Prostatype Genomics

Sector: Diagnostics

When lives matter

Redeye initiates coverage of Prostatype Genomics, a company offering a prognostics test that supports the critical decision by prostate cancer (PCa) patients and specialists as to treatment type, avoiding the pain of over-treatment.

Prostatype offers much needed prognostic decision support

The ability to test for PCa has improved dramatically over the past decade or two, and more extensive PSA screening is supported by an expanding range of tests and imaging, raising PCa detection rates. The ability to treat PCa has also improved with advanced radiation therapy, brachy-therapy and robot-assisted radical prostatectomy (surgical removal of the prostate). Unfortunately, treatment still entails considerable life quality impairments, such as urinary incontinence and erectile dysfunction. Fortunately, a majority of PCa patients can remain under active surveillance ahead of active treatment. Prostatype Genomics' test can establish the P-Score, prognostics to support the critical decision of when to undertake active surveillance following PCa diagnosis. The Prostatype test goes beyond the original biopsy assessment of three stem cell genes (IGFBP3, F3 and VGLL3), and a demonstrated ability to confirm and reclassify one-third of PCa patients in several published and presented studies.

A solid market opportunity

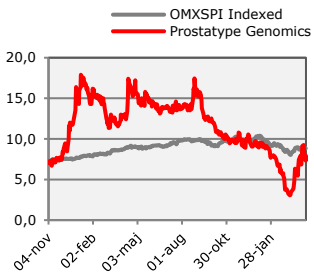
Every year, >1.4m men are diagnosed with PCa, growing by 4-6 percent. There is a strong rationale to avoid over-treatment and the resulting elevated costs and reduced quality of life.

Key Financials (EURm)	2020	2021	2022E	2023E	2024E
Sales	3	3	8	31	78
Sales growth	405%	-97%	48232%	469%	168%
EBITDA	-13	-15	-19	-13	7
EBIT	-13	-16	-20	-15	4
EBIT Margin (%)			-408%	-53%	5%
Net Income	-15	-16	-20	-15	7
EV/Sales	222,5	13568,6	24,2	6,5	2,4
EV/EBITDA	neg	neg	neg	neg	25,7
EV/EBIT	neg	neg	neg	neg	44,9

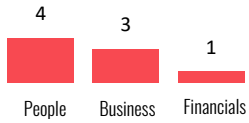
FAIR VALUE RANGE

BEAR	BASE	BULL
5	22	53

PROSTATYPE VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	PROGEN.SE
Market	First North
Share Price (SEK)	7,9
Market Cap (SEKm)	119,8
Net Debt (SEKm)	-19,1
Free Float (%)	71
Avg. daily volume ('000)	28

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Investment Case

Prostatype benefits from a well-established clinical rationale

The good news for men is that many prostate cancers have an indolent course. As a result, many patients can safely opt for active surveillance when diagnosed with PCa classified as low risk, with the patient subjected to regular surveillance. The clinical dilemma is that while it is possible to diagnose (Dx) PCa with a high level of precision, it is often distinctly challenging to establish the risk of future PCa progression based on standard of care (SoC). There is an obvious need and rationale for a prognostic test that contributes to a safe decision in opting for active surveillance and avoiding radical treatment, which brings with it frequent adverse side effects, including urinary incontinence and erectile impotence. Extensive over-treatment is an established problem for both patients and specialists. The risks associated with active surveillance for correctly classified low-risk patients are reassuringly microscopic by comparison.

Prostatype targets a significant market

More than 1.4m men (2020 Globocan) are diagnosed with PCa annually (incidence), with 2.5 percent global growth related to an aging population and lifestyle changes. Nearly 50 percent of new PCa cases are in North America and Europe. One in eight men can be expected to suffer from PCa. The decision to choose radical therapy is obvious for some patients (variations between countries) once diagnosed. Metastatic PCa is excluded (some six percent, with country-specific variations, some of whom are inoperable), forming part of the high-risk group of some 20 percent of PCa patients. The core target group is low-risk PCa, a larger group of men aged <70, of whom 40-45 percent could be expected to have low-risk PCa. The second target group is the low intermediate risk PCa patients, at some 35-40 percent. In short, there is both a clinical and a life quality reason for well above 50 percent of PCa patients aged below 70 to use a Prostatype test. The target group aged above 70 is smaller but still substantial.

Prostatype offers proven precision and an established price range

Gene-based tests are well established on the US market. In the PCa setting, the price range is set at USD 3,000-5,000 per test. The net supply price is, of course, lower, and the European price level is, we believe, likely to be some 25-35 percent below the US price point. European markets also tend to be more challenging regarding access to private and public funding. This is likely also to be the case for Prostatype's European markets.

Prostatype has an excellent opportunity to secure a long growth period

It will take many years to penetrate the PCa market. The target market includes all low-risk PCa patients at the point of diagnosis plus a significant proportion of patients preliminarily classified as intermediate risk. Once Prostatype is well established here, we expect improved support from the public pay market and some help from patients who eventually need a second biopsy during active surveillance following initial diagnostics. The primary market for Prostatype is patients with a recent result from an initial biopsy. The decision to screen for PCa is likely to remain controversial in many countries. However, the decision to use a Prostatype test, with high-quality prognosis, should be straightforward and welcome among a more significant proportion of these men. When designing treatment, it is more rational to use more predictive tests than to reduce PSA screenings at the expense of an increased mortality rate.

Counter-Thesis

The market for gene-based tests is less mature in Europe

The European markets remain somewhat cautious towards gene-based tests in general. However, we point to the expanding acceptance of gene-based tests and markers for new therapies. Given this and the trend towards specialized and personalized care, we expect a gradual acceptance of gene-based tests in Europe. The rate of innovation in cancer care and changed attitudes in the wake of the COVID-19 pandemic could accelerate this process.

The timing and level of contribution from the public pay market are uncertain

Initially, Prostatype Genomics' focus is on the private market, including the private pay and private insurance markets. The US public market will likely improve, with increasing acceptance among specialists thanks to clinical experience and expanded clinical support. In Europe, future launches are likely to be an extended process, with significant variations between countries. Clinical support, clinical experience, and other health-economic studies are likely to drive support from the European public market.

Alternative competitive tests will emerge eventually

In attractive and large markets, competition will always emerge. It is essential that Prostatype Genomics penetrates the market over the next five years and continues improving its offering. Prostatype is AI-integrated and supported by a proprietary database that provides improved precision over time. We also expect Prostatype Genomics to collaborate with other diagnostic and prognostic companies, in line with its recent Swiss collaboration with Proteomedix. Combined tests (m) often improve the precision further.

Key Catalysts and Key Risks

Key catalysts

Securing one or several US lab partners

Prostatype Genomics targets access to the US market through a CLIA approval, requiring a CLIA-classified US lab partner. Several PCa test peers share this route to the market. Once it has established a US lab partner, we expect a US launch within six to 12 months.

Expanded scientific support

The company has already secured scientific study support. We expect it to expand the body of clinical evidence in comparable studies with established tests and in studies combining Prostatype with other tests. This also includes presence in PCa conferences and support from established KOLs.

US launch

After gaining access to a CLIA-certified laboratory and given a smaller lab-centric validation study, Prostatype Genomics would have a good opportunity to launch in 2023.

Extended European launch

Prostatype has already launched in the UK. The ability to scale up the UK launch supported by rollouts in Germany, Switzerland, Italy, Spain, Portugal, and the Nordic countries is the primary trigger during 2022E.

Commercial partners

Commercial partners such as Capio, CCL Eligen Diagnostica and BioPortugal will be essential in gaining access to both the private specialist market and, eventually the public market.

Access to the public reimbursement market

Broader acceptance of gene-based tests in Europe will eventually bring more favorable guidelines and public reimbursement. There is no formal resistance regarding access to the US public market, and we expect improving market penetration once Prostatype Genomics has built sufficient awareness among US specialists.

Key risks

Slow general private pay acceptance

Prostatype Genomics needs to convince specialists and newly diagnosed patients that the Prostatype test will support treatment decisions and protect quality of life.

A slow US rollout

The US market is the largest and the most dynamic market. The company's ability to compete and secure commercial and clinical partners there will be decisive. Without US support, the company's sales outlook would be very different.

Limited resources

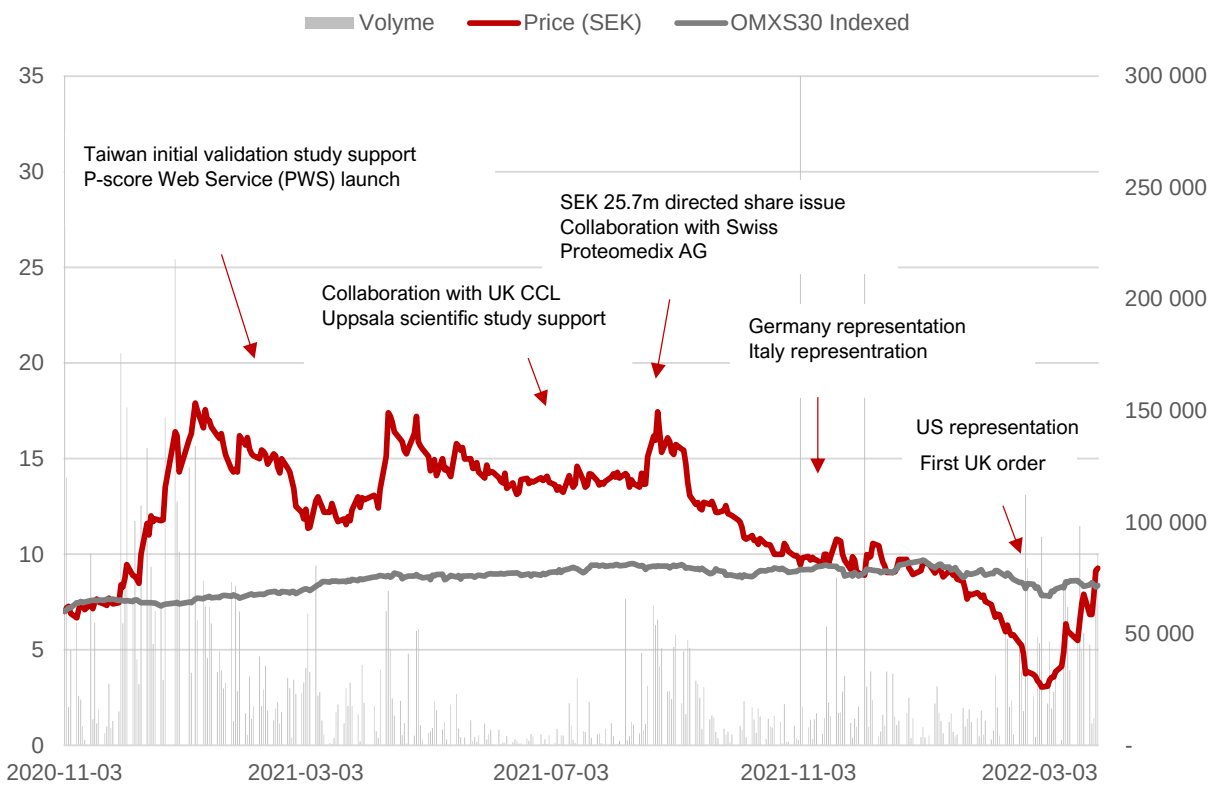
Prostatype Genomics is a smaller company with a promising test. It will need to secure strategic collaborations both to expand scientific support and to roll out Prostatype commercially.

Regulatory delays

Prostatype is a test used to assess the risk of future progression of PCa, and the test needs to be compliant with regulations. Prostatype is CE-approved, and the company is well underway toward securing CE IVD approval. The risk for any delays seems to us to be very small. The US market is crucial, and Prostatype is in the process of securing CLIA certification by collaborating with a CLIA-certified laboratory. The company needs to ensure that it secures an additional limited validation study. There is always a small risk of delays, but the US process is progressing well.

Share Price Performance

Share price and events following the introduction on First North in November 2020



Source: Prostatype Genomics, Redeye Research

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Company Description

Prostatype Genomics has developed a gene expression test based on three carefully selected embryonic stem cell genes taken from the initial biopsy to diagnose prostate cancer. The test can be regarded as a prognostic gene-based test that is distinctly different from those used to diagnose PCa. Diagnosis can be seen as the natural starting point and the actual source of biopsy material for the Prostatype test. In short, Prostatype Genomics develops and commercializes the molecular gene-based prognostic with the ability to stratify prostate cancer patients into risk categories and provide support regarding the treatment decision.

The company was founded in 2007 having evolved from work by a research team at Cancer Center Karolinska (Karolinska Institutet, Stockholm, Sweden) into a new predictive PCa test. The method stems from the founder Chunde Li'sideas and early collaborations with Professor Patric O Brown (Stanford, US) and Sune Rosell (mentor, former professor at KI and earlier Research Director at Astra). The company was initially named Chundsell. The Prostatype test has evolved and improved since 2007, and the current incarnation is now ready for advancing to clinical and commercial launch. This progress towards a significant global market also resulted in the company's listing on the Swedish stock exchange (First North) in late 2020.

The years 2007 to 2014 can be regarded as development for the first clinical test, which was eventually CE-marked in 2016, with support from the company's main owner, Creathor Venture, and expanded collaborations with companies such as Minerva Biolabs AG (a German contract manufacturer), Roche Diagnostics, Scandinavian Gene Synthesis DNA, and Amp Tech GmbH. Prostatype Genomics moved into the clinical validation stage in 2017-2019, the stage essential before winning clinical acceptance and interest. This validation process was initiated soon after the CE approval and the development and extension of the patent portfolio.

Prostatype has already been introduced in some regions of the Nordic market parallel to the clinical validation process under the guidance of Joakim Hagvik, Head of Nordic sales during this period. The clinical validation and support process will remain important in bolstering the initial launch, supporting improved future solutions, and promoting acceptance among specialists, payers, and patients. In the most favorable outcome, tests such as Prostatype can also become a new standard of care.

Clinical validation is also essential for future geographical expansion, including entry into the US market. Following the CE mark and transfer from a research candidate to an early clinical and commercial predictive test, the company recruited Fredrik Persson as CEO in 2017, changed its name to Prostatype Genomics in 2019, and secured a Swedish stock market listing on First North in late 2020. See the table below for an overview of the company's historical progress.

Prostatype Genomics has evolved since 2009

Corporate History

2007	Founded as Chundsell Medical AB. The company is a spin-off from KI CCK (Karolinska Institute, Stockholm, Sweden)
2011	Jan Erik Collin become CEO at Chundsell Medical
2012	SEK 5m funding and presentation of Prostatype at ASCO 2012 (US Cancer Conference)
2014	The first version of Prostatype is developed
2016	Prostatype test is CE marked (1/2016)
2017	P-score is added to Prostatype (8/2017) Fredrik Persson is appointed CEO after Jan Erik Collin
2018	Advanced discussions with partner for China Secures 7.5m in financing (convertible) Initiates the validation study in Malmö, Sweden
2019	P-score is launched in Sweden initially Study support from a Swedish study in Lund, Sweden. Strong data where Prostatype switched approximately 30% of patients. Conducted by Urologist Göran Ahlgren.
2020	Early expansion and introduction of Prostatype in Germany, UK and Sweden The company changes name from Chundsell Medical to Prostatype Genomics COVID has a negative impact on the initial Prostratype during 2020 and 2021 IPO with a November listing on Nasdaq First North Growth Market placing SEK 37.5m priced at SEK 9.65kr per share expanding sales and marketing resources as well as converting some debt. Validation study in Taiwan. Earlier studies are completed in Sweden and Germany
2021	Prostatype Genomics AI solution and the supporting data based is available as a cloud-based solution. The launch of the P-score Web Service (PWS) Switching contract manufacturer from Epigenomics to Minerva Biolabs and switching to a dry powder solution. Initiation of the PCa test collaboration with Swiss Proteomedix AG In August SEK 24.7m is raised in a directed share issue to support the Proteomedix collaboration and European expansion The P-score study in Lund is completed and sent in for review in The Journal of Urology Iberia distribution by signing Eligen Diagnostica and BioPortugal Lda as regional distributors. Uppsala, Sweden study support based on 71 patients. The results will be fully published at the AUA (US) congress in May 2022 UK collaboration with the British laboratory company Cambridge Clinical Laboratories ("CCL"). This involves both introducing Prostatype in CCL labs as well as in other urological labs in UK and Ireland. Italian representation entering the Italian market German representation entering the German market Taiwan Scientific Validation support (interim reesults) Initial pilot study in China
2022	The remaining convertibles from the IPO expired in February with a limited conversion as the share price was below the strike price of SEK 10.90kr Prostatype Genomics establish a subsidiary on the US market. The objective is to offer Prostatype as a LTD test and to establish a collaboration with partners providing access to to a network of CLIA-accredited labs

Source: Prostatype Genomics, Redeye Research

Prostatype has raised some SEK 91m to date. With its IPO in October 2020, Prostatype Genomics raised SEK 37.5m, of which SEK 15.8m was new growth capital. Since the IPO, the company has raised a further SEK 24.9m. Its current cash position is SEK9.8m.

