installations have been performed with more scheduled. Benchmark tests are currently used to monitor instrument performance to establish the optimal frequency of regular maintenance and these will be turned into technical specification documents. Training activities between FT and MV are already taking place to enable FSE's to support the technology. MV will share extensive knowledge in serviceability of high-end MS instrumentation. Statistics on the use of spare parts will be generated to establish minimum stock levels and spare part classification into consumables, field replacement units and engineering items.

3.7 Cooperative synergies

The methodology to support the tech-to-market plan is reflected in the structure shown in Figure 1, highlighting the specific role of the TopSpec partners involved and also in Figure 2 showing the SWOT analysis map for assessing key aspects of the business plan. FT will translate the Omnitrap platform from an advanced prototype device to a beta pre-production level instrument. The transition requires activities across the board involving reduced scale R&D and more comprehensive technology development activities to standardize procedures and facilitate productization, service and support. Partner MV, with ZefSci will be responsible for field support, marketing and sales. MV has extensive knowledge in analytical instrumentation and ideally suited for supporting the technology in the field through its extended service and sales network in Europe and in the US, capitalizing on accumulated experience with Orbitrap MS systems.

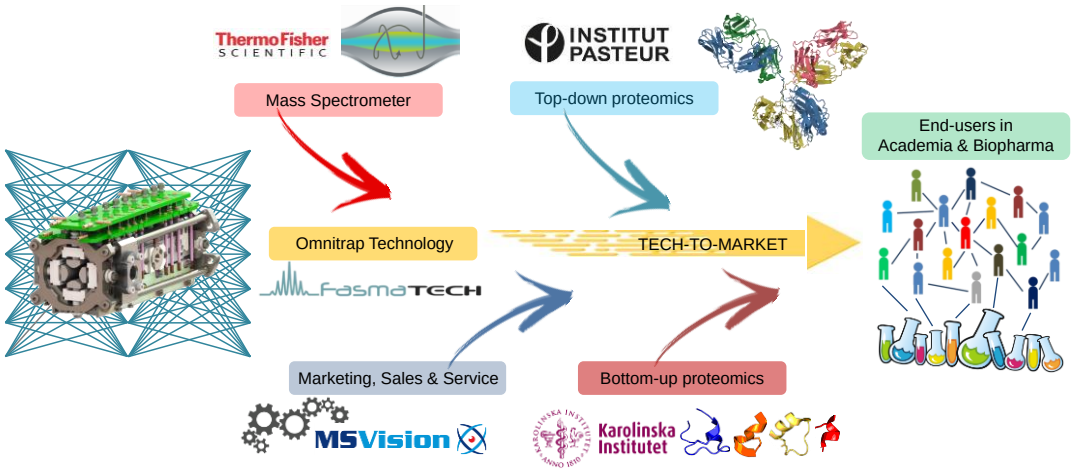

Figure 1. Structure and TopSpec partner roles for commercializing the Omnitrap platform and popularizing the technology in the wider scientific community.

TF is dedicated to provide access to different MS platforms (Q Exactive/Exploris instruments) to connect the Omnitrap technology. This is a highly advantageous route to market for the Omnitrap platform, due in part to the extreme performance of the Orbitrap mass analyzer and also in part to the remarkable enhancements in the ion processing capabilities of this new hybrid analytical instrument creating a highly dynamic product. Two application sites will be established (IP, KI) where potential customers will access the technology, supporting marketing activities through the generation of high-quality information for publications and promotional material and the establishment of a dynamic customer base. IP and KI are top ranking research centers in Europe in the field of life sciences and highly credible sites to develop top-down and bottom-up applications to validate the technology. Both IP and KI will be active sites for promoting the technology through their extensive collaboration networks and access to unique samples, as well as by demonstrating the technology to potential customers. For example, being part of the European proteomics infrastructure EPIC-XS, IP already provides transnational access (TNA) to external users.

