

Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

2020 Annual Investors Update

In 2020 we focused on product development, team expansion and clinical publications. OncoHost successfully dealt with clinical and financial challenges imposed on us by the COVID-19 pandemic and reached significant milestones towards commercial launch in 2021. In addition to the professional achievements, the company closed a fast CLA round of approx. 1M USD and is in the process of first closing a round of approx. 5M USD.

Report highlights:

Product

- Minimal viable product version developed.
- PROphet® report developed and now tested with oncologists.
- Early Technology Review process with EXCITE international was initiated. As part of the process, a board of US and EU payors are developing our economic value proposition for payors.

Clinical operations

- 14 active clinical sites in Israel and the US are recruiting patients for our clinical trial. More to be opened soon (including leading sites like Mayo clinic, Rutgers cancer center, Fox Chase and others).
- Over 360 patients recruited to the PROphetic trial (NCT04056247). Patient samples analyzed in our lab and in the US lab.
- Clinical results of the platform in lung cancer and melanoma presented at the leading oncology meetings (ASCO, AACR, ESMO, ESMO-precision medicine, and SITC).

Awareness

- Publications in all leading conferences (ASCO, ESMO, AACR).
- 3 lectures given at professional meetings (SITC, ESMO-MAP and European lung cancer conference).
- We appeared in two TV segments i24 News and in over 15 popular outlets (such as Forbes, Scientific American, Yahoo finance and others).

IP

- IP status: 5 new provisional patents were filed, ONCO-008 entered national phase in Europe, Japan, Canada, Australia, Israel and China. In addition, we received four trademarks.

Team

- We hired a new head of bioinformatics and a new CTO. Both hold PhD's in mathematics and are experts in machine learning.
- We now have a world class scientific advisory board that includes US based key opinion leaders and a Nobel prize winner.

Funding

We successfully completed a CLA round of ~1M USD and are currently in the process of closing a B round of ~5M USD with significant oversubscription.

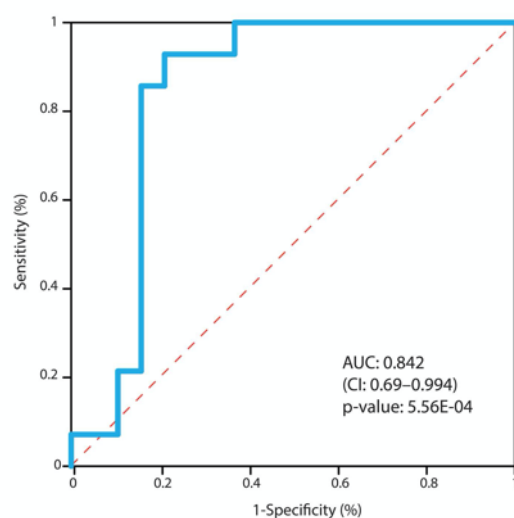


Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

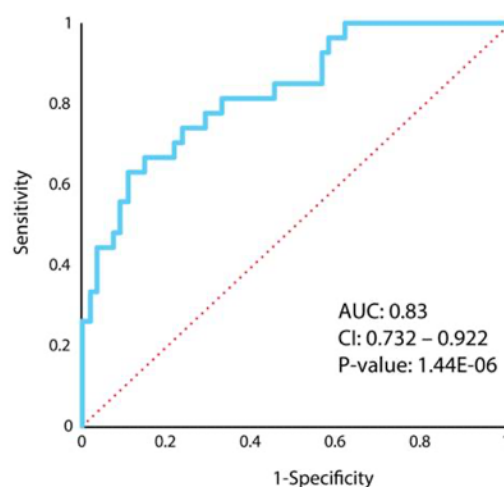
Product:

Our first commercial launch is planned for 2 indications: Lung cancer (NSCLC) and Melanoma. Current results from our clinical trials demonstrate excellent accuracy with an AUC (Area Under the curve) of over 0.8 for both lung cancer and melanoma (see fig 1).