People and Ownership

The company has seven employees, of whom five are in senior management.

Management and Board

Prostatype Genomics Senior Management

Fredrik Persson, CEO since 2017. B.Sc in Business Administration and Economics, University of Lund. 30 years of international life science industry experience in leading positions with focus on operational and organizational growth.

Michael af Winklerfelt. CFO and COO since 2020. MBA in Finance & Strategy Concentration, Emory University, USA. M.Sc in Economics and Business Administration, Stockholm School of Economics. Wide-ranging international experience working for multinationals in US, Europe and China.

Lidi Xu, CTO since 2019. Ph.D. in Medical Science, Karolinska Institute, Stockholm, Sweden
M.Sc., Stockholm University, B.Sc in Bioscience, Beijing University, China
Senior Medical Scientist specialized in oncology. Ten years of experience in research, project design and implementation. In-depth knowledge in the cancer biology field

George Skinner, Vice President Commercial Operations since 2020. BSc from University of Toronto (Canada). North America and European experience in device and in vitro diagnostics initially at Boehringer Mannheim GmbH (now Roche Diagnostics), senior positions and product launches at Byk-Sangtec GmbH (now DiaSorin), Gen-Probe Inc. (now Hologic), MDx Health, and many others. This also includes numerous urological oncology biomarkers such as PSA, BTA stat, PCA3, and SelectMDx.

Dilruba Ahmed, Quality Control Manager since 2019. Ph.D. in Medical Science (cancer biology), M.Sc. in infectious disease control, Karolinska Institute, Stockholm, Sweden.
Bachelor of Pharmacy and M.Sc. in Pharmaceutical Science. Ten years of experience from research and pharmaceutical product management experience

Source: Prostatype Genomics

CEO Fredrik Persson was recruited to the company in 2017 when it entered clinical and commercial phases. He brought 30 years of life science experience to the company. In 2021 and 2022, the company has also added collaborations in countries such as Germany, the UK, Ireland, Italy, Spain, and Portugal. This includes expanding the network of specialists who can secure access to essential and leading clinics. In the Nordic region, Prostatype Genomics is introducing Prostatype directly, based on its own lab and thanks to Head of Nordic Sales Ulrica Flock. A US presence will likely result in an expanding US employee base during 2022 and 2023. Prostatype Genomics has a board that offers access to substantial network and extensive experience, essential for a smaller company.

Corporate and Advisory Board

Prostatype Genomics Corporate Board and Advisory Board

Corporate Board

Anders Lundberg, Chairman (Independent Board Member since 2017). M.Sc. Mechanical Engineering, KTH, Stockholm, Sweden. Founder and CEO of a telecom equipment supplier later brought to a successful IPO in 2011 on OMX-Nasdaq. Member of the board of AJ Lundberg Kapitalförvaltning and Modern Car Group International AB. Deputy member of the board of Sollentunahem AB, Sollentunafastigheter 1,2 and 3 AB,

Dr. Michael Häggman, Independent Board Member since 2018. M.D, Ph.D. associate professor, department of Urology, Akademiska University Hospital, Uppsala, Sweden. More than 30 years' experience practicing as urologist with an extensive national and international network among urologists. Other assignments incluide; general partner in Skrotum Kommanditbolag and deputy member of the board of Kardinaltalet AB.

Karlheinz Schmelig, Board Member since 2013. BSc in Business Administration, DHBW Mannheim, Germany. MBA, Kelley School of Business, Bloomington, USA. MD of Creathor Venture Management GmbH, Bad Homburg (advisor). Other assignments includes Senior Advisor to German Ministry of Research and Development, former member of the Invest Europe Venture Council. Experienced in many aspects of scaling companies into global technology and industry leaders across various healthcare subsectors.

Håkan Englund, Board Member since 2019. Academic courses in economics, chemistry and polymer technology (Uppsala University and Royal Instiurte of Technology in Stockholm, Sweden). CEO and owner of JDS Invest. +30 years of operational and investment experience from life science and health care industry with focus on commercialization and business development. Senior management positions at Pharmacia Biotech and Phadia.
This involves extensive senior diagnostic experience, business development and M&A.
Other assignments include; Chairman at SecureAppBox, Board Member of Antrad Medical, (Norway) networks. Håkan brings an extensive national and international relevant network.

Advisory Board

Rolf Skoglund. MSc, Business Investor, 20 years experience of start-up industry. This includes Advisory Council Member at EQT Ventures, Partner at ThinkOut AB, member of the IT-section at IVA and a member of STING Business Angels

Dr. Christoph Petry, Independent Board Memeber since 2019. Doctor Max-Planck Institute for Medical Research, Heidelberg. Ex founder, MD, CEO of Sividon Diagnostics. Head of Diagnostics and Siemens Healthcare Diagnostics Molecular Research Germany.
Ten years in different postitions at Bayer. Dr Petry is currently also MD at m2p-labs GmbH I microbioreactors, Germany

Source: Prostatype Genomics

Anders Lundberg has been chairman since 2017 and brings with him extensive entrepreneurial experience. Dr Michael Häggman offers substantial specialist skills and is also involved in expanding the scientific support for Prostatype Genomics. Karlheinz Schmelig is also Managing Partner in Creathor Ventures, the largest shareholder of Prostatype Genomics for many years.

Ownership

Prostatype Genomics Shareholders		
Holder	Capital (%)	Votes (%)
Creathor Venture	20,4%	20,4%
Nordnet Pensionsförsäkring	7,0%	7,0%
Håkan Englund	4,9%	4,9%
Anders Liljeblad	4,5%	4,5%
Staffan Ek	3,6%	3,6%
Chunde Li	3,4%	3,4%
ID Invest AB	3,1%	3,1%
Göran Dybner	2,4%	2,4%

Source: Holdings (2021-12-31)

Notably, founder Chunde Li remains a substantial shareholder with a current stake of 3.4 percent. We also recognize that Creathor Venture and some larger private holders have stakes together exceeding 30 percent, a combined holding large enough to handle the risk of an opportunistic bid on the company at the current low valuation. Creathor Venture is an experienced venture fund based in Switzerland and Germany. The fund has invested EUR 230m in 220 tech and life science companies.

Prostatype Genomics has received at least SEK 91m in funding over the past ten years (Creathor Venture's contribution is undisclosed, but the minimum investment is EUR 0.5m, and its investment in Prostatype Genomics is probably more significant considering that Creathor Venture is the primary owner.

Prostatype Genomics secured investment and funding via the STING (Stockholm Growth and Innovation based in Kista, Sweden) incubator in 2012 and a grant from EIT (European Institute of Innovation and Technology) as one of five companies of 29 applicants in 2020. Its latest substantial funding was a directed share issue of some 1,901,891 shares at SEK 10.90 each in October 2021, one year after its First North listing, which raised SEK 21.8m at SEK 10.90 per share in new growth funds.

Prostatype, the company's prognostic test, is innovative, based on a different technology than the most established current methods. This benefit can only be converted into a business opportunity with a decent return on investment if it is also protected by IP rights. Below, we show some of its most essential IP protection.

Patent and IP

IP portfolio - Genetic markers for staging and classification of Pca		
Contry	Status	Valid until
Europe	Approved	2032-10-24
China	Approved	2032-10-24
Hongkong	Approved	2032-10-24
Japan	Approved	2032-10-24
USA	Approved	2034-03-21
Canada	Approved	2034-10-01

Source: Prostatype Genomics

The most recent patent was approved for Canada in January 2021 and is valid until 2034, like its US patent.

The Prostatype test is also based on important algorithms, and its expanding database suggests scope for additional IP protection on top of the opportunity to further develop Prostatype into new versions in the future. The collaboration with Switzerland's Proteomedix AG in 2021 can also bring opportunities to develop Prostatype further, extending the IP window even more.

The current patent portfolio protects the company in its core launch market of the Nordic region and in larger markets in Europe, as well as the US and China. We can probably expect Prostatype to extend its IP portfolio in Asia and the Middle East, too.

The Prostatype Test Proposition

Why is the Prostatype test needed?

Not only is prostate cancer (PCa) still deadly but it also reduces quality of life and poses unjustified and unnecessary concerns for middle-aged and older men. In many ways, PCa is for men what breast cancer is for women, with the difference being the problematic and expensive level of severe over-treatment of PCa patients. For men, PCa is second only to lung cancer in cancer mortality in most countries.

One in eight men can expect a PCa diagnosis during their lifetime, and this cancer has a relatively high prevalence in the Nordic region. Approximately 75-80 percent of diagnosed men have a non-aggressive tumor, meaning active surveillance is perfectly adequate therapy during the first ten years after diagnosis. The actual prognosis for an individual patient diagnosed with PCa depends on how early the tumor is discovered. In countries where PSA tests are widely used for screening (early detection of PCa), the likelihood of early discovery is higher, and the market for active surveillance and a reliable predictive test tends to be more significant. The +75 age group tends to account for a majority of PCa-related mortality at a rate often above 75 percent of total PCa mortality.

In reality, 75-80 percent of men diagnosed have local PCa. Of these, some ten to 25 percent have locally advanced PCa. A majority will undergo radical prostatectomy (RP) as part of their treatment, this being the gold standard for this type of PCa. The actual level of low and very low-risk PCa is 50-70 percent. A Swedish study (Intensity of Active Surveillance and Transition to Treatment in Men with Low-risk Prostate Cancer, European Urology Oncology, June 2019) is a

good example. Only around 50 percent of these patients received active surveillance from 2008 to 2017. One reason for the high level of over-treatment is insufficient access to prognostic tools. Patients who suffer from advancing PCa during active surveillance will be detected, hence the "active" (regular PSA tests and eventually imaging and a second biopsy). In this study, 13 percent of the active surveillance patients were finally upgraded to active treatment.

This suggests 20-30 percent over-treatment based on the current standard of care (SoC). Including 25 percent of PCA patients initially classified as intermediate risk would take up the level of over-treatment by some five percentage points, suggesting 25-30 percent over-treatment of all patients diagnosed with local PCa. Historically, the lack of prognostics tests has resulted in:

- A high level of surgery with radical prostatectomy among patients with low and even very low risk of PCa progression based on the initial staging of local PCa
- A low level of surgery among patients with advanced PCa where radiotherapy tends to be combined with chemo- and hormone therapy
- Uncertainty regarding the treatment of intermediate-stage PCa where surgery was also avoided

The benefits of active surveillance are obvious, especially when the actual risk of PCa progression for low, very low risk, and a proportion of intermediate-risk PCa is generally particularly low. The challenge is, of course, that the actual risk in the individual case is unknown, and this, together with cancer-related stigma, contributes to excessive use of radical therapy. As more scientific support has evolved for active surveillance, the adoption of this has also increased, and there is a trend towards:

- Increasing use of active surveillance among PCa patients initially classified as very low and low risk
- Increasing use of surgery among some PCa patients initially classified as intermediate risk
- Generally increasing use of imaging (especially MRI) supported by more or less established tests that typically support the initial diagnostic
- Early-stage using active surveillance for a proportion of some PCa patients initially classified as intermediate risk

Because of the insufficient prognostic tests, the use of active surveillance remains unnecessarily low, and patients actually opting for this tend to switch and undertake surgery within three to seven years based on episodes of elevated PSA levels. The lack of adequate prognostics tests also results in a very low level of active surveillance use among PCa patients initially classified as intermediate risk. Most countries and regions are moving towards individual variations. This highlights an obvious need for improved prognostics tests to reduce:

- The burden of unnecessary advanced treatment
- The problem with substantial adverse side effects resulting from excessive treatment
- The stigma attached to having diagnosed PCa with an uncertain risk of progression.

This is also the framework into which the Prostatype test is being introduced clinically. The objective is to allow patients to safely opt for active surveillance, supporting the current standard of care in terms of diagnostics and initial staging tools.

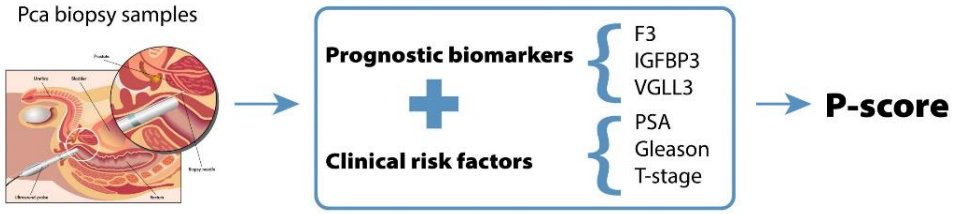
The Prostatype test explained

The Prostatype is now ready to be used clinically and is approved for clinical use in Europe. The reasons to use Prostatype is very straightforward:

- Prostatype is based on the biopsy, complemented with test results that are part of the ordinary PCa diagnostic process (PSA, Gleeson, and staging)
- Prostatype can reclassify approximately one-third of PCa patients compared with the initial staging, which is based on tests with insufficient prognostics
- An increasing body of scientific support supports Prostatype
- Prostatype offers a test result within 12-24 hours, and the solution is cloud-based

The solution is now scalable, and the test kit (Prostatype RT-qPCR) has improved further with the switch from a liquid-based substance to dry powder, which improves the logistics and distribution of the hardware. The image below shows the test kit and the actual P-Score outcome.

The critical parts in the Prostatype Test



The P-Score indicated the risk for ten-year progression and the result delivered as a web-based service "P-score Web Service"

Source: Prostatype Genomics, Redeye Research

Prostatype P-Score is a calculated algorithm supported by AI using a proprietary software and a self-learning database. The Prostatype test's performance and precision will improve as the database expands with more PCa patients. Currently, the database is based on 4,000 patients, including 600 with long-term clinical outcomes and treatment.

Each test is based on a biopsy taken as a normal part of SoC during PCa diagnosis. Once a patient is identified as being at risk, biopsies are used to confirm PCa, with needles inserted into the prostate through the skin behind the scrotum (trans-perineal) or from behind (transrectal). The latter carries a greater risk of infection, and in both cases, it is possible for a tumor to be missed, although a trans-perineal biopsy tends to be more precise.

Each Prostatype test has the capacity to process up to 16 tissue samples, and each test is delivered with one unique code. The test is based on the discovery that three stem cell gene types (IGFBP3, F3, and VGL3) provide a fingerprint that can result in a robust ten-year prognostics outlook regarding the risk for PCa progression. For each patient, this footprint is compared with the 600-patient database. This calculation is carried out by an AI-supported algorithm. The actual individual P-Score also partly based on several well-established clinical biomarkers

- PSA (prostate-specific antigen) is a standard blood-based (protein) test that provides a convenient and inexpensive indication of an enhanced risk for PCa. This test has low precision but can be used for screening elevated cancer risk ahead of imaging and a decisive biopsy. PSA levels are measured using ng/ml; levels below 3ng/ml are considered normal.
- Gleason score is based on the biopsy, and it is used to grade the PCa in the staging process. The score measures a two-level deviation and mutation from the actual biopsy versus normal health tissue (Grade group 1-5 or Gleeson Score 1-10 in the alternative traditional system).
- T-stage is based on the digital rectal examination and MRI-findings. The biopsies are examined and graded by the pathologist and a histopathologically based grading (ISUP or Gleason sum) is assigned

The resulting P-score readout is in integers of 0-15, each integer indicating an associated prostate-cancer-specific mortality (PCSM) probability in ten years. If the patient is classified by P-Score as in the low-risk (green 0-2) group, then his PCSM is below 3.4 percent. If the patient is classified in the intermediate-risk (orange, 3-5) group, his PCSM is less than 10.8 percent. And if the patient is in the high-risk group, his PCSM is above 10.8 percent.