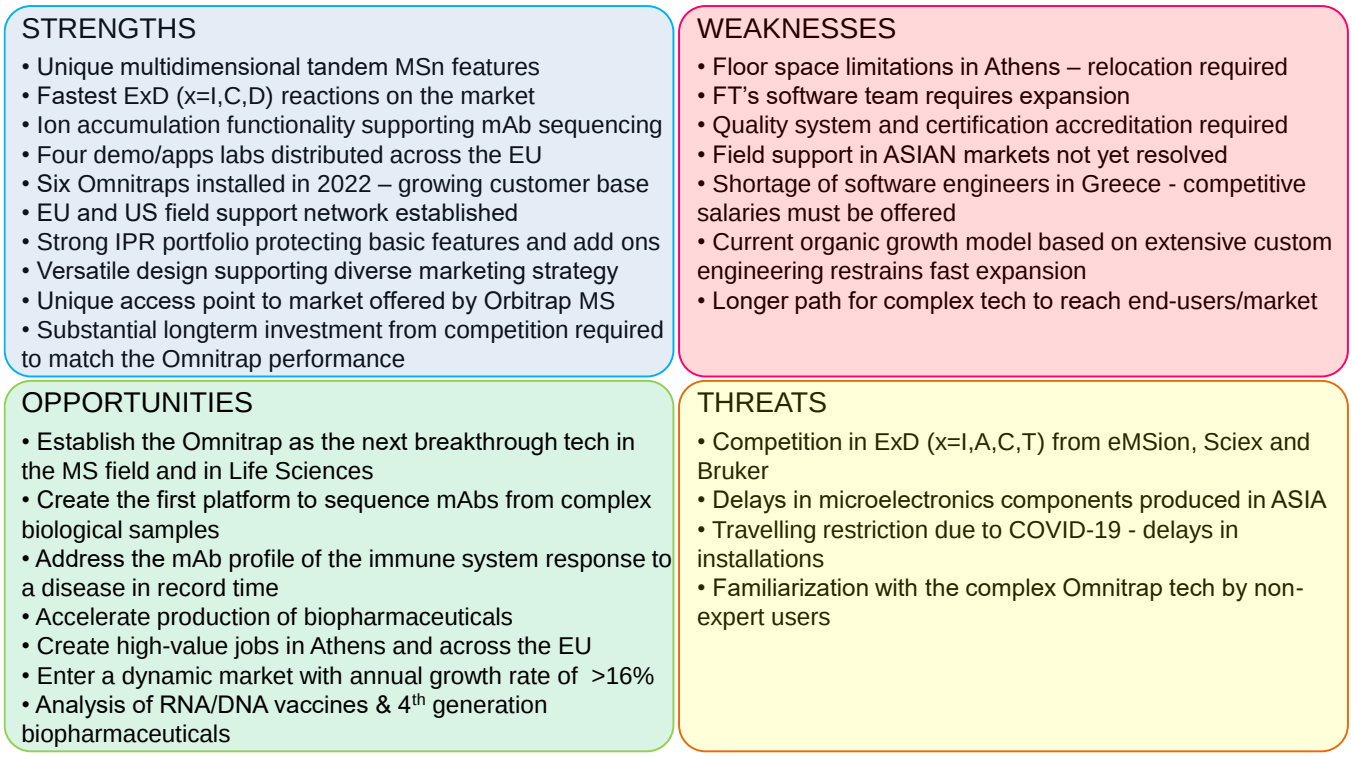

Figure 2. SWOT analysis of the plan for the business development model of the Omnitrap product