Fig 1: ROC curves for NSCLC and Melanoma



Melanoma (Published at the ASCO 2020)



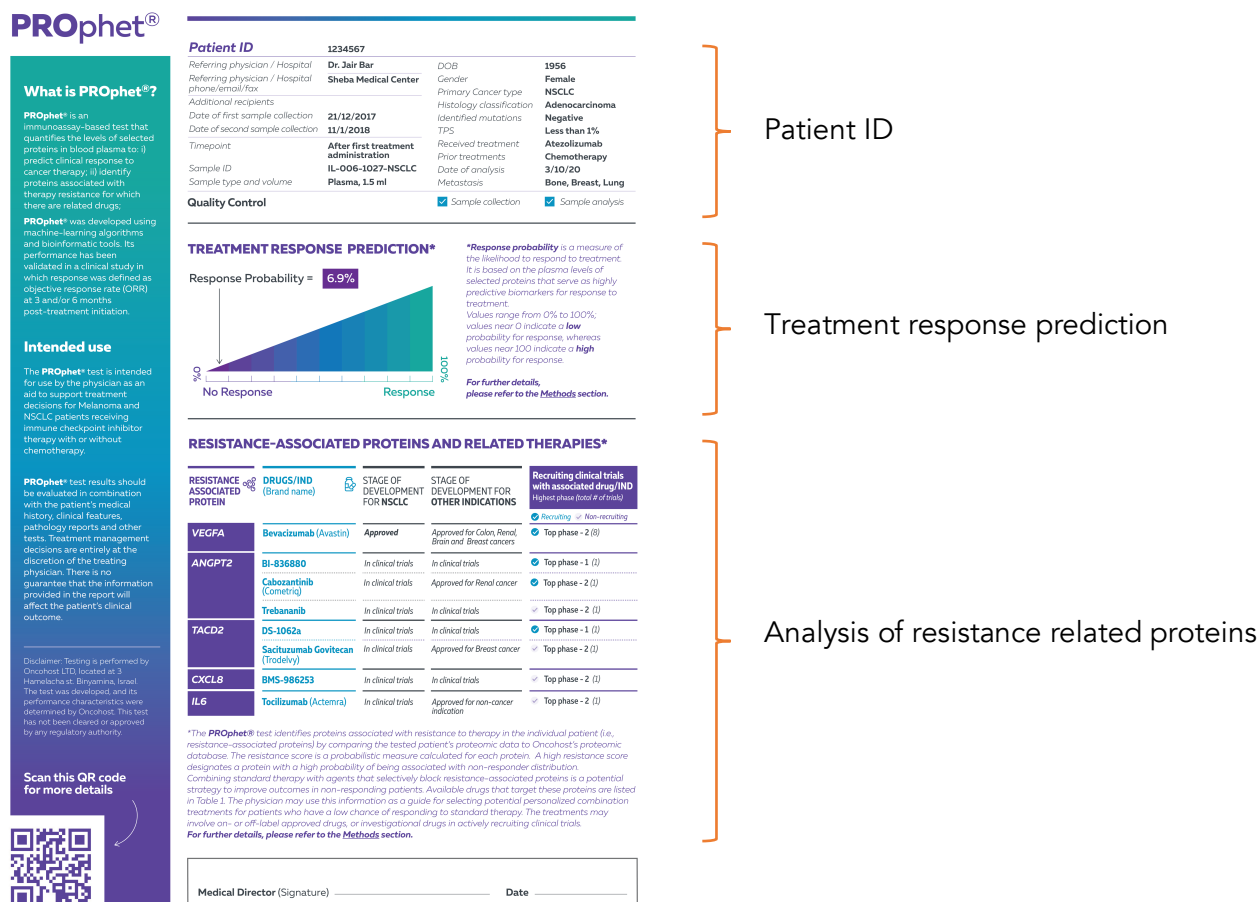
Lung Cancer (Published at the AACR 2020)

Further analyses yielded similar results and were published later in 2020. R&D is ongoing with a focus on further improving accuracy and performing additional clinical validation. We also further developed our PROphet[®] report. The full report will be a 15-20 page document including an executive summary page and all the necessary clinical information for the clinician. Please refer to fig. 2 for an example (real case study). The report is now being tested for clinical utility and value demonstration with oncologists and later this year with US based payors and patient advocacy groups.



Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

Fig 2: PROphet® report example



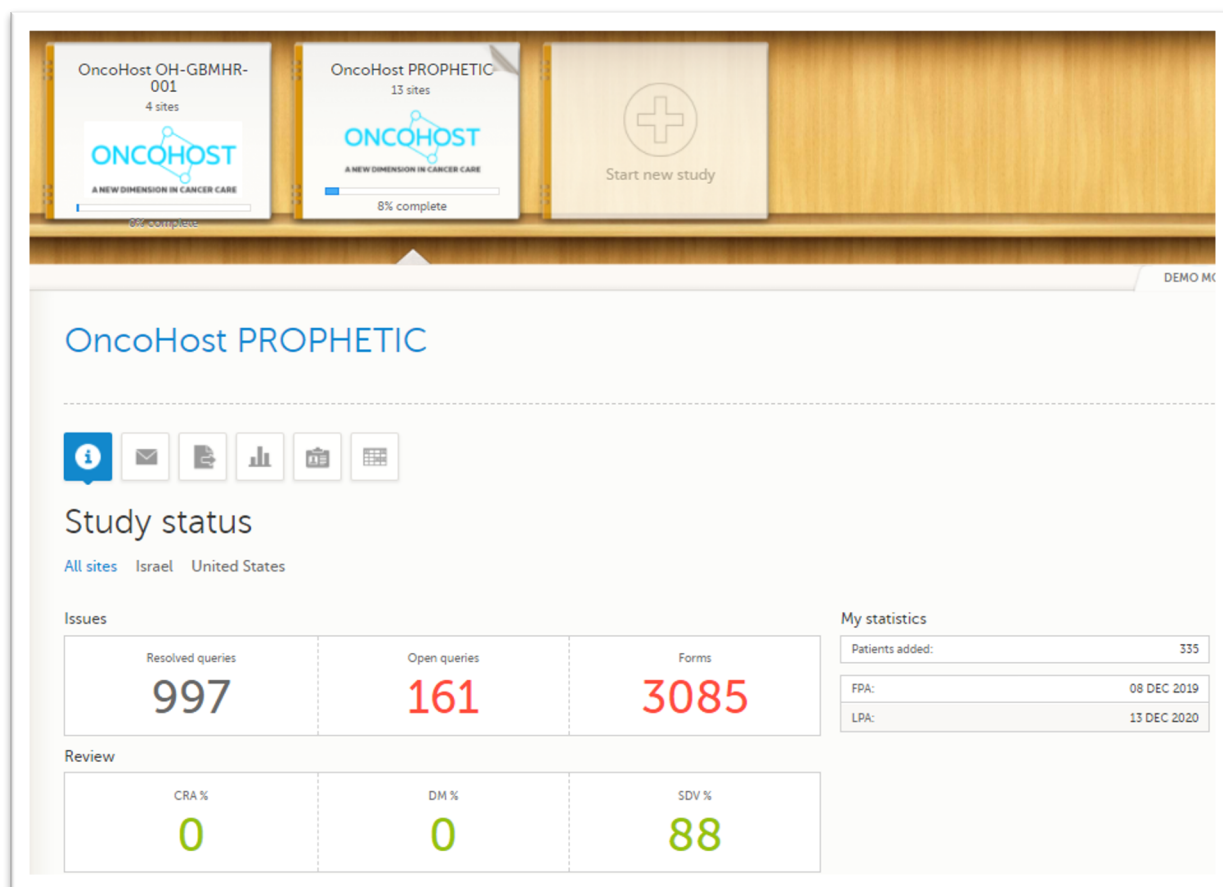
Clinical trial:

Clinical operations

We are currently running a prospective multi-center clinical trial ([NCT04056247](#)) with 13 sites in Israel and 3 centers in the US. We plan to open five more sites in the US as well as three sites in the UK. We use a cloud-based platform (see fig 4) to collect the data and run in-house monitoring and quality assurance for the trial. Currently our database contains data from ~350 patients and we plan to recruit ~400 more patients during 2021. The trial is testing our response prediction capability vs. the standard clinical practice (response assessment at 3, 6 and 9 months) as well as our ability to predict adverse events. Data are continuously analyzed in order to further improve the machine learning capabilities.

Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

Fig. 4: Cloud based data collection system for the PROphetic trial (screenshot)



IP:

OncoHost submitted 26 IP related applications covering US and ROW with 5 patent families:

1. Diagnostics of host response
2. Treatment based on host response
3. Algorithm for predicting response to therapy
4. Host signature for predicting response to therapy in non-small cell lung cancer patients
5. Specific molecules/proteins use patents