The well-established method for PCa risk stratification is the D'Amico system, which is based on the same clinical biomarkers as those listed above. The limitations are perhaps intuitive as they are based on biomarkers primarily used for diagnosing PCa and not mainly to assess the future risk for PCa progression. The D'Amico system has been used since 1998.

The traditional D'Amico system is typically used for PCa risk stratification

Risk Group	Parameters	Intervals
Low	PSA	≤ 10 ng/mL
	Gleason Score	6 (grade group I)
	cT	1c and 2a
Intermediate	PSA	>10 ≤ 20 ng/mL
	Gleason Score	7 (grade group II and III)*
	cT	2b
High	PSA	>20 ng/mL
	Gleason Score	>8 (grade group IV and V)
	cT	2c

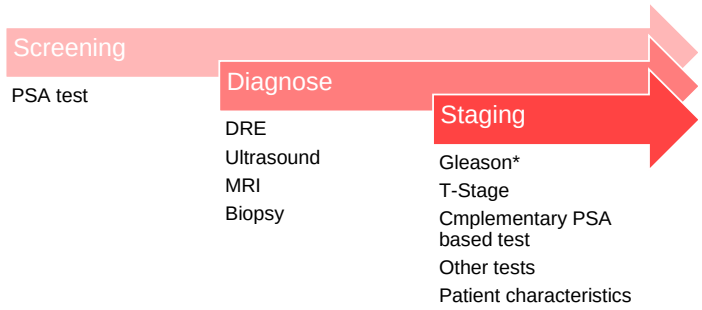
** Intermediate risk Gleason Score 7 includes group 3+4 and 4+3*

Source: Redeye Research

The table above is somewhat simplified. The low-risk group also includes the very low-risk group (low PSA density and low levels of cancer core) and two different intermediate groups as guided by the cell pattern (Gleason 3+4 or 4+3). Men with low risk tend to have a 12-year mortality risk of 2.8 percent compared with 10.8 percent and 17.5 percent in the intermediate and high-risk groups, respectively.

The PCa diagnostics are supported by ultrasound and MRI (magnetic resonance imaging) and the traditional digital rectal exam (DRE). None of these contributes directly to P-Score, although the MRI provides indirect support, being part of the standard of care in most high-GDP countries, by improving the ability to find and exclude metastatic prostate cancer (mPCa) and advanced local PCa. The chart below illustrates a standard PCa diagnostic workflow that can be initiated by one or several elevated PSA tests.

The diagnostics workflow for PCa



Source: Redeye Research

The staging can be seen as the starting point for assessing PCa in different severity categories. The process is efficient in PCa detection and has also evolved to become more efficient in detecting mPCa and more advanced PCa. However, it remains insufficient when assessing the risk of future PCa progression for patients with low, very low risk, and even among those initially staged with intermediate-risk PCa. This well-established fact has been recognized in many studies and publications.

The problem with insufficient prognostics tests has become even more problematic over the past ten to 15 years, with increasing use of active surveillance, greater use of PCa screening (public and private), and active senior citizens expecting to protect the quality of life at the age of 50-70 and beyond. This is where the Prostatype test can make a difference, and this opportunity requires scientific support. Changing attitudes among specialists, new standard of care, and interest among patients almost always requires robust scientific support.

Prostatype is already supported by robust scientific support

The most substantial study performed to date is a large retrospective study including 716 patients was undertaken in Malmö and Lund (Sweden) during 2008-2017 and published in The Journal of Urology, September 2021. The study was undertaken by Dr Göran Ahlgren among others, and the study is under review for publishing in The Journal of Urology (2021, September), a publication with a normal impact score.

The 716 patients were diagnosed during 2008-2010 and received an eight- to ten-year follow-up. The P-Score was measured based on the historical biopsy at the time of diagnosis and then assessed against the actual outcome in terms of progression and mortality over the ten years to 2017. The method was the established P-Score based on three stem cell gene signatures (IGFBP3, F3, VGLL3) together with the normal clinical parameters (Gleason score, PSA, and T-stage). The P-Score was then compared with the traditional risk stratification method based on D'Amico (see the table above on page 22).

In the study, 365 patients had valid data (D'Amico, P-Score, and full follow-up), 49 had mPCa at the time of diagnosis (13 percent), and patients developed mPCa during the follow-up (15 percent). 33 patients died as a result of to PCa (nine percent)—a good illustration of the importance of excluding a patient from the mortality and mPCa group (24 percent of the population). We refer to the common D'Amico method for risk stratification but sometimes other standards are used, such as EAU, NICE, AUA or NCCN (see Appendix 1). In reality, the differences are minor, and the result is very similar, also suggesting similar levels of limited precision in providing adequate prognosis.

- The P-Score was high for all patients who died during follow-up.
- The P-Score was superior to D'Amico in predicting both death and mPCa ($p<0.0001$)
- The P-Score showed superior correlation versus D'Amico in PCa mortality (0.89 vs 0.77, $p<0.0001$)
- The P-Score demonstrated superior correlation versus D'Amico in mPCa (0.86 vs 0.77, $p<0.0001$)
- Each unit of the P-Score had an HR of 1.48 in predicting PCa-specific death ($p<0.0001$)

These results are surprisingly robust, in our view. When it comes to a post-biopsy decision, the specialist and the patient need to make an informed and correct decision. This study also compared the result of risk staging based on the more precise P-Score (based on the above) and the D'Amico method, as illustrated in the following table.

Scientific support for Prostatype P-Score from the 719-patient study in Malmö, Sweden

Original Risk Classification	P-Score	Patients	Confirmed classication	Pca Mortali
Low	Low	10	77%	0%
	Intermediate	3	23%	0%
	High	0	0%	0%
Intermediate	Low	40	37%	0%
	Intermediate	60	55%	0%
	High	9	8%	0%
High	Low	13	10%	0%
	Intermediate	39	31%	0%
	High	72	58%	22%
Local Advanced	Low	1	1%	0%
	Intermediate	4	6%	0%
	High	64	93%	27%

Source: Prostatype Genomics, Redeye Research

The P-Score will thus add value to the low-risk and the intermediate-risk group of patients in a clinical setting. Patients assessed as being at high risk based on traditional methods are likely to be excluded from active surveillance, even if the P-Score suggests that the initial grading is inflated. Among patients originally assessed with low- or intermediate-risk PCa, 43 percent were switched based on the correct P-Score, and ten percent of these were moved from low and intermediate risk and 33 percent were shifted down (all from the intermediate risk group).

This Malmö study represents strong support for P-Score, in our view. The outcome of a surprisingly high number of correct switches from the intermediate-risk group to the low-risk group also suggests that patients originally classified in the intermediate group with a Gleason 7 (3+4 and not 4+3) together with other positive factors (such as node) could opt for active surveillance based on P-Score (some 37 percent of all patients classified as intermediate risk). We also point to the 23 percent of patients originally classified as low risk who were reclassified as intermediate risk. This is also clinically meaningful as it could contribute to more active surveillance with reduced risk. In reality, the adherence to the active surveillance protocol tends to vary and some of these patients may also opt for more advance treatment based on their P-Score.

The results also suggest that the P-Score could allow some patients to make a safer transfer from high risk to intermediate risk, resulting in additional radical prostatectomy procedures with a safer outlook for patients in this category. This switch is probably more likely for those with a longer life expectancy.

The study points to a combination of different clinical benefits, such as:

- Patients newly diagnosed with PCa can safely opt for active surveillance protection with a positive effect on both quality of life and peace of mind (the proportion of low-risk patients increased from four percent to 20 percent). This is a strong proposition for private pay in particular.
- Patients originally graded as high risk or with locally advanced PCa could opt for radical prostatectomy based on an improved therapeutic effect and potentially improved life expectancy (30 percent of the high-risk group was moved down based on the P-score).

The study showed an unusually low proportion of patients originally classified as low risk patients (four percent). Normally, we would expect at least 20-30 percent, with the intermediate-risk group accounting for some 30-35 percent, and high risk for 40-45 percent. The high-risk group in this

study was unusually high at 61 percent. The improved staging based on the P-Score was much closer to what could be expected in this group. In a more normal patient population, we could probably expect the P-Score:

- To confirm the low-risk classification, allowing patients to safely opt for active surveillance
- To switch more patients to intermediate risk
- Similar high level of switches from intermediate risk to low risk, increasing the proportion of active surveillance
- A reduced number of switches from high risk to intermediate risk.

The high level of switches from intermediate risk and low risk is important for many reasons, the quality of life and clinical benefits being central. The high level of switching also supports the future market opportunity for Prostatype Genomics. The results also confer the scientific evidence of the past five to ten years, pointing to as much as 40-55 percent of patients in the intermediate-risk group having a more favorable risk outlook. The difference in risk between these groups could be as significant as 300 percent or even more. The core future market for P-Score is the low-risk group, but it could also add value to the process of identifying intermediate-risk patients with a low risk of PCa progression.

Additional test confirming the Malmö/Lund study is important. We also expect Prostatype Genomics to initiate further studies supporting the local and regional launches in some markets. In reality, this can also be a necessity to operate in some markets, such as the US and China. In this context, these would be clinical validation studies.

In August 2021, Prostatype Genomics announced results from a 71-patient study in Uppsala, Sweden, which will also be presented at The American Urology Association congress 2022 (May 13-16). This study tested the P-Score correlation between the initial biopsy and the later biopsy when patients underwent prostatectomy. By default, this was a high-risk group, and if useful, the P-Score should have a high correlation when testing the prognostics ability. Secondly, the study tested the P-Score's ability to handle PCa tumor differentiation. As PCa progresses, the tumor tends to be increasingly homogenous, and a robust test needs to be able to handle this challenge. Otherwise, the prognostics ability could be volatile and dependent on the location of the biopsy in the same prostate (in theory). The latter aspect tested the robustness of the P-Score. The overall results are illustrated in the table below:

Scientific support from the 71-patient study in Uppsala, Sweden

Measured	Comparing	Patients	Correlation	P-Value
Prognostic P-Score	(Original biospy vs later biopsy/tissue)	71	**0.83-0.84**	**<0.001**
Tumor gene expression/differentiation	Dominant structure vs non-dominant PCa structure	71	**0.83-0.84**	**<0.001**

Source: Prostatype Genomics, Redeye Research

The correlation relating to both prognostics ability and the robustness of tumor differentiation was reassuringly high expressed in terms of correlation: 0.83-0.84.

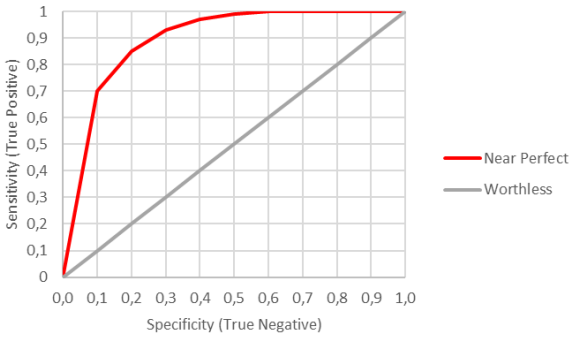
In this study, the c-statistic was a high 89 percent and equal to AUC when it comes to testing. This suggests that the P-Score test has high prognostics precision, offering a solid positive predictive value in this case when used to indicate both low and increased risk of PCa progression, in this case. To put this in perspective, a result of >0.7 (AUC) is considered good and a result near 90 percent is very high, indicating a very high probability of setting a correct PCa risk staging and ten-year outcome with the P-Score.

We also highlight a fundamental difference in terms of screening for PCa and correctly assessing the risk for progression: the risk for an individual male aged 55-59 to test positive in a specific year is very low or <1 percent. A PSA test thus needs to be extremely accurate to avoid false positives triggering many investigations and biopsies that then prove negative.

With a prognostics test such as the P-Score verifying an existing risk assessment, the actual probability for PCa progression is much higher than one percent. For patients with an initial staging of low risk, the risk for progression is, if correct, is 2-3 percent, and for favorable intermediate-risk PCa patients, it is five percent with a <2 percent mortality risk. These levels are representative for men aged <60.

This is still a low probability, which is an issue for the traditional and standard method to assess progression risk (with an inferior ability to prognose progression risk versus the P-Score). The traditional method will result in falser low-risk PCa (falsely suggesting intermediate or even high risk of progression) than a more precise test because the test needs to be accurate to overcome this challenge, given the high proportion of true low-risk PCa). Another way to describe this relationship is illustrated in the chart below, which is based on a precision close to 0.90.

An illustration of fundamentals (AUC approximately 0.89 and 0.77)



The precision in terms of sensitivity and specificity is important. This curve is an illustration of a near perfect vs a near useless test. It is also very important to consider the prevalence in the population which can result in insufficient negative or positive predictive power (false positives or false negatives)

Source; Redeye Research

In a test like the P-Score, with scientific support for high precision, we can expect fewer instances of false low-risk PCa (higher proportion) and false intermediate-risk PCa (lower proportion). The benefit of reducing the number of false higher-risk PCa will increase when the test is used on higher-risk patients and on older patients, based on the increasing actual probability in these groups.

This dynamic could also result in a forward launch where we can expect the P-Score to be used and introduced initially among low-risk PCa based on private (out of pocket and private insurance pay) and a later stage of the launch where the P-Score is increasingly validated and accepted and used for older men, those with a higher risk, and based on increasing support from public pay.

The P-Score has also been tested in Taiwan in a smaller study that provided similar results to the Malmö/Lund and the Uppsala studies. Among these 28 patients (with records including a five-year follow-up period), the results from Malmö/Lund and Uppsala were repeated: approximately one-third of the patients were reclassified and a high proportion of these were reclassified from intermediate risk to the low-risk group. This study was conducted in co-operation with Professor Jacob See-Tong Pang at the renowned Chang Gung Memorial Hospital in Linkou, Taoyuan. This study is continuing with an expanded second stage.

Over the next six to 18 months, we can expect additional studies that are likely to expand the scientific support:

- In the US, a lab-specific validation study can be expected to support the CLIA-accredited P-score test, and the Laboratory-Developed-Test-based launch.
- We can expect a 100-patient pilot study in mainland China in collaboration with Nanjing Gulou Hospital. If successful like earlier studies, this pilot study can evolve into a more extensive registration study in China. This is a market with increasing PCa incidence (from previously below the global average), with some 220,000 new PCa cases per year, which is approaching US levels.
- Additional validation studies in target markets have been conducted by leading reference clinics in Germany and will potentially also be carried out in Middle Eastern and Asian markets.
- Eventually, we also expect health-economic studies to support later potential expansion into the public pay market. These studies could also help the private insurance pay market.

The prognostics precision with the P-Score is promising, as indicated in several studies, and one important reason is probably that stem cell provides important tumor-specific information.

Prostatype Genomics has a straightforward business model, selling the test system including the kit (Prostatype RTqPCR-kit), access to the patient database, and access to the software producing the P-Score. The P-Score software is offered as a cloud-based service. The Prostatype P-Score test has some important advantages:

- It is based on the biopsy already taken as part of establishing the initial PCa diagnostics
- It is a genetic test based on stem cells, giving it the potential to provide more prognostics information in the individual PCa case
- It is the only gene-based test available as a kit and soon also based on a dry powder formulation
- It produces a result after just 12-48 hours, faster than other gene-based tests
- In publications and posters to date, there has been a clear indication of clinical support

Each individual patient is exposed to a treatment decision that is far from obvious. In most cases, there is a high level of both real and perceived uncertainty, and there is often a stigma relating to cancer. The uncertainty stems from both the initial risk status and the uncertainty regarding the individual actual risk of PCa progression. This uncertainty is especially high for intermediate-staged PCa, but there is a considerable issue of incorrect staging in many PCa cases.

As a result, there is both a clinical rationale and a commercial opportunity to use the Prostatype P-Score for many patients beyond just those staged with very early or a very late stage PCa. Once a patient enters into active surveillance, there is a future risk for repeated elevated PSA values that could result in a new biopsy. For these patients, there is also a second opportunity to take advantage of and a new opportunity to support a treatment decision with the Prostatype P-Score.