3.8 Market potential, positioning and competition

The global proteomics market was estimated at $25.9 billion in 2021 and will grow at a rate (CAGR) of 16.6% to 55.9 billion in 2026 (Markets and Markets Proteomics Market Report). The COVID-19 pandemic has negatively affected the expected growth, however the medium-to-long term growth is expected to stabilise or accelerate, as the pandemic emphasised the importance of protein and DNA research to governments and the public. Other macroscopic market drivers include increased healthcare investment, advancement of personalised medicine and rising investment in R&D. The pharma industry accounts for the highest share of the proteomics market, however innovative applications mature in the academic and small biotech segments first, which is the main target of the Omnitrap product in this starting phase of market development. Europe has high share of the geographical market segmentation, with some of the pioneers in the field, however North America is the largest segment. The current addressable market of MS-based proteomics is ~1 B$ which corresponds to ~2000 MS units/yr. According to industry portal Biotech Gate, there are more than 7,000 biotech companies with therapeutics and diagnostics focus and another 9,000+ providing R&D services. mAbs are a key technology across the industry, with most large pharma companies having mAb products in the market or in their pipeline. The unique competences of Omnitrap platform for the analysis of Abs can play a pivotal role in the advancement of this field. We expect that the primary demand for the Omnitrap platform will be shown by Research departments of these companies, especially for analytes deviating from the simplest mAb pattern, such as antibody-drug conjugates, bi-specific antibodies, polyclonals, etc.

The primary market for the Omnitrap platform will be created by advancing the technology in the top-down proteomics arena. There are more than 10,000 Orbitrap MS systems operating globally, with an annual growth of 10-12% and a significant amount of users (~500 of so-called "early-adopters") will be interested to upgrade

their instruments and access novel top-down workflows. There are 500+ industrial research institutions worldwide active in the field of mAb development and a similar number of academic groups. All the above are prime targets for employing the upgrade path branch of the business model. The size of the market in bottom-up proteomics and the analysis of small molecules by EID, a unique feature of the Omnitrap technology, is considerably larger compared to the top down community (~2,000 instrument sales/yr compared to ~200) and efforts in this direction will be undertaken by application developments in Stockholm (KI) and in Athens (FT) and through MV and their North American partner ZefSci by extending its marketing and sales activities in this area of research.

The business model for downstream exploitation of the technology includes direct sales to academic and industrial researchers supported by standard software (Proteome Discoverer) or use of open access tools (MaxQuant). Sales will be of two main types, (a) new devices with Exploris 480 units and (b) upgrades of existing Q Exactive instruments. Matrix options will also be available to configure the platform to specific customers' needs, from an entry level configuration with access to ExD and collisional activation, to a fully featured flagship platform with access to all possible fragmentation tools. Basic platforms will also create a significant marketing/business opportunity for providing upgrades to existing customers. For this business model to succeed the platform should be robust and maintain its reputation as a workhorse technology, thus it is essential to enhance FT's methodology as laid out in the section on infrastructure. The list price for the basic Omnitrap platform (~350k euro) will cover the installation fee, warranty, preventive maintenance during the first year, and offer a sales margin before internal overheads of ~50%. This is expected to increase to ~65% when sales exceed the 10 instrument/yr threshold. Add-on functionalities will be made available and will include the hydrogen-based dissociation source, a new VUV diffuse light source and an ion mobility drift cell. The different add-ons will be offered at high price, emphasizing their uniqueness and exceptional performance. Considering the two direct sales in the US in 2022, a reasonable target is to achieve a total number of ~10 units/year in direct sales within the next three years, creating an annual revenue of >3.5M euros with a gross profit margin higher than 60% for partners FT and MV. The proposed pricing of the Exploris/Omnitrap hybrid positions it well below comparable universal instruments like the Orbitrap Eclipse and the most recent Ascend, while offering a much wider and more versatile arsenal of fragmentation methods. This perfectly fits with the focus market of "early adopters", targeted by the proposed business model.

Specifically for the analysis of mAbs, multidimensional multiple-stage capabilities can be found only on Thermo Scientific Tribrid™ instruments, albeit, the efficiency on these state-of-the-art commercially available systems is lower, while the advanced ion accumulation functionality available only in the Omnitrap technology. In addition, the wide energy range in ion electron interactions and the additional ion activation methods with reagent ions and radical atoms distinguish the Omnitrap technology from the Tribids, reducing commercialization risk considerably. Furthermore, while the Tribrid family of systems are pushing for automation and are largely dedicated to high throughput, the Omnitrap is unique in providing in-depth characterization of proteins/polynucleotides with an entirely novel set of ion activation methods incorporated in each step of a tandem MSn process. Experiments similar to the MS3/MS4 workflows reported in TopSpec have not been reported on any other MS platform due to limitations in the number of ions available at MS2 level. In addition, EID is highly suited to the analysis of singly charged molecules where ETD/PTR available on Tribrids is not applicable. Differences between ultraviolet photodissociation (UVPD) in Tribrid systems, for the determination of double bonds in lipids, and the Omnitrap VUV light source are yet to be explored. There is a significant degree of complementarity between the Omnitrap and the Tribrids, which eliminates any

commercialization risks associated with TF maintaining such a unique access point to market for the Omnitrap platform, since TF will extend the capabilities of Orbitrap-based MS technology offered to its customer base.