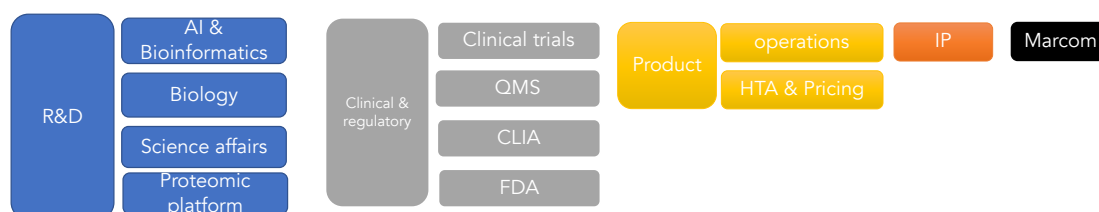
Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

Team:

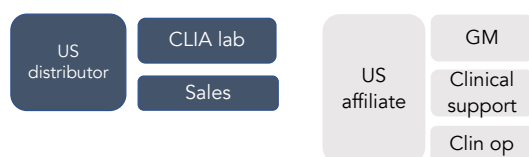
Two new team members were hired. Head of Bioinformatics – Dr. Itamar Sela, a returning scientist from the NIH with expertise in machine learning and bioinformatics of genomics. CTO- Dr. Yonatan Elon, an experienced manager of R&D teams developing artificial intelligence systems. Both are highly trained scientists with significant industry experience. See fig 5 for high level company structure:

Fig 5:

OncoHost 2020



OncoHost 2021 (US market entry)



Scientific advisory board (SAB):

We now have a SAB in full capacity with US and Israeli leading oncologists, KOLs in the relevant indications, world renowned biologists and pharma experts. Our newest members to the SAB are:

1. Prof Aaron Ciechanover- a Distinguished Research Professor in the Faculty of Medicine at the Technion – Israel Institute of Technology in Haifa, Israel. Among many accolades he was awarded are the 2000 Albert Lasker Prize for Basic Medical Research, the 2002 EMET Prize, the 2003 Israel Prize for Biological Research, and the **2004 Nobel Prize in Chemistry**. Among many academies, Ciechanover is member of the Israeli National Academy of Sciences and Humanities, the European Molecular Biology Organization (EMBO), the American Academy of Arts and Sciences (Foreign Fellow), the National Academies of Sciences (NAS) and Medicine (NAM) of the USA (Foreign Associate), the Pontifical Academy of Sciences at the Vatican, and the Chinese Academy of Sciences (CAS; Foreign Member)
2. Prof. David Carbone - David Carbone is Professor of Internal Medicine, Director of the James Thoracic Oncology Center at the OSUMC. He graduated summa cum laude from



Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

Amherst College in 1977 and received an MD and a PhD in Molecular Biology and Genetics at Johns Hopkins University in 1985. After an Internal Medicine internship and residency at The Johns Hopkins Hospital, he did a Medical Oncology fellowship at the National Cancer Institute in Bethesda, MD. His research interests have been focused on **lung cancer and specifically proteomic and expression signature development**, lung cancer genetics, tumor-associated immunosuppression mechanisms, proteogenomic profiling of lung cancers to guide the development of novel therapeutics and targeting novel immunosuppression mechanisms.

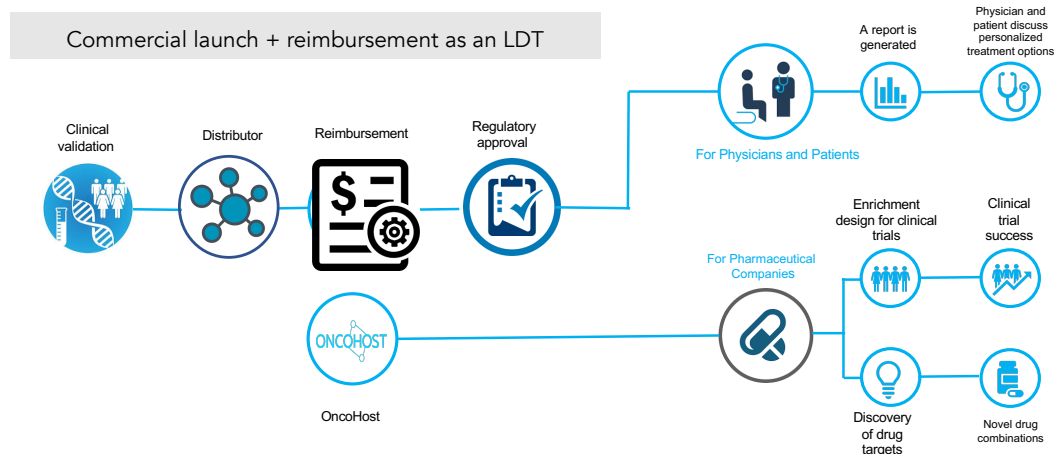
I am proud we were able to assemble a world class SAB to support our journey.