There are some established tests that can be used to support the treatment decision and the staging of PCa:

- Oncotype Dx: A gene- and biopsy-based prognostics test for low- to intermediate-risk PCa
- Prolaris: A gene- and biopsy-based prognostics test for low- to intermediate-risk PCa
- Decipher: A genomics- and biopsy-based emerging prognostics test supporting PCa
- SelectMDx 3: A urine-based test to support a diagnosis of PCa
- ProMark: A gene- and biopsy-based emerging and promising prognostics test

Some of these genomics tests have also established a US pricing benchmark in the USD 3,500-5,000 range. Their actual precision is more mixed to judge from the clinical evidence. Most of these tests tend to be used in diagnostics, where precision tends to be higher than when assessing the risk of future PCa progression. Their predictive ability can sometimes be improved by combining them with one or several less advanced and cheaper established PCa tests. In the US, several of these gene tests are also already accepted and established with public reimbursement, private pay (private insurance companies), and guidelines such as the US NCCN and ASCO, and NICE in the UK.

Some patients are prepared to pay extra for supportive genomic test, especially in the US. There is a difference in terms of public reimbursements between in the US and Europe, as European countries tend to have a more conservative attitude towards genomics testing in general. We expect these attitudes to change thanks to support from gene-based tests in oncology and many other areas of precision medicine.

There is a considerable market opportunity for a rapid and precise test such as the Prostatype P-Score. More than 1.4m patients are diagnosed with PCa annually, at a 2-4 percent annual growth rate. Some 56-57 percent of these are diagnosed in North America, Europe, Australia, and New Zealand—regions with generally good access to premium care.

Market Dynamics and the Diagnostics Process

The PCa market and the diagnostics process

The global PCa market is a major cancer market with >1,400m new cases each year, representing a growth rate of some two to three percent annually. Mortality rates are also increasing, unfortunately. PCa can be seen as a lifestyle-related cancer with major variations internationally. Regions with high incidence rates, such as the US and the EU, account for more than 43 percent of all new PCa cases, even though they represent less than ten percent of the total global population (see the table below). For similar reasons, the growth rate tends to be higher in regions with low PCa prevalence rates, such as China, while the growth rate is more modest in areas with increased rates of PCa. High-PCa regions tend to have higher GDP; the ability to secure PCa diagnostics testing tends to be higher, the rate of negative lifestyle changes lower, and this is balanced by the gradually aging population.

Sweden is, unfortunately, a rather extreme example, with the highest incidence rate (PCa per 100,000 inhabitants) in Europe (which is already high in an international context) and probably worldwide. Sweden also has a mortality rate that is more than twice the US level, possibly due to limited PSA screening in Sweden.

Global outlook for the PCa market

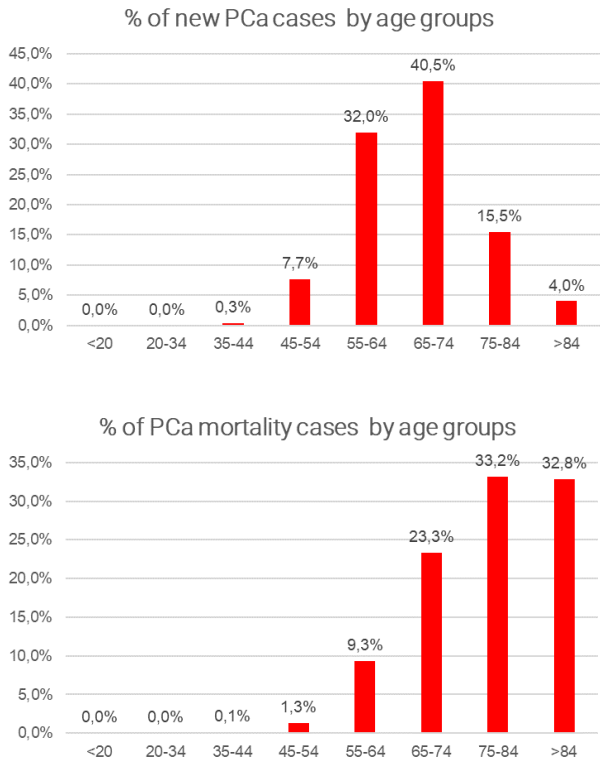
Region	Population (M)	Dx per 100k	New PCa	Growth*	Mortality per 100k	Growth*
WW	7 935	17,8	1 414 259	3,1%	4,7	2,5%
US	330	81,5	268 490	1,3%	10,5	2,6%
EU	447	76,1	340 000	1,5%	17,2	-1,0%
China	1 412	4,3	60 300	8,6%	1,9	9,3%
Some Countries						
US	330	81,5	268 490			
Sweden	10,4	105,5	10 919			
Norway	5,4	101,0	5 433			
Denmark	5,8	81,5	4 752			
Finland	5,5	85,0	4 701			
Germany	83,2	77,0	64 095			
Austria	8,9	65,0	5 796			
Swiss	8,6	70,0	6 020			
UK	67,2	85,5	57 473			
France	67,4	101,0	68 064			
Netherlands	17,4	74,5	12 993			
Belgium	11,6	70,6	8 163			
Spain	47,4	69,5	32 908			
Italy	59,6	75,5	44 960			
Taiwan	23,6	31,2	7 350			
Turkey	84,3	35,0	29 505			
Japan	125,8	84,4	106 139			
Brasil	212,0	45,9	97 278			
Saudi Arabia	34,8	6,3	2 193			
Egypt	102,3	9,5	9 719			
China	1412,0	4,3	60 300			
Australia and New Zeeland	31	62,8	19 282			
Total in selected countries			926 533		Proportion of global market:	66%

**Out growth rate is mainly based on histroical growth*

Source: Globocan, Statista, Redeye Research

It is important to understand that PCa incidence rates are strongly correlated to age profile among men, regardless of the country-specific PCa prevalence level. Men under the age of 45 tend to have minimal PCa risks. The following charts offer a good illustration of age groups and PCa dynamics:

. The difference in age-related PCa prevalence and mortality in the US market

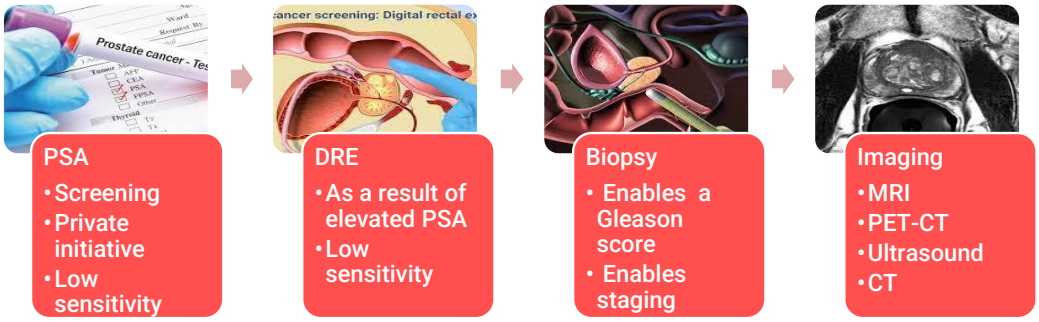


Source: SEER 21 (2012-2018), Redeye Research

They also indicate the five- to 15-year lag from initial PCa diagnosis to the escalation of later disease progression. The average age at the time of diagnosis is 65-66, and at least some 20 percent of newly diagnosed patients have a life expectancy of less than ten years, regardless of PCa risk, and some 5-10 percent of newly diagnosed patients have mPCa, with an inherently reduced life expectance. In the US, PSA screening tends to be more common than in many European countries, where the point of diagnosis is likely to be somewhat delayed.

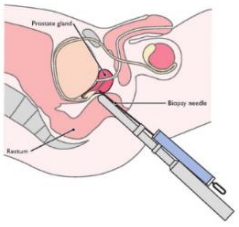
It is important to understand that the mortality rate is driven by metastatic (especially bone metastatic PCa) and, to some extent, advanced regional PCa. The five-year mortality survival for mPCa is 28 percent (distant mPCa), while the ten-year relative survival (versus no PCa) for all PCa is 98 percent in the US, falling to 95 percent after 15 years (Johns Hopkins). The chart below provides an overview of the screening and diagnostics during the PCa process.

The process of screening for and diagnosing PCa



PCa test/biomarker	Type	Stage	Established	Precision
Patient profile	Characteristics	All	SoC	Limited
PSA	Serum (blood)	Screening + Diagnose	SoC	Limited
DRE	Manual	Pre Biopsy	SoC	Limited
MRI or mpMRI	Image	Diagnose	SoC	Useful
Biopsy	Tissue based biopsy	Diagnose	SoC	High
PHI	Serum	Screening + Diagnose	Supporting	Limited.
4K Score	Serum	Mainly Diagnose	Supporting	High
PCMT	Tissue based biopsy	Diagnose	Supporting	Moderate
Select MDx	Urine gene based	Diagnose	Supporting	High
PCA3	Urine	Diagnose	Supporting	Moderate
Confirm MDx	Tissue based biopsy	Diagnose	Supporting	Moderate
ExoDx Intelliscore (EPI)	Urine gene based	Diagnose	Emerging	Moderate
Prolaris	Tissue based biopsy	Prognostic	Supporting	Robust
Oncotype Dx	Tissue based biopsy	Prognostic	Supporting	Moderate
Decipher	Genomic, biopsy, tissue	Prognostic	Supporting	High
ProMark	Tissue based biopsy	Prognostic	Emerging	Moderate
PTEN	Tissue based biopsy	Diagnostic	Emerging	Unclear
Prostatype P-Score	Tissue based biopsy	Prognostic	Emerging	High

PCa biopsy



Magnetic resonance imaging (MRI)

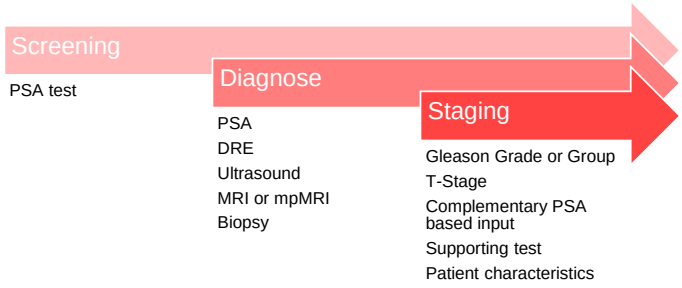
Source: Redeye Research

The methods used to diagnose PCa are standardized, with results offering a high level of certainty when it comes to establishing the PCa diagnosis. The blood-based PSA and the manual DRE (digital rectal examination) can be seen as part of this screening. Diagnosis is mainly based on a biopsy taken using an 18G caliber needle guided by ultrasound (as in the image above). This

tissue is then used to establish the presence of PCa and to stage the tumor, which contributes to the initial risk group stratification.

MRI imaging is increasingly used, more often in the form of multiparametric (Mp-MRI). The MRI helps to establish the risk and presence of metastatic PCa or mPCa, which is a severe form of PCa, and this can be expected in 5-10 percent of new PCa cases. MRI can also improve the precision of risk staging for PCa with advanced or very advanced PCa. Several smaller tissues are taken when proceeding with a biopsy, and these are then examined under a microscope to establish the presence and the degree of abnormalities in the samples. The biopsy is recommended by a urologist, and the tissue is assessed by a pathologist using a microscope, resulting in a pathology report. This report will establish the presence of PCa and its grading. This contributes to the risk grading and the therapy decision.

PCa grading and staging result in an initial, often uncertain, risk group



Grade Group	Gleason Score	Related Risk Group	PCa differentiation
1	Up to 6	Low to Very Low	The cells look similar to healthy cells = well differentiated
2	7 (3+4)	Intermediate often favorable	Most cells still look similar to normal prostate cells
3	7 (4+3)	Intermediate often less favorable	The cells look less like normal prostate cells
4	8	High	Some cells look abnormal
5	9-10	Very High	The cells look very abnormal

Risk Group	Parameters	Intervals		% of PCa patients	
Low (LR)	PSA	≤ 10 ng/mL		Low	High
	Gleason Score	6 (grade group I)		20%	30%
	cT	1c and 2a			
Intermediate (IR)	PSA	>10 ≤ 20 ng/mL	All Intermediate (IR)	40%	50%
	Gleason Score	7 (grade group II and III)*	Favorable	14%	25%
	cT	2b	Unfavorable	20%	33%
High (HR)	PSA	>20 ng/mL			
	Gleason Score	>8 (grade group IV and V)		20%	25%
	cT	2c			

** Intermediate risk Gleason Score 7 includes group 3+4 and 4+3*

Source: Redeye Research

The chart above is rather simplified. A more extensive overview of the staging process is included in Appendix 3. The inputs from the biopsy, staging, the MRI imaging, the PSA, and patient characteristics result in an initial risk rating.

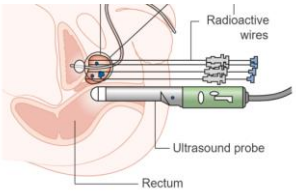
There are several different established risk rating standards as illustrated in Appendix 1, the most established being the D'Amico system. This may seem like a major issue but in reality:

- The systems are similar, with limited variations in output
- The differences are overshadowed by the fact that, regardless of standard used, the risk assessment often fails to convert into a robust therapy recommendation

The purpose of the risk assessment is to provide a robust framework for the critical decision to match the PCa with the appropriate therapy in the individual case. (See the table for established therapies on the next page.) Most of the innovation with premium prices goes towards improving the care for PCa patients with metastatic PCa or very advanced high-risk regional PCa.

The therapy for patients with local PCa is largely established, and one of the more dramatic recent changes is the wide adaptation of MRI-based diagnostic support and the use of robot-assisted prostatectomy. Both these have become very well-established parts of the standard of care. The other major change is the acceptance of active surveillance and a wide range of initiatives to improve the PSA-based test. In this landscape, there is a strong rationale for an improved prognostics test to assess the risk for disease progression.

Typical PCa primary therapies after completed PCa grading and risk staging

Therapy	PCa Risk Group	Comment	
Active Surveillance	Low risk Part of Intermediate Risk Often life expectancy >10 years	Increasing use over the last 5-15 years Improves quality of life Requires regular test like PSA, DRE and less often secondary biopsies and mpMRI	
Watchfull Waiting	Low risk Some Intermediate Risk Life expectancy <10 years Some high Risk	Passive treatment Limited regular follow up Risk of uncontrolled Pca progression when life expectancy <5 years	
Radical Prostatectomy	Traditionally part of Low Risk Part of Intermediate Risk A small proportion of High Risk	Typically executed with robot surgery support Removal of glands and seminal vesicles A trend towards RP and away from ERBT Negative side effects Reduced qulaity of life Including impotence and incontinence Combined with pelvic lymphnode dissection	
External Beam RT (EBRT)	Often Intermediate Risk Pca Frequent among High risk PCa	Improved hardware and software Often image guided Often a Combined Therapy Still frequent moderate negative side effects Less frequent a strict cure More of a preventive Therapy	
Brachy Therapy	Some Intermediate Risk Pca Frequent among High Risk PCa	Internal radiation Therapy Generally less severe side effects vs surgery Still significant negative side effects	
Hormone Therapy (ADT)	Intermediate and High Risk Often part of a combination Part of SoC in mPCa	Negative side effects Reduces quality of life Risks includes sexual dysfunction, metabolic, syndrome, depression	
Chemotherapy	Frequent in more severe Pca High risk PCa and mPCa Often second line treatment	Well established negative side effects Reduces PCa progression	

Source: Redeye Research

There are different guidelines for advising and setting the standards for professional urologists, and we show the European ESMO Clinical Practice Guidelines in Appendix 3. In the US, there is the AUA/ASTRO/SUO, while the UK has the NICE guidelines. The starting point is the initial risk assessment, and this needs to be complemented with:

- Individual patient characteristics, such as life expectancy and general health
- The patient's input in the decision, which will be influenced by individual preferences towards the risk of PCa progression
- Individual attitudes to exposure to therapy-related adverse side effects and reduced quality of life.

The decision is even more difficult since it is obvious that the initial risk assessment often fails to reflect the individual risk of actual PCa progression. Luckily, this is less of an issue for the most advanced PCa, such as mPCa and very high-risk or advanced regional or local PCa. On the other hand, the actual choice of different therapies tends to be less wide-ranging in these cases.