The eMSion ExD cell currently available on a wide range of analytical platforms (Agilent, Waters, Thermo Fisher) and EAD (Sciex) are competitive technologies, however, the enhanced efficiency/speed of fragmentation combined with a unique set of multi-dimensional MSn workflows establish the superior performance and universality of the Omnitrap platform while reduce the risk for successful commercialization of the technology considerably. Additional commercialization risks are further moderated by the ultra-high resolution of the Orbitrap providing the highest quality mass spectra, supported further by the fact that partner TF holds ~65% of the proteomics market share and provides the best possible customer base to promote the technology.

3.9 Investment readiness

FT and MV have successful track record in high level executive commercial positions in global MS manufacturing companies (Waters, Shimadzu) and have experience in managing global operations with multi-million EUR annual revenue. FT is an entrepreneur-led highly innovative company with a strong track record of scientific and technical excellence, proven by its loyal and expanding customer base as well as its distinguished participation to several EU-sponsored projects. The company, having achieved the up-to-date growth with minimal equity dilution (81% is founder/employee owned), has been focusing on high-end, complex custom engineering solutions that require the full attention of its highly skilled R&D team, limiting the scope for rapid growth through the development of product lines. The strategic choice is to transition from custom engineering instrumentation to a high-end product reflecting the unique competences of the team, which are supported by a comprehensive IPR portfolio created around the Omnitrap technology.

MV was founded in 2004 and has established an extensive network of customers and prospects in this market. The company's founder and current CEO was one of the investors in Micromass, and contributed to its establishment and to its acquisition by Waters Inc. MV has been growing steadily organically, and by financing its operation by cashflow only it is still 100% founder/employee owned. The company is very experienced in marketing and in field support of MS instrumentation and has an excellent reputation in instrument modifications for high mass applications, now looking for new tech to sell and support, with a highly motivated team of product sales specialists and senior support engineers. MV is ready for growth and also to expand into the north American market in collaboration with Zefsci. The Omnitrap platform is a high margin proprietary product that would fit seamlessly with MV's strategy. The potential of the Omnitrap upgrade for the Q Exactive series is especially interesting since MV has been offering similar aftermarket technology upgrades for 15 years already, and has found that selling such hardware provides a very healthy margin. Overall, the team has members with proven experience in global business and distribution channel development and management for high-value complex analytical instruments.

By raising funds through the completion of an extended range of custom engineering projects, FT is a unique example of an SME arriving to a beyond-the-state-of-the-art technology organically, without external investment. The opportunity to grow further through participation in FET projects (TopSpec, ARIADNE) has had a tremendous impact on the TRL and potential of the technology, and an EIC Transition proposal (AURORA) has been submitted with the aim to bring the Omnitrap platform to TRL6. The AURORA consortium consists of FT, TF, MS, IP and KI, the TopSpec partners that are pivotal in bringing the Omnitrap product forward. The development plans, outlined both here and in the AURORA proposal highlight the increased level of maturation of the entrepreneurial team that was necessary to bring the Omnitrap platform to this level

of performance and simultaneously create unique marketing opportunities by offering the technology as an add-on to high-end platforms of at least one major MS manufacturer. FT has elected a new Board of Directors (BoD) in Q1 2022 including two investment professionals to support the productization activities by raising additional capital (www.bloomberg.com/profile/person/22098667) and securing the route to market.