Go-to- Market:

We plan to launch our product for the first 2 indications in Q3 2021. We will follow the business model of Foundation One and Guardant 360, namely, sell via the laboratory developed test (LDT) pathway working with a US based distributor (Protean BioDiagnostics) that also owns a CLIA certified lab. OncoHost will manage the business development efforts with Pharma companies as illustrated in fig. 6. The Service workflow is depicted in fig. 7.

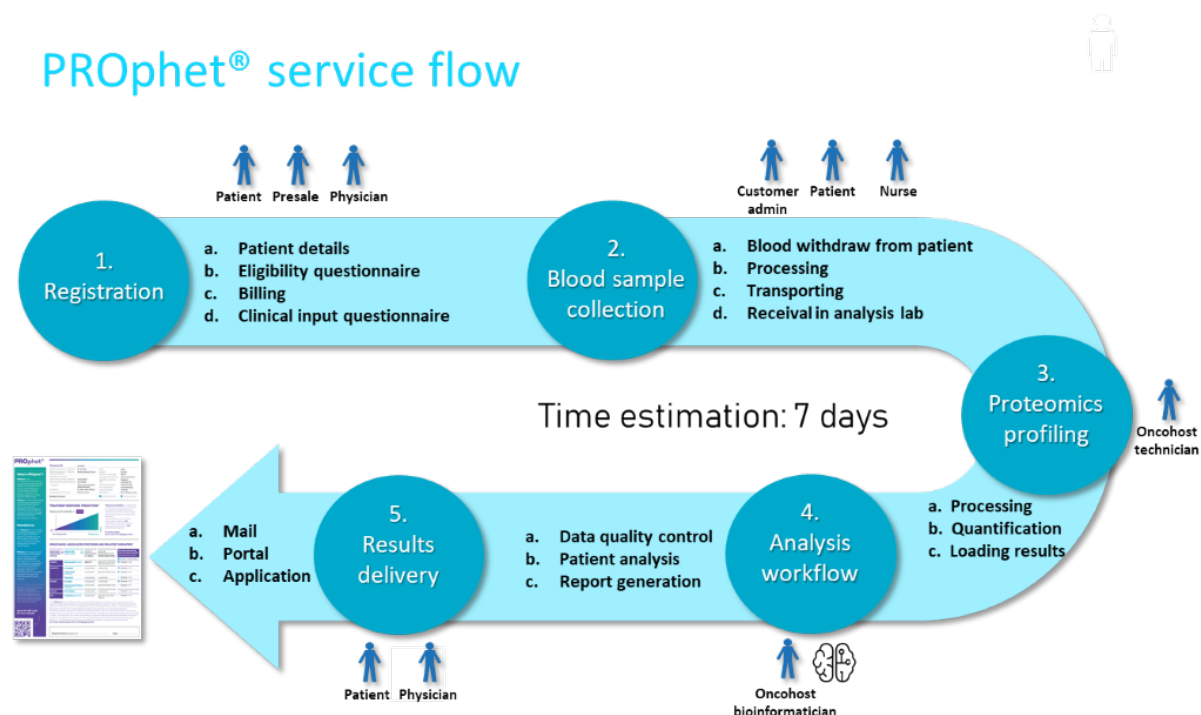
Fig 6:

Commercialization and Marketing Strategy



Delivering on the most pressing issue in oncology today, by leveraging cutting edge proteomic and AI-based host response science to improve cancer patients' outcomes

Fig 7: Service workflow



Summary:

2020 was a challenging year with delays in our clinical trials and financial issues imposed by COVID-19. I am happy to update that with a lot of hard work and commitment from the team and our collaborators we were able to overcome these obstacles. We managed to bridge the financial gap with a well-timed CLA round followed by an oversubscribed round B. We increased our head count with strong talents and are now ready to push forward on two fronts - Product with a planned launch in Q3 2021 and R&D as we improve our platform capabilities and add more indications.

I'd like to thank you again for your support and belief in our journey. On behalf of myself and the team, we are committed to continuing our hard work towards bringing PROphet® to the market.

Happy(ier) new year!

Sincerely,

Ofer