As illustrated on page 31, there is also a strong correlation between age and the rate of severe PCa. As a result, this group of PCa patients tends to have a lower life expectancy of less than ten years and sometimes less than five years (often regardless of the type of PCa), which further reduces the number of relevant PCa therapies for these patients.

This is not the case for PCa patients initially assessed with low- and intermediate-risk PCa. If we exclude the MPCa patients (typically <10 percent of those initially diagnosed with PCa), the proportion of low- and intermediate-risk PCa can be 70-80 percent of diagnosed patients, and even if we exclude intermediate-risk PCa patients with unfavorable risk, this group still accounts for some 35-60 percent of patients with an initial PCa diagnosis. There is also a tendency for the PCa risk profile to vary with age, as illustrated below.

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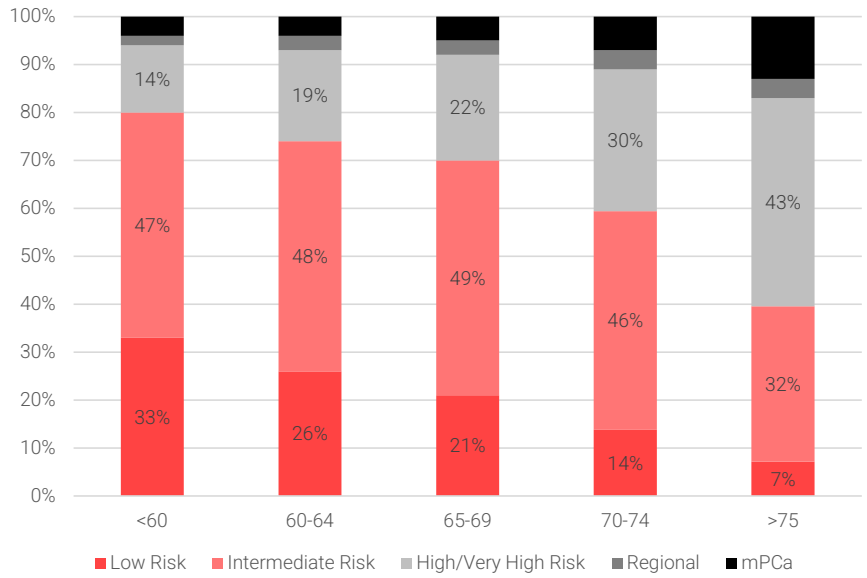
The PCa risk segmentation tends to reflect the age group

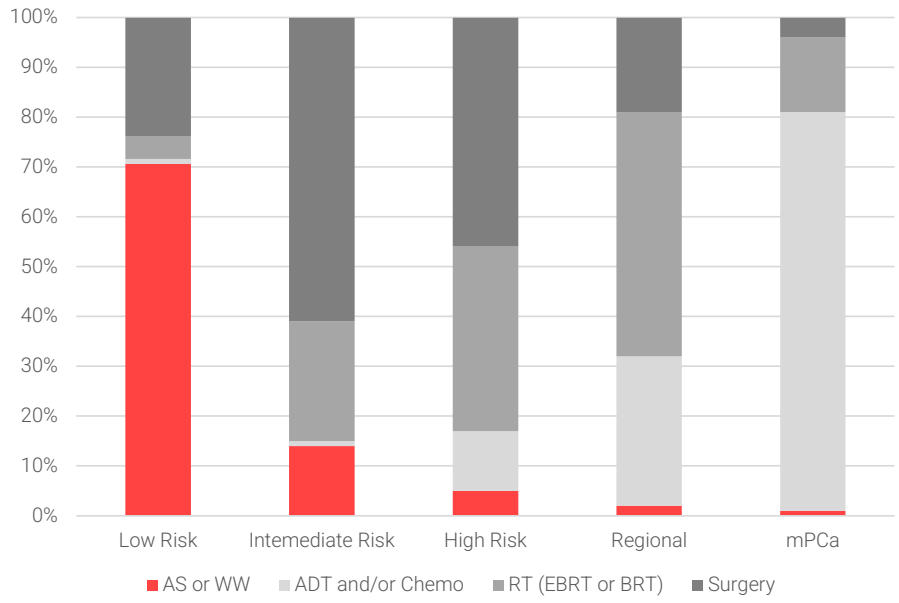


Source: Prostate Cancer Outcome Registry Australia and New Zealand

These risk group dynamics are intriguing and suggest that the low-risk PCa group is in the range of 21-33 percent among patients aged under 70, while in the same age group, the level of intermediate-risk PCa is surprisingly stable at 46-47 percent.

It is reasonable to expect that the proportion of favorable intermediate-risk PCa patients is higher in the less senior age groups in this category. This data has been collected from the extensive and detailed Prostate Cancer Outcome Registry Australia and New Zealand, based on nearly 40,000 patients between 2015 and 2018. This is probably a good proxy for most high-GDP regions.

PCa treatment is, of course, strongly related to risk status



Source: Prostate Cancer Outcome Registry Australia and New Zealand

The proportion of active surveillance is high at 71 percent in the low-risk group, also represented by PCa patients below the age of 70. This proportion has increased from 54 percent since 2015—a trend we recognize in countries such as the US, the UK, and Sweden.

The low proportion of active surveillance in the intermediate-risk group is 14 percent, up from 12 percent, although it is increasingly apparent that the intermediate-risk group includes a very high proportion of patients with low risk for PCa progression over ten years. A very high proportion of new PCa patients are in the intermediate-risk group. The very high 60 percent level of surgery (prostatectomy) among them suggests that as many as 50 percent of these patients are still exposed to unnecessary adverse side effects and reduced quality of life on account of surgery.

We expect the proportion of active surveillance to increase in the intermediate-risk group in the future, with the introduction of improved prognostics tests contributing to this change. We can also see this early trend in increasing use of active surveillance among intermediate-risk patients from low levels in countries such as the UK and the US, despite insufficient prognostics tests.

The Prostatype Opportunity and Commercialization Outlook

The Prostatype launch and future market penetration

Prostatype has the advantage of targeting a much larger market of >1.4bn newly diagnosed patients globally, with a disproportionately high number of patients in premium markets such as the US and Europe.

This opportunity is further improved by an established price point range for relevant genetic tests. The US market list price for such tests is in the USD 3,250-4,000 range per test. We expect a gross list price level of around half this or USD 1,750-2,500 in Europe and other affluent markets, with a slightly deeper discount in the RoW. We also include a 15-20 percent rebate versus the list price and a margin (or shared net price) to distributors and commercial clinical partners of some 50 percent. We illustrate our base case for this in the table below.

List to net prices going forward

Price point

Segments	**Low**	**High**
Rebate compared with the list price	15%	10%
Partner and distributor share	50%	40%
US market (USD)		
- List price	3 250	4 000
-Net contribution	1 381	2 160
-Net contribution (SEK)	12 984	20 304
Europé and affluent markets outside US (USD)		
- List price	1 463	1 800
-Net contribution	622	972
-Net contribution (SEK)	5 843	9 137
Other relevant markets RoW (USD)		
- List price	1 138	1 400
-Net contribution	483	756
-Net contribution (SEK)	4 544	7 106

Source: Redeye Research

During 2022 and 2023, we can expect more direct, early volume sales, possibly with modest volumes and sometimes at a higher net price than later on once the expanded network of commercial collaboration partners drives sales volumes. We can also expect the Nordic proportion of sales to decrease after an expansion in US and international sales after 2022 and 2023.

Overall PCa prevalence is an important starting point. Still, as illustrated earlier in this report, it is important to establish a realistic view regarding the appropriate, relevant part of the overall PCa market. We directly exclude some features of the PCa markets, such as the mPCa segment,

almost all the high-risk segments, and regional PCa. We are then left with the relevant market of PCa patients initially staged as low and intermediate risk, still a substantial proportion of PCa patients.

We prudently split the intermediate-risk group in two and exclude intermediate patients initially staged with unfavorable PCa (including Gleason grade 7 of the subtype 4+3). Cancer tends to come with a reasonable level of stigma, and so patients rated with unfavorable intermediate-risk PCa are probably less likely to pay for a premium test privately to protect recent quality of life when many or possibly most of these patients are instead deeply concerned about diminishing life expectancy.

The remaining group is still substantial, and even if we exclude all patients aged over 75 (who are unlikely to be candidates for active surveillance), we are still left with nearly 45 percent of all PCa patients

More and more studies and guidelines highlight the importance of shared decision-making (SDM), informing the patient and encouraging them to be part of the therapy decision. This is positive for the treatment experience. It is also important for the treatment result, as the patient can decide on their exposure to negative treatment effects.

The American Urological Association (AUA), American Society for Radiation Oncology (ASTRO), and Society for Urologic Oncology (SUO) recognize the importance of SDM, recommending that clinicians utilize this for patients diagnosed with prostate cancer.

This trend is, in our view, positive and also favorable for the introduction and use of supporting tests such as the Prostatype. Patients are also more likely to be willing to consider a test privately if prudently informed financially. In our base case, we assume that 40 percent of low-risk PCa patients will be prepared to pay personally (private pocket insurance) over the next five to ten years. This figure could prove overly conservative on the US market and less conservative in Europe for the first five years.

Among favorable staged patients in the intermediate-risk group, we use a lower 30 percent rate as these patients can be expected to be somewhat more likely to consider active therapy directly, especially as this path remains the most frequent alternative, despite the gradual shift towards active surveillance for them. We also adjust for different countries and accept and share private pay, as shown in the following table.

Our outlook for a list of net prices for Prostatype

Our base case market penetration levels

Segments	Proportion (%)
Excluding	
-mPCa	-8%
- Patients aged >75 at the time of initial Pca	-20%
Modifying factor	
- Large proportion of PSA screening	110%
- A healthcare system with a larger proportion of private pay	120%
- A healthcare system with a low proportion of private pay	75%
Low risk	
- Proportion of PCa	25%
- Potential private pay	50%
- Prostatype market share 2030	40%
Intermediate Risk	
- Proportion of PCa	45%
- Of which initiatlly staged as favourable	45%
- Potential private pay	33%
- Prostatype market share 2030	15%

Source: Redeye Research

The strategy for penetrating these markets reflects the limited size of Prostatype Genomics, and we believe it will expand through regional collaborations supported by necessary and supportive validation studies. In Europe, Prostatype Genomics secured a CE mark in 2016 ahead of supporting validation studies, which is particularly important for market penetration. Over the past six to 12 months, the company has expanded the framework for a regional introduction in several countries, the progress of which and what to expect ahead are illustrated in the following chart.

Prostatype launch outlook

Launch outlook	2021	2022e	2023e	Comment
Nordic	Active	Active	Active	Organisation in place
Spain	Presence	Early presence	Active	Representation in place
Portugal	Presence	Early presence	Active	Representation in place
Germany	Presence	Local study	Early launch	Representation in place
Switzerland		Preparing	Early presence	Collaboration in place
UK	Presence	Early introduction	Active	Collaboration in place
Ireland	Presence	Early introduction	Active	Collaboration in place
US		CLIA partner	Early launch	Setting up presence
Taiwan	Local study	Introduction	Early launch	Positive interm results
China	Presence	Local study	Larger study	Uncertain timing
Italy	Presence	Early introduction	Active	Representation in place
Benelux		Target/Presence	Early launch	Potential presence in 2022
France		Target/Presence	Early launch	Potential presence in 2022
Saudi Arabia			Target/Presence	Early launch
Brazil			Target/Presence	Early launch
Japan			Target/Presence	Early launch
Egypt			Target/Presence	Early launch

Source: Prostatype Genomics, Redeye Research

There have been some significant signs of progress lately. The collaboration with Switzerland's Proteomedix (August 2021) introduces a development collaboration through which we can expect the Prostatype test to be used with Proclarix from Proteomedix. Proclarix is a blood-based test that improves on the PSA test. When using Proclarix (EU approval with CE-IVD), precision improves, especially in identifying patients with actual PCa and improving the ability to exclude PCa (and reducing the number of false positives). The clinical value is probably mainly to reduce the number of unnecessary PCa investigations. Currently, some 50 percent of PSA tests are negative. As a result, there is no cannibalization between the two tests; Proclarix is about reducing unnecessary biopsies (with no PCa) and Prostatype is about reducing unnecessary therapies based on positive biopsies (with PCa and low risk of progression). This non-exclusive collaboration involves both marketing in Europe and US activities as well as future pilot and validation studies.

The UK collaboration with Cambridge Clinical Laboratories (CCL) initiated in August 2021 is also important, and this has recently resulted in the first UK Prostatype order. CCL provides access to networks of labs that are well established and process a wide range of tests. CCL is now also offering the Prostatype test. This first UK order is, of course, good news. CCL can also promote Prostatype to uro-oncological facilities across the UK and Ireland. In late 2021 CCL launched a new PCa test suite including Prostatype, Proclarix, PSA, Select MDX (urine-based mRNA biomarker test), with Prostatype as a post-diagnostics test. The UK market launch is, at this stage, the most advanced for the company, with good prospects for additional sales and orders during 2022. The UK PCa market is also attractive as care there needs to improve. Screening, detection, and treatment in the UK were hit by the COVID-19 pandemic. There are some 64 urologist centers in the UK, with approximately 300 laboratories likely to evolve into some >40 regional lab organizations.

Of course, the US market is crucial both as a premium market with a high incidence rate of PCa and as a relatively homogenous market with access to both private and public payers. There is also a readiness there to accept innovation earlier than in Europe in general. Prostatype Genomics has recently established a US presence, Prostatype Genomics, Inc. The US market includes:

- Some >4,200 urologist centers, around 12 percent of which perform prostate biopsy procedures, and of these just 470 are academic medical centers
- Some 10,700 practicing urologists (AUA 2018), more than 55 percent of whom work in private practices
- A higher concentration in the south east and south west
- Some 260,000 CLIA-certified labs

Prostatype Genomics will not need 510 (k) approval under the current regulations. Its US market access will probably be based on a CLIA waiver; there are some 1,400 tests existing and being used with US CLIA status. Prostatype is a straightforward test based on existing tissues, existing imaging, and existing PCa tests. It will be classed as a waived test rather than a more complex test. CLIA has established three categories of tests: waived tests; moderate complexity tests; and high complexity tests.

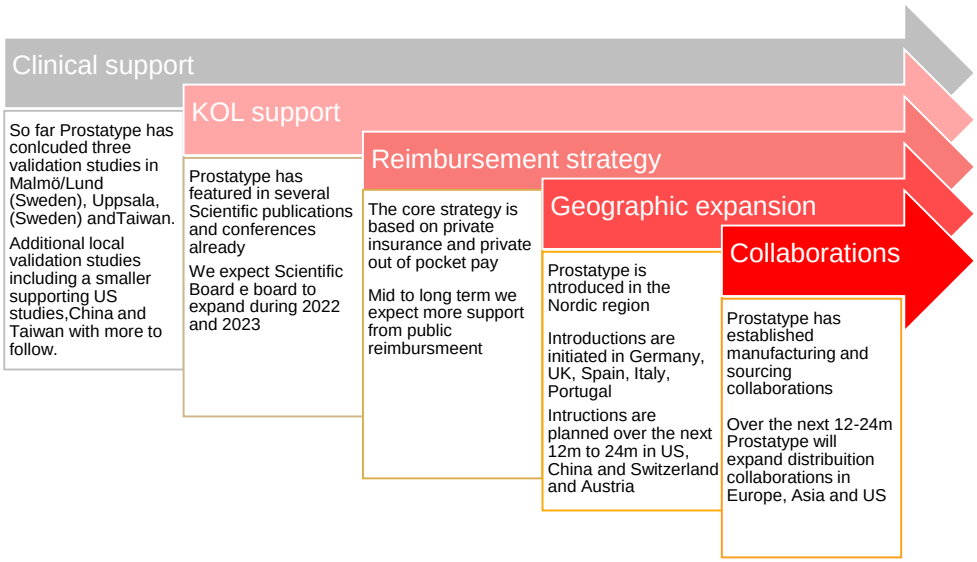
Other comparable tests that are already more established are also classed as CLIA-waived tests, such as the 4K Score, PCA3, Oncotype Dx, and Confirm MDx. All are used based on CLIA.

The CLIA certification requirement will require Prostatype Genomics to gain access to one or several CLIA-accredited labs. The Centers for Medicare & Medicaid Services (CMS) regulates all clinical labs (except research) through the CLIA regulation.