Building on its excellent R&D and innovation track record, FT will seek additional external funding (first round investment) to support the upscaling operations. This will allow the organization to increase the number of dedicated personnel/manager for productization, relocate at a new facility to improve internal processes to meet the increasing demand for the Omnitrap technology, while maintaining a smooth-running operation without risking its cash flow position. The combination of a highly innovative technology platform, an excellent product/market fit, the high potential of the total accessible market and the scale-up preparations secured by the appropriate first round investment activities will make FT an ideal investment opportunity to finance the next growth phase (second round investment). The addition of investment professionals to FT's team will bring the necessary fresh look in supporting scale-up activities through external investment, particularly during the current transition phase where Omnitrap installations are planned and new orders are being received. To this end, FT is already in discussions with "Benchmark International" for evaluating the company in order to attract an array of suitable offers from prospects that understand the qualities and nuances of the Omnitrap tech & business and have the necessary resources to support growth.

Sales and collaboration agreements: TF is committed by a "letter of intent" signed by the Vice-President and General Manager of the Life Sciences MS business unit to support the Omnitrap product development strategy granting licenses to FT on a royalty-free basis. Access will be provided to the latest instruments (Exploris) through software upgrades that enable integration. No exclusivity or first-rights access terms are considered, terms highly in favor of FT. Integration with the Q Exactive instrument series will continue to be provided through TF's R&D group. Following the initial rollout of the Omnitrap product (TRL6), a deeper co-marketing and value-added resale relationship will be explored. In the unlikely case that such negotiations are not mutually satisfactory, the Omnitrap technology could be additionally expanded to other MS platforms. The Omnitrap platform has already been coupled successfully to TOF MS and new IPR is being generated to enable the coupling of the technology with other large MS manufacturers (Waters Corp), securing alternative routes to market. A separate agreement between FT and TF on the instrument application programming interface (IAPI) has been signed. These programming tools will support th Omnitrap-Orbitrap MS integration further. Additional collaboration agreements involve the use of Proteome Discoverer to analyze Omnitrap data and compare results with the more standard methods using Prosight PC and the Sequest search engine to support validation. An exploitation plan has been developed by partners FT and MV to promote the tech and a memorandum of understanding (MoU) has been executed, defining sales, marketing, warranty, service and support terms.

3.10 IPR management

The Omnitrap is a registered trademark in EU and in the US. A family of patents has been structured to protect the core technology in Europe, US, Canada and Japan (US10381214B2; US11114292B2; US9978578B2; EP3411897B1; EP3901985A4; CA3013117A1; JP2019505966A). A series of continuation/divisional applications have been defended successfully and the scope of the claims has been expanded. Such protective measures set insurmountable barriers to competitors for developing technology with similar performance. At the same time, several trade secrets of the design (electronics, mechanical and software) developed through years of intensive R&D secure the advanced character of the technology further. A second family of patents is being developed around the ion mobility device coupled to the Omnitrap (US10763097B2;

EP3570312A1) and a new patent application disclosing the design of the hydrogen atom-ion source was filed recently in Europe/UK. These different patent families create a vital working space in the extremely crowded MS IPR landscape to support the successful commercialization of key enabling ideas and solidify the business development model. A “Collaboration Agreement” between FT and TF is already in place defining “Background” and “Joint” inventions. The entire IPR portfolio for the basic Omnitrap platform including the add-on functionalities belongs exclusively to FT. Any joint inventions that may arise during the deeper integration of the technology with Orbitrap-MS will be owned jointly by FT and TF. No other partners are expected to contribute with IPR in this project, however, NDA agreements are already in place. Additional IPR that may arise from enhancements in ExD performance using static magnets, advances in RF technology, DDA methods and coupling of the Omnitrap platform to TOF will be owned exclusively by FT.

Overall, the IPR landscape is very tidy and cannot limit the market potential. FT’s impressive IPR portfolio is managed through two well established law firms with strong experience in physical sciences and mass spectrometry, namely Appleyard Lees based in the UK and the DP-IP group located in the US. Long-standing relationships have been established and both legal teams have deep knowledge of FTs patent portfolio producing cost-effective prosecution services and freedom-to-operate searches.

4 pI Trap

“Tandem high resolution pI Trap” has been registered as an international patent No. PCT/EP2021/064686.