The FDA recognizes a Laboratory Developed Test (LDT) as an in-vitro diagnostics test that is manufactured by and used within a single laboratory (a laboratory with a single CLIA certificate). One lab can cater to many urology centers, and we can expect Prostatype Genomics to secure access to an expanding number of certified labs over the next two to three years. One larger CLIA lab can perform up to 100,000 sample tests per week (including all tests, not just Prostatype). There are larger companies and organizations with access to a network of CLIA-certified labs; one example is Laboratory Corporation of America.

The CLIA-certified lab that collaborates with Prostatype Genomics will need to conclude a new limited validation study to operate as an LDT test. Once validated, Prostatype Genomics can start using the test on US patients. We regard this as a low-risk study supported by the robust results in earlier studies in Uppsala and Malmö/Lund.. An LDT test can be seen as a specific CLIA lab-certified test, and additional labs will require new validation studies. We expect the first validation study to be completed in late 2022, with an early US sales contribution from early 2023.

Company objectives



Source: Prostatype Genomics, Redeye Research

The timing of this US progress is also important since it will reduce regulatory risk. If the Prostatype test is established and used clinically in early 2023, this would also reduce the risk of any changing CLIA waiver and LTD lab regulatory changes. Established tests tend to be accepted under newly modified regulations and can often be allowed to adapt to new rules gradually. There is no imminent pending US regulatory overview, but the prospect of a new LTD regulation has been debated. We regard this as another reason for a fast US Prostatype introduction over the next six to 12 months.

We regard the CLIA/LTD pathway as a regional expansion plan that can allow Prostatype Genomics to establish the Prostatype test in US regions. Actual use will depend on:

- The ability to expand collaborations and secure access to additional US regions
- Securing exposure to and publication at conferences such as the AUA annual meeting in New Orleans (May 13-16, 2022).
- Supporting the Prostatype test with additional positive validation studies and additional heath-economic studies.

Prostatype Genomics is also undertaking good early launch progress in Europe, with expanding presence and access to the Italian, Spain, Portugal, and German markets. These are also the markets where we expect most European support in 2022 and 2023, supported by the Nordic region.

A supporting initial study has already been completed in Taiwan, and the full results can support a collaboration partner there and local market launch in 2023. Prostatype Genomics is also in the process of establishing a collaboration partner for the larger Chinese market. PCa prevalence is modest in Asia, but the large population is a substantial potential future market. Over the next three to five years, it is reasonable to expect China to remain a private pay market in this segment.

We expect Prostatype Genomics to progress in the Nordic regions with a direct sales model on the whole. The added scientific support and improved financial resources after the IPO in late 2020 have improved the Nordic outlook, and we expect improved sales during 2022 and 2023. Following the disruption of the COVID-19 pandemic, we expect an increased throughput of patients testing for PCa. The number of normal patient throughput decreased by some 25-40 percent during the COVID-19 pandemic, both in terms of patients diagnosed and being treated for PCa. This is also in line with or better than many other European countries. The number of patients diagnosed and living with PCa has trebled over the last 20 years in Sweden owing to:

- Increased general live expectancy
- Improved care for late-stage PCa patients
- Earlier detection of PCa.

The increased number of patients living with PCa will put pressure on the healthcare system in Sweden and other similar countries. One way to handle this challenge is to invest in improved PCa testing, supporting risk staging and resulting in a higher level of active surveillance and watchful waiting (involving less regular control and fewer follow-ups than active surveillance).

Our view is that Prostatype Genomics targets an increasingly dynamic, large, and growing market, avoiding competing with different tests that support screening and actual diagnosis of PCa. The market for supporting risk staging and the choice of therapy after diagnosis is, in our view, less competitive but also less well established. The table below illustrates the launch outlook, including Prostatype Genomics' own objectives:

Country rollout and sales objectives from Prostatype Genomics

Launch and Sales Objectives	2021	2022e	2023e	Comment
Nordic	Active	Active	Active	Organisation in place
Spain	Presence	Early presence	Active	Representation in place
Portugal	Presence	Early presence	Active	Representation in place
Germany	Presence	Local study	Early launch	Representation in place
Switzerland		Preparing	Early presence	Collaboration in place
UK	Presence	Early introduction	Active	Collaboration in place
Ireland	Presence	Early introduction	Active	Collaboration in place
US		CLIA partner	Early launch	Setting up presence
Taiwan	Local study	Introduction	Early launch	Positive interm results
China	Presence	Local study	Larger study	Uncertain timing
Italy	Presence	Early introduction	Active	Representation in place
Benelux		Target	Early launch	Potential presence in 2022
France		Target	Early launch	Potential presence in 2022
Middle East		Target	Early launch	Potential presence in 2022
Prostatype's sales target (SEK'm)		15	60	

Source: Prostatype Genomics, Redeye Research

The UK sales from the CCL network have already started, and we expect follow-up orders later in 2022. We also set a high probability for a contribution from the Nordic and Swiss markets this year. The launch support in 2021 was still impaired by the pandemic, and Prostatype Genomics entered 2022 with its sales momentum at least six months delayed. The company has made very good progress lately, but its 2022 and 2023 targets are probably still somewhat challenging. Our Base Case sits a little lower than these objectives for 2022E and 2023E, see page 54. We base our Base Case sales on a realistic market penetration of the key target markets, as seen in the dynamics in the following table.

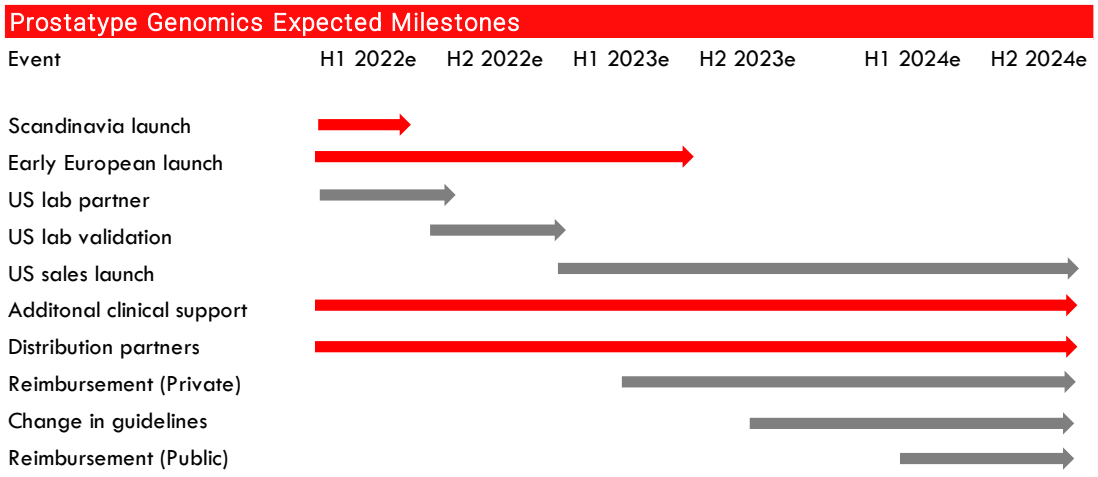
Key market launch and penetration outlook

Region	Population (M)	Growth*	Dx per 100k	New PCa	New Local PCa	Growth
WW	7 935	2,5%	17,8	1 414 259	1 025 338	3,1%
US	330	2,6%	81,5	268 897	194 951	1,3%
EU	447	0,4%	76,1	340 000	246 500	1,5%
China	1 412	9,3%	4,3	60 300	43 718	8,6%
Some Countries						
US	330	2,6%	81,5	268 897	194 951	1,3%
Sweden	10,4	0,7%	105,5	10 919	7 916	2,6%
Norway	5,4	0,6%	101,0	5 433	3 939	2,3%
Denmark	5,8	0,3%	81,5	4 752	3 445	1,1%
Finland	5,5	0,2%	85,0	4 701	3 408	0,8%
Germany	83,2	0,2%	77,0	64 095	46 469	0,8%
Austria	8,9	0,4%	65,0	5 796	4 202	1,5%
Swiss	8,6	0,3%	70,0	6 020	4 365	1,1%
UK	67,2	0,6%	85,5	57 473	41 668	2,3%
France	67,4	0,2%	101,0	68 064	49 346	0,8%
Netherlands	17,4	0,6%	74,5	12 993	9 420	2,3%
Belgium	11,6	0,6%	70,6	8 163	5 918	2,3%
Spain	47,4	0,5%	69,5	32 908	23 858	1,9%
Italy	59,6	-0,3%	75,5	44 960	32 596	-0,8%
Taiwan	23,6	0,2%	31,2	7 350	5 329	2,0%
China	1412,0	9,3%	4,3	60 300	43 718	8,6%
Turkey	84,3	1,1%	35,0	29 505	21 391	4,1%
Japan	125,8	1,1%	84,4	106 139	76 951	4,1%
Brazil	212,0	1,1%	45,9	97 278	70 527	4,1%
Saudi Arabia	34,8	1,6%	6,3	2 193	1 590	6,0%
Egypt	102,3	1,9%	9,5	9 719	7 046	7,1%
Australia and New Zeel.	31	1,5%	62,8	19 282	13 979	2,5%
Total in selected countries				926 941	672 032	

Source: Redeye Research

Our overall market growth expectation is based on a mix of historical growth and the forecast from Datamonitor. As for the US market, our outlook is mainly based on the historical growth level. Sales for 2025E-2030E will require further scientific support, which we expect from additional analytical validation studies. Some of these are already planned or initiated. The US launch is the main sales driver for our outlook for 2025 and beyond. The first step is to secure access to a CLIA-certified laboratory, and then to initiate a lab-centric analytical validation study. The chart below illustrates some of the more important milestones:

Key market launch and penetration outlook



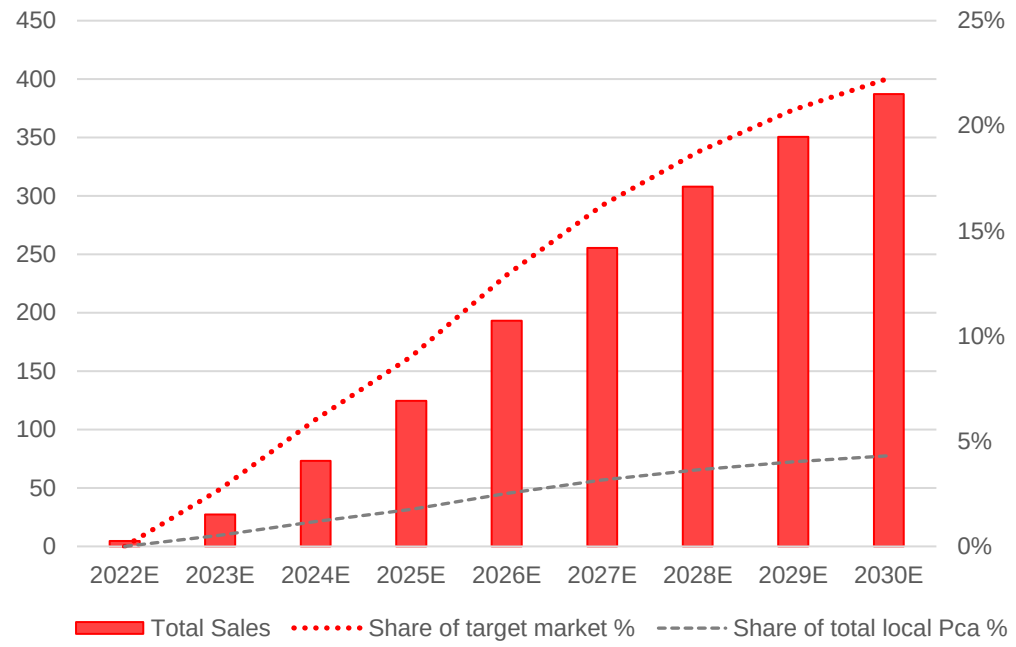
Source: Redeye Research

The Nordic, European and US launches have already been initiated. UK partner CCL has already brought in the first sales there. We are looking forward to sales progress through the Proteomedix collaboration (mainly in the DACH region).

The most important trigger over the next three to six months is the signing of a US CLIA-certified lab and the ability to secure a timely limited validation study. This would imply US sales towards the end of 2022 or in early 2023. Given experience from this lab and clinical use, Prostatype Genomics would be in a good position to expand its US presence and use further, as well as to establish the Prostatype test under the present CLIA regulation.

The following chart illustrates our Base Case in terms of market penetration and the market share of the relevant markets.

Total sales and market penetration to 2030E (SEKm)



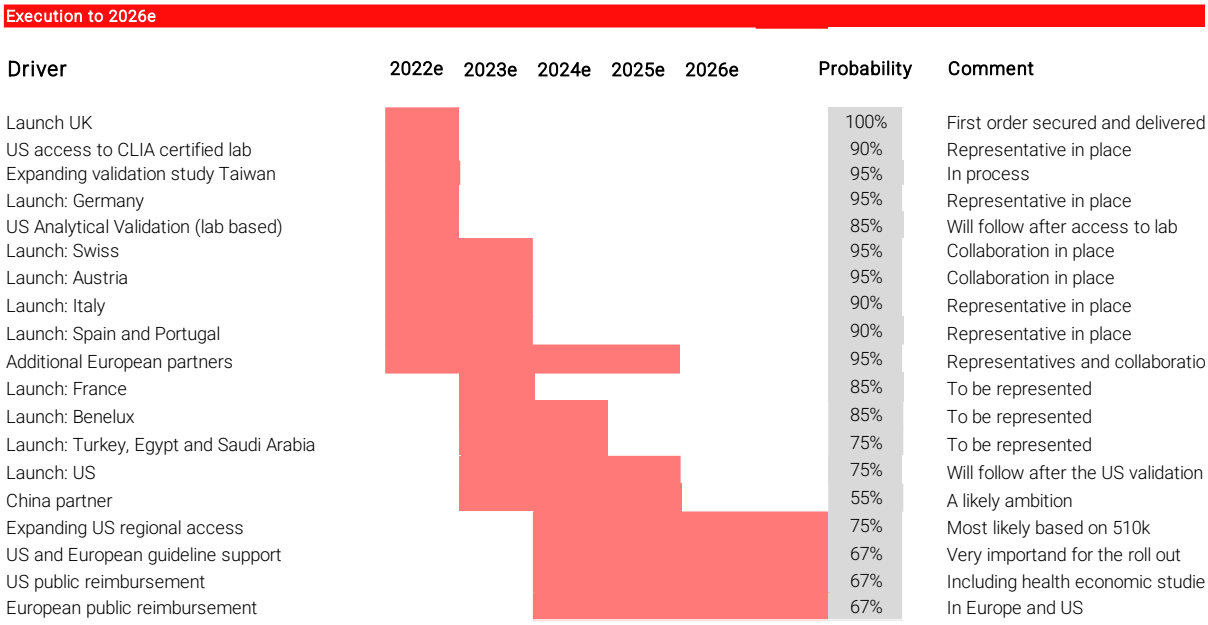
Source: Redeye Research

Our Base Case to 2030E is for sales of SEK 389m, with a growth rate approaching ten percent. This does not include any support from PCa patients with unfavorable intermediate risk or any support from PCa patients taking a secondary biopsy that indicates an increased risk for progression.

If Prostatype Genomics can secure support from US and European guidelines and public reimbursement, this support for our Base Case is probably overly conservative. The prospects for securing this are good, considering that tests such as Oncotype Dx and Decipher have both some public reimbursement and support from guidelines. Without any public reimbursement support and guideline recognition, our Base Case would probably be overly optimistic, especially after 2026E.

The main risks are delays, the timing of future additional collaborations, and a lack of financial resources to convert good prospects into reality. The chart below illustrates our view on the risks relating to key milestones after associating probabilities with some key milestones.

Market rollout to 2026E (SEKm)



Source: Redeye Research

Even if Prostatype Genomics successfully establishes market access, the future level of penetration will depend on its ability to repeat and expand the scientific support further. This will partly depend on financial resources combined with its ability to secure support from strategic collaborations that are willing to support additional studies. The absence of forward-looking clinical studies based on new patients is not relevant in these setting, in our view. Retrospective studies supporting an improved ability to assess the future or follow actual risk will be enough in this space. It can take five, ten, 15 or even 20 years for the actual risk to materialize.

Savings and clinical advantages will matter for future market shares. Note that for the intermediate-risk group of patients, the savings in the table above hide the fact that the higher-risk of this intermediate group heads into surgery at a higher cost, and the favorable intermediate-risk group should go into active surveillance. The savings in the favorable intermediate group alone should be distinctly positive, considering that the cost of robot-assisted surgery is nearly USD 12,000 per procedure (range of USD 3,000-26,000 in the US) and the cost for active surveillance is USD 1,100. So far, the standard of care is still biased toward surgery in favourable intermediate-risk groups, even if there is a clear and slow shift toward active surveillance. More frequent use of assisting tests such as the Prostatype can contribute to this shift.

An indicative overview of potential savings and improved quality of life

Therapy	Type	Initial (USD)	Annual (USD)	Side effects
Radiation Therapy (RT)	Combination	34 000	800	Substantial
Adjuvant RT (aRT)	Combination	29 000	800	Moderate
Prostatectomy (PT)	Definitive	10 000	800	Substantial
Androgen Deprivation Therapy (ADT)	Preventive	3 000	3 000	Moderate
Combination (PT, RT and ADT)	Combination	High	800	Substantial
Active Surveillance (AS)	Regular	Low	1 100	Minimal
Monitoring	Regular	Low	800	Minimal

Savings	Year:	1	1-5	0-10	Comment
LR (USD)		6 900	4 270	5 039	QoL and economic benefi
IR (USD)		400	-1 354	-1 363	QoL benefit
Overall (USD)		3 991	1 713	2 129	QoL and economic benefi

Therapy	Risk	Initially	After 1 years	After 5 ye
AS	LR	69%	59%	36%

Source: Redeye Research

The clinical alternatives and the competition are also important to consider. The list below includes some of the more established tests for screening, diagnostics, and PCa risk-staging. Many of these are biomarkers, and most target the screening and diagnostics parts of the process.

It is very important to understand the difference between diagnostics and a supporting prognostics test/biomarker such as the Prostatype. Some more established tests have been studied in both diagnostics and prognostics settings, and typically their precision is significantly lower in prognostics. This is perhaps what we should intuitively expect.

Diagnostics relate to a static situation, whereas prognostics are associated with a dynamic current and future process. This is probably one reason why the Prostatype test performs relatively well: it adds information based on RNA extraction, and RNA tends to be a more relevant base when assessing the dynamic aspect.

Alternative and related tests

PCa tests/tools	Type	Stage	Established	Precision
Patient profile	Characteristics	All	SoC	Limited
PSA	Serum (blood)	Screening, Dx, Staging	SoC	Limited
DRE (rectal examination)	Manual	Dx, Staging	SoC	Limited
MRI or mpMRI	Image	Dx, Staging	SoC	Useful
Biopsy	Biopsy	Dx, Staging	SoC	High
PHI	Serum	Screening, Dx	Supporting	Limited.
4K Score	Serum	Mainly Dx	Supporting	High
PCMT	Biopsy	Dx	Supporting	Moderate
Select MDx	Urine gene based	Dx	Supporting	High
PCA3	Urine	Dx	Supporting	Moderate
Confirm MDx	Biopsy	Dx	Supporting	Moderate
ExoDx Intelliscore (EPI)	Urine gene based	Dx	Emerging	Moderate
Prolaris	Biopsy	Prognostic	Supporting	Robust
Oncotype Dx	Biopsy	Prognostic	Supporting	Moderate
Decipher	Genomic, biopsy, tissu	Prognostic	Supporting	High
ProMark	Biopsy	Prognostic	Supporting	Moderate
PTEN	Biopsy	Diagnostic/Prognostic	Emerging	Unclear
Prostatype P-Score	Biopsy	Prognostic	Emerging	High

Source: Redeye Research

There are, however, some biomarkers that are partly established and recognized, such as Prolaris, Oncotype Dx, and Decipher. These tests are also recognized in the US guidelines (NCCN). They have either some public reimbursement or private reimbursement (as indicated in the Blue Shield Cover, which is relevant for a significant minority of Americans). Most of these tests have also been introduced based on CLIA regulation rather than the FDA's 510 (k) pathway, even if Prolaris is FDA-approved and Oncotype Dx is included in both the NCCN and the ASCO guidelines as a prognostic genomic assay. Both these tests are priced in excess of USD 3,000 on the US market. Prostate and cancer guidelines are updated regularly, and with more scientific support and established clinical experience, we believe the Prostatype test has a good opportunity of joining the guidelines over the next two to four years.

The use of prognostic biomarkers or genomic assays will rise with the increasing use of active surveillance and of PSA screening tools. More patients will be diagnosed with local early or intermediate-risk PCa, and a large proportion of these patients will be both willing and able to finance a reliable prognostics risk test to support their critical treatment decision.

There is an understandable and rational skepticism towards general PSA-based screening of men aged above 50 or 55 since general screening results in both a high level of unnecessary biopsies and MRI scanning despite actually missing a majority of PCa cases (failed screening, in this respect). There is a trend towards increased use of screening financed either privately or by public reimbursement. In many countries, it is enough to proactively argue for a PSA test that will be financed publicly. This trend contributes to increase the number of actual PCa cases, a large majority will have 95-98 percent relative life expectancy (this differs between countries).

Once patients are screened and diagnosed correctly, there is a different and, in our view, more straightforward argument for using a prognostics test to support the treatment decision:

- There is a strong life quality argument to improve risk staging
- There is a clinical argument for improving risk staging
- If the test has sufficiently high precision, there is a strong argument for both private and public reimbursement to improve risk staging

A significant minority are also likely to consider private, out of pocket pay based on robust scientific support and increased awareness of testing.

Our View on Sales and Financials

Prostatype Genomics has a good opportunity to support patients and professionals ahead of the necessary decision to commit to the most appropriate therapy. This is a straightforward decision for only a small minority of patients; for a majority, this is a decision based on insufficient information or, to be more precise, an initial indication that is at best correct in two cases out of three.

The fact that general relative life expectancy with PCa can be >95 percent does not diminish the trauma associated with the decision by a patient to expose themselves to a small and distant risk of PCa progression balanced against a very substantial and often immediate risk of reduced quality of life. Many will be prepared to dig into their own pockets for valid support and a solution to this dilemma. The table below illustrates our base case for support from the countries we include in future sales forecasts for Prostatype Genomics at this stage.

Potential contribution from countries to 2030E

Sales	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US	0	6	30	53	89	115	138	152	165
Nordics	0	1	1	2	4	5	5	6	7
Germany	1	3	6	10	14	18	21	22	24
UK	2	5	8	11	15	20	23	25	27
France	0	3	7	9	10	12	13	15	16
Italy	1	3	6	8	11	14	15	16	16
Spain	1	6	7	9	11	13	15	16	17
Austria	0	0	1	1	1	2	2	3	3
Swiss	0	0	1	1	1	2	2	3	3
Netherlands	0	0	1	2	3	4	5	6	7
Belgium	0	0	0	1	1	2	3	3	4
Taiwan	0	0	1	1	1	2	2	2	2
China	0	0	1	3	6	9	12	17	21
Turkey	0	0	1	2	3	4	5	7	7
Japan	0	0	0	4	9	15	21	25	29
Brazil	0	0	0	5	8	13	17	22	25
Saudi Arabia	0	0	0	0	0	0	1	1	1
Egypt	0	0	0	1	2	2	3	4	6
Australia and New Zeeland	0	0	1	2	3	5	6	7	8
Total Sales	5	27	74	125	194	257	310	352	389
- Growth %		*475%*	*168%*	*70%*	*55%*	*32%*	*20%*	*14%*	*10%*
Share of total local Pca %	0%	1%	1%	2%	3%	3%	4%	4%	4%
Share of target market %	0%	3%	6%	9%	13%	16%	19%	21%	22%

Source: Redeye Research

Our Base Case for 2022E and 2023E is modest compared to the company's previously stated ambitions. Still, the impact of COVID-19 and the only gradually expanding network suggests that commercial execution has been delayed by at least six months compared to its ambitions of late 2020 and early 2021. The progress made during the past six months suggests that Prostatype Genomics has regained some good momentum into 2022, though.

Some milestones are very important in the near term. We point to the UK follow-on orders later in 2022, which would validate the potential support from its partner, CCL. This is also an important reference customer for future expansion in the UK and elsewhere in Europe. CCL is currently in the process of rolling out a new PCa test suite to service the UK's NHS, featuring the Prostatype test. The signing with CCL and the first order of SEK 0.24m is already very positive, in our view, as CCL only accepts tests it can comfortably handle to comply with the EQA (External Quality Assessment) standard and genomic testing is central to its growth ambitions.

In Europe and the US, other larger laboratory companies and organizations offer a wide range of clinical test solutions, including NeoGenomic, Labcorps, Quest Diagnostic, OPKO Health (Bioreference Lab), German Limbach group, Unilabs.Synlab, Sonic Healthcare, Cerba Healthcare, Biogroup, and Group Innovie. Prostatype Genomics has opportunities to expand by approaching urologists and urology oncologists (fellowships) country by country, as well as through additional collaborations such that with CCL and Proteomics.

The US market is very important, in our view; sales on the US market account for 40-46 percent of future sales for 2026E-2030E in our Base Case. The first step to unlock this potential is to secure access and support from a CLIA-rated lab, followed by executing a limited, lab-specific validation study before the lab can start processing clinical and commercial tests in order to:

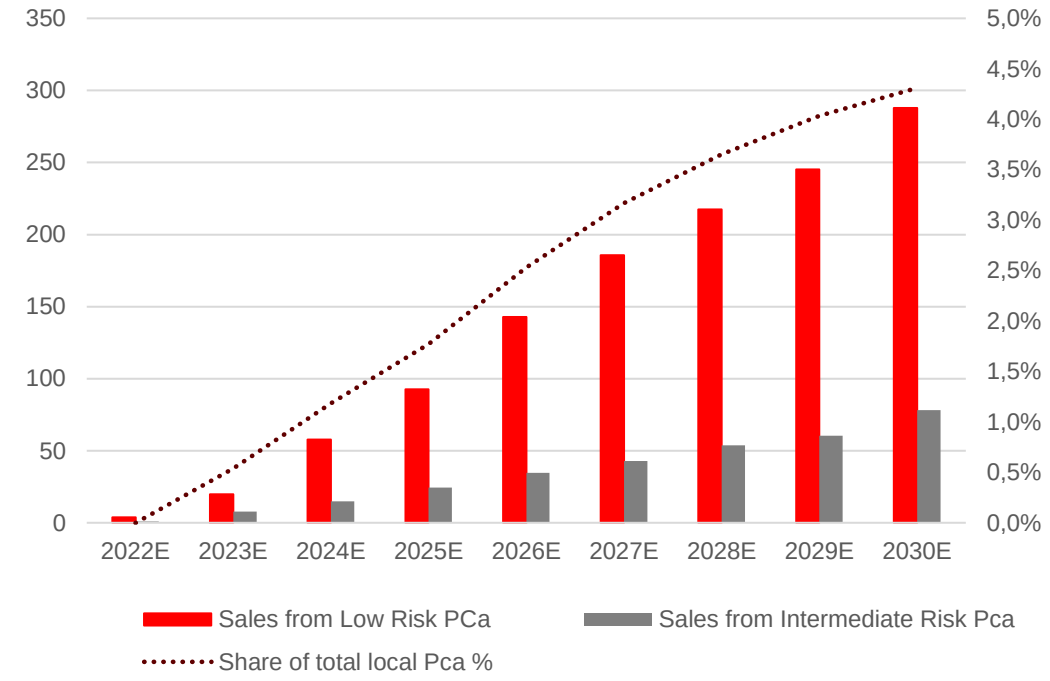
- Secure sales momentum,
- Increase awareness
- Offer additional study support
- Establish US reference labs
- Establish a base from which Prostatype Genomics can expand its sales organization
- Secure additional US partners

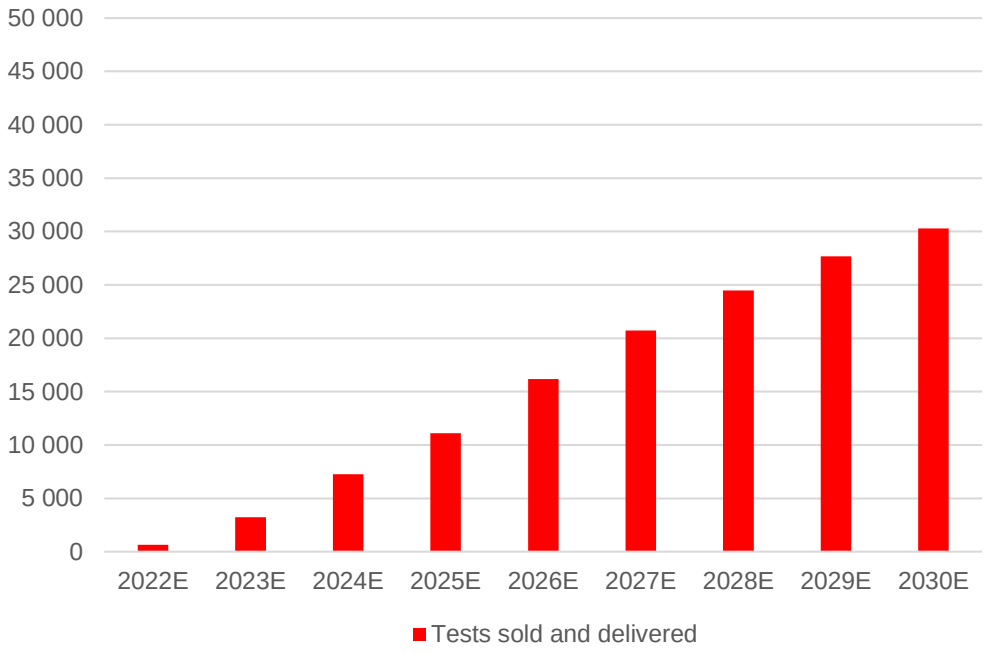
This process is also likely to reduce the US regulatory risk. The CLIA and LDT pathway can be subject to a regulatory overview over the next five years, although this is probably higher risk for new and less established tests. During these processes for regulatory changes, established tests can sometimes be grandfathered into the new system or be allowed a generous transition period. We also point to the opportunity to expand the US network at the AUA (American Urology Association) annual meeting (May 13-16, 2022), at which the Prostatype test will be featured with the presentation of the recent Uppsala study results.

In the Nordic region, Prostatype Genomics plans to sell directly and process the tests at its own laboratory. Ulrika Flock, Head of Nordic Sales as of 2021, brings extensive experience from Sigma-Aldrich, Quiagen, and TrioLab, along with a broad and particularly relevant network of regional urologists. Thanks to the support from the published Malmö and Uppsala studies, we expect Nordic sales to pick up during 2022.

The primary market is low and intermediate risk PCa patients, in line with both the current standard of care and the guidelines. The Prostatype test should reclassify some patients intermediate to low risk, as indicated by the two studies in Sweden and the initial study in Taiwan. This is one reason why we include some support from intermediate-risk PCa patients, the other reason being the increasing evidence that patients classified with favourable intermediate-risk PCa also have a very low risk of PCa progression. This group will also benefit from enrolling in active surveillance without any meaningful increase in the risk of the disease's future progression. The following graph shows our Base Case sales split between low-risk and favorable intermediate-risk PCa until 2030E.

Potential contribution from the patient segment to 2030E





Source: Redeye Research

The core low-risk PCa market represents 70-78 percent of sales versus intermediate risk in our Base Case. The contribution from the intermediate-risk group is less certain, especially initially, in our view. Still, part of this contribution is the result of the use of the Prostatype test reclassifying a large majority of patients from intermediate to the low-risk group. This proportion was in excess of 75 percent in the Malmö study. Another way to look at this is that 43 percent of patients in

these two groups were reclassified. Three out of seven patients paying for the Prostatype test are recommended to switch. More than two of three of these (76 percent) will be recommended for safe active surveillance, protecting their current quality of life.

This is both a strong argument for using the Prostatype test and explaining why we include some support from the intermediate-risk group. Approximately 50 percent of these can safely be reclassified into the low-risk group, which also implies an increasing body of scientific support. A very significant proportion of patients initially staged as favourable intermediate-risk PCa has a very low risk of future PCa progression. Our potential intermediate-risk group contribution in our Base Case could thus prove quite conservative.

Alternative scenarios for our key value drivers (SEKm)

Sceanrios	Base	Bull (+)	Bear (-)
Prostatype Price	3 625	10%	-20%
Relevant Private Pay LR Market (%)	50%	15%	-15%
Relevant Private Pay IR Market (%)	33%	10%	-10%
Prostatype Potential Market Share LR (%)*	40%	15%	-15%
Prostatype Potential Market Share IR (%)*	15%	10%	-10%
US Market Share			
- US: LR	23%	10%	-10%
- US: IR	12%	10%	-8%

Source: Redeye Research

When we change some of our key value drivers, we get a better understanding of the sensitivity to the future price of Prostatype, the penetration of the low-risk PCa group, and the readiness to pay for a prognostics test privately:

- A ten percent increase in the overall Prostatype price increases EPS by 16 percent in 2030E.
- A 15 percent reduction in the proportions of patients willing to pay privately reduces EPS by 38 percent
- A ten percent increase in the US low-risk market share increase sales by ten percent for that country and overall sales by 16 percent in 2030E

One interesting opportunity is the very real future market of patients undergoing a second or a third biopsy after having started on active surveillance. This market will increase as more patients opt for active surveillance. A large proportion of the patients now progressing to directed treatment could safely stay on active surveillance if using a reliable risk assessment marker such as Prostatype. The primary market is urologists (private), but Prostatype is probably also relevant for a proportion of the pathology segment.

P&L overview to 2025E

Income Statement	2021	2022E	2023E	2024E	2025E
Sales	2,5	8,1	31,5	77,9	129,1
Growth (%)		224%	287%	147%	66%
Cost of Revenues	-0,3	-0,9	-3,1	-7,0	-10,3
Gross Profit*	2,2	7,2	28,3	70,9	118,8
Gross Profit Margin (%)	88%	89%	90%	91%	92%
Research and Development	-1,5	-3,1	-4,9	-8,3	-12,7
Staff Cost	-8,0	-13,9	-21,7	-34,9	-40,8
Other External cost	-8,5	-9,8	-13,1	-17,8	-24,1
Other Op. Expense / (Income)	0,0	0,0	-1,2	-1,8	-2,4
EBITDA	-15,5	-19,2	-12,6	6,9	36,1
EBITDA Margin (%)		-236%	-40%	9%	28%
Amortization	-0,1	-0,5	-2,1	-3,0	-4,1
EBIT	-15,6	-19,7	-14,7	4,0	32,0
EBIT Margin (%)	-620%	-242%	-47%	5%	25%
Interest Income	0,0	0,0	0,0	0,1	0,2
Interest Expenses	-0,1	-0,1	-0,3	-0,4	-0,4
EBT	-15,6	-19,8	-15,0	3,6	31,8
Income Tax Expenses	0,0	0,0	0,0	0,0	-6,5
Effective Tax Rate (%)	0,0%	0,0%	0,0%	-20,6%	-20,6%
Net Income	-15,6	-19,8	-15,0	2,9	25,2
Recurring Net Income	-15,6	-19,8	-15,0	2,9	25,2
Net Income Margin (%)	-623%	-243%	-48%	4%	20%
EPS	-1,0	-0,9	-0,7	0,1	1,2

** Adjusted for capitalized development cost*

Source: Redeye Research

Our Base Case for sales of SEK 8.1m in 2022E increasing to SEK 31.4m in 2023E is approximately is below Prostatype Genomics' earlier ambitions. We regard our sales expectations as achievable but far from undemanding. Prostatype has initiated sales in the UK, and early repeat orders and support from the Nordic region, Spain, and the DACH region will be required early on. These are also the markets where Prostatype has established collaborations, representation, and sales. In the UK, its partner, CCL, is offering Prostatype in a suite of prostate cancer tests. We can expect Prostatype Genomics' Swiss partner to offer Prostatype together with Proteomedix's Proclarix test. Two tests can sometimes add to the precision (a synergistic combination of tests is sometimes referred to as "multiomics") and thus improve the market access.

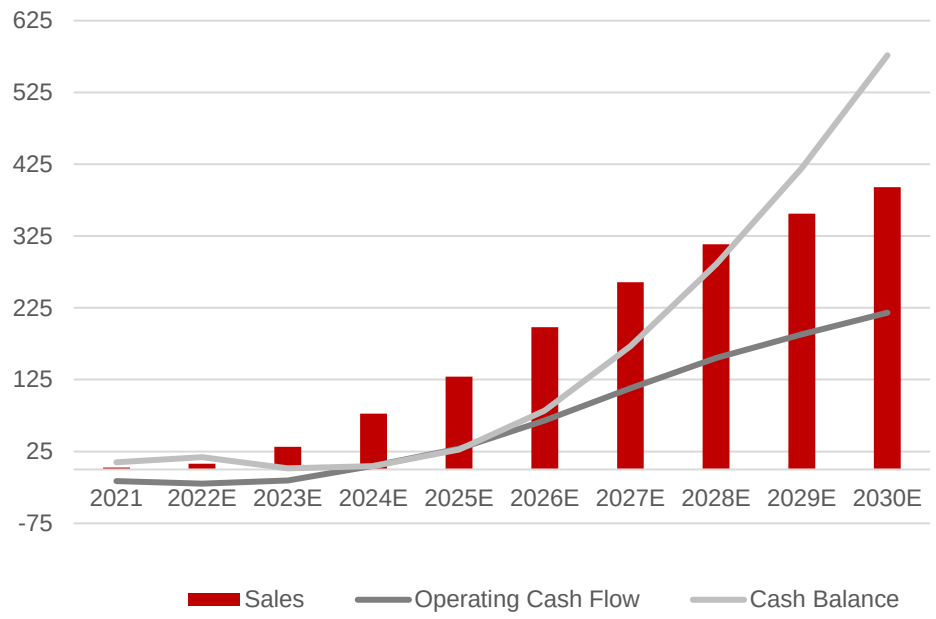
Prostatype's gross margins in the US will be considerably above the European gross margins, and the increasing volume support from the US launch in 2023E will contribute to higher gross margins after this point. Our other opex forecasts are probably conservatively high, and if and when Prostatype can secure additional commercial partners in key markets, we are likely to reduce our operational cost expectations.

Cash position and optimistic cash flow estimates

Prostatype ended Q4 2021 with some SEK 9.8m in cash and SEK 10.5m in liquid short-term assets. 2022E and 2023E represent two years of market access and future growth investments. We expect Prostatype to break even in terms of cash and EBITDA towards the end of H2 2023E. As a result, we expect Prostatype to raise additional growth capital in late 2022E or early 2023E. Our policy is to include this when it is likely within one to two years. In our Base Case, Prostatype adds SEK 30m of growth capital at a 30 percent discount to the current share price, increasing the number of shares. Given the progress made over the past six months and the positive reaction on the back of the UK order, we see a likelihood for a positive stock revaluation, reducing the dilution from the additional required growth capital.

Considering Prostatype's attractive position, the recent positive news flow, and the anticipated significant sales ramp-up, we judge that investor interest can be high despite the overall equity market conditions and even though we do not rule out a directed share issue to finance its plans. In our view, a directed share issue should even be considered a potential catalyst for the share if Prostatype can continue to execute on its commercial rollout during 2022E. The chart below illustrates our Base Case operating cash flow and the company's cash position through 2030E.

Our Base Case sales, operating cash flow and the company's cash position through 2030E (SEKm)



Source: Redeye Research

Competitive Landscape

Prostatype's competitive advantages and alternatives

For most patients, the alternative is no support from sufficient prognostics tests or biomarkers. All patients diagnosed with local PCa will, typically together with their urologist, face the decision to commit to therapy or sometimes the absence of active therapy. All patients will also be informed based on the result of the diagnostic process.

Diagnostic staging is, even if correct, not a reliable prognosis in terms of the future risk of PCa progression. It is simply a snapshot or a still image (also literally) that offers limited information regarding the dynamic process, especially for less advanced PCa.

Together with patient characteristics, PCa staging provides a general guideline but with very poor precision in individual cases. For many (probably most) patients, the alternative to the Prostatype test is to take this decision without any additional prognostics support.

Some tests and biomarkers can be used but most support the diagnostics process. One limitation is that most of these tests tend to have reduced sensitivity and specificity (sometimes more adequately referred to as AUC, ROC, or predictive power) in the prognostics setting. In this category, we point to established tests such as:

- Select Dx from MDx Health (US)
- 4K Score from Opko Lab (US)
- Confirm MDx from MDx Health (US)

The advantage is that these are well established, covered by guidelines, included in reimbursement, and supported by extensive scientific support. Such tests can often be seen as more advanced PSA tests with low price points (USD 100-350). However, all this relates to the diagnostics setting. As a result, these tests are less relevant in terms of actual relevant competition, but they can hinder the speed of the Prostatype test's acceptance and future market penetration. We list the more relevant tests below, including if they are reimbursed and covered by guidelines.

Supporting, competing, and emerging tests

PCa tests/tools	Approval/Guideline/Reimburse	Stage	Established	Precision
Patient profile		All	SoC	Limited
PSA	Yes	Screening, Dx, Staging	SoC	Limited
DRE (rectal examination)	Yes	Dx, Staging	SoC	Limited
MRI or mpMRI	Yes	Dx, Staging	SoC	Useful
Biopsy	Yes	Dx, Staging	SoC	High
PHI	FDA/Yest/Partly	Screening, Dx	Supporting	Limited.
4K Score	CLIA/Yes/Private	Dx	Supporting	High
PCMT	FDA/No/No	Dx	Supporting	Moderate
Select MDx	FDA/Yest/Partly	Dx	Supporting	High
PCA3	CLIA/Yes/Private	Dx	Supporting	Moderate
Confirm MDx	CLIA/Yes/Private	Dx	Supporting	Moderate
PTEN	No	Dx	Not in PCa prognostic	Unclear
ExoDx Intelliscore (EPI)	CLIA/Yes/Private	Dx	Emerging	Moderate
Prolaris	FDA/Yes/Yes	Prognostic staging	Supporting	Robust
Oncotype Dx	CLIA/Yes/Yes	Prognostic	Supporting	Moderate
Decipher	CLIA/Yes/Partly	Prognostic	Supporting	Moderate
ProMark	CLIA/Yes/Partly	Prognostic	Supporting	Moderate
Prostatype P-Score	CLIA/No/No	Prognostic staging	Emerging	High

Source: Prostate Cancer Outcome Registry Australia and New Zealand

Only a handful of tests can be used for prognostics support with the level of precision that is relevant in this setting. The precision of these more relevant tests can vary among patient groups, patient characteristics, and tumor stages. In this group, we point to tests such as:

- Prolaris from Myriad Genetics (US)
- Oncotype Dx from Exact Science (US)
- Decipher from Genome Dx (US)
- ProMark from Metamark (US)

Tests with prognostics values are typically far beyond the less advanced urine or serum-based test and are instead molecular tests or prognostics tissue biomarkers, like the Prostatype test.

Decipher (CLIA-certified) is mainly used to prognose the risk of recurrence after surgery and is not a decision tool directly after the first PCa diagnostic. If publicly reimbursed (Medicare), the test must be used within the guidelines to claim public reimbursement.

The Oncotype Dx test from Exact Science is based on RNA and comes with a price tag (list price) of USD 4,100. It is also CLIA-certified. The results take approximately two weeks (compared with one to two days with the Prostatype test). The scientific support for Oncotype Dx in the prognostics setting for low- and intermediate-risk PCa patients is still limited. To improve future acceptance, studies supporting its clinical use and switching patients, combined with clinical benefits, are probably needed. The indicative AUC (precision) is moderate at 0.69-0.79, but this is in a patient setting where active surveillance was used after surgery (second-line active surveillance).

ProMark can also be used to support risk stratification. There is scientific support for an indicative precision for AUC of 0.61-0.74, which is a moderate level of precision. The list price is USD 3,800, and the test is CLIA-certified with guideline support and private reimbursement.

Prostatype and Prolaris are probably the most relevant tests in prognostic risk-staging, and we regard Prolaris as the most relevant competition and comparable test. The Prostatype test has early scientific support that suggests it could be very competitive in terms of precision. Prolaris has the advantage of an established price point (USD 3,500-4,000 per test) and being covered by guidelines (FDA approval from 2013). Prolaris makes ambitious claims regarding the ability to switch patients to active surveillance and away from Rt and surgery. Perhaps more importantly, Prolaris is supported by an extensive body of evidence, mainly based on retrospective studies supported by indirect evidence of professionals switching patients in clinical practice. As with other tests and candidates in this area, it is not possible to undertake prospective randomized studies. The Prolaris test sold USD 25m in 2020. This is in line with what we expect from Prostatype on the US market by 2030E, assuming its ability to replicate the scientific support to date in additional larger studies.

In summary, this segment has been proven, with an established path to the market either through CLIA certification or via the FDA route. Guidelines already recognize this opportunity. List prices range from USD 3,400 to USD 4,250 on the US market.

Valuation

Our indicative DCF Base case value range is SEK 21-23 per share

Prostatype Genomics has advanced the Prostatype test to the early launch stage. Scientific support, European approval, and the US approaching CLIA certification (including the validation study) are all in the process of being completed later this year. Collaborations and representations are in place for several key markets and the prostate cancer market has matured to a stage where a test such as Prostatype is likely to be in demand for a larger group of patients, including a larger proportion of patients initially staged with intermediate-risk PCa.

At this stage, ahead of volume sales, we prudently set a WACC of 12.3 percent and a capital structure with 100 percent equity funding. Together with our Base Case for future growth through 2030E, our DCF value is thus SEK 22 per share, as shown in the table.

Our DCF value

DCF-Valuation					
Return on Equity	12,3%	Growth f'cast 22e-26e, CAGR	122%	rNPV forecast period, SEK'm	404
Equity Risk Premium	7,5%	Growth f'cast 26-3e, CAGR	19%	rNPV terminal, SEK'm	139
Risk free rate	2,5%	Long Term growth	2%	Net cash, SEK'm	19
Prostatype Beta	130%	Long Term EBIT-margin	15%	Shareholder value, SEK'm	562
Tax rate	20,6%			Capital Required , SEKm*	30
Rate of Equity funding	100%			Number of shares (diluted)	26,7
WACC	12,3%				
Corporate cost of Debt	6%			**Value per share, SEK**	**22**

** Assumed additional future required equity funds*

Source: Factset, Redeye Research

Our Base Case also includes an increase in growth capital of SEK 30m (net) in late 2022 (could also be early 2023). We apply a 30 percent discount to the current share price and the resulting dilution from the increased number of shares is approximately 37 percent. The real actual dilution will depend on:

- Prostatype Genomics' commercial and clinical progress over the next six to nine months, for which we have a positive outlook
- The general stock market, for which we have no firm view on its recovery prospects during 2022. The current level of uncertainty will eventually improve to more normal levels, though.

The company can also engage in collaborations and partnerships that could contribute financially directly or indirectly (reduced investment requirements), which can have an impact on the growth capital. We see good prospects for future collaborations in both US and Europe.

The company's ability to secure a US commercial launch will probably be the most important value driver during 2022 and 2023, in our view. To succeed and compete on the US market is important financially and is the best "boot camp" for global progress. In a reasonably positive scenario, the company's value proposition is significantly higher than our SEK 21 Base Case both because the WACC improves as execution risk diminishes and because a financially strong company can operate with a more efficient capital structure with a less equity funding.

A successful diagnostics or testing company will also have good opportunities to secure future innovations or collaborations that extend its actual patents. For now, we apply a very low terminal growth combined with slashed terminal margins. The collaboration with Switzerland's Proteomedix is an early example of a collaboration that could evolve in this direction.

Relative value support as early as 2023E and 2024E

We have also considered the peer valuation environment. One challenge is that most listed international companies tend to be significantly larger and several of these tend to grow through acquisitions. This is also an opportunity for Prostatype Genomics, in our view. Its test could prove very useful combined with diagnostics tests and other complementary tests offered to urologists, pathologists, labs, and oncologists at different stages by larger companies; even more so if Prostatype can secure an early volume launch in both Europe and the US by 2023.

The following table provides an overview of some relevant comparable companies using 2025E forward EV/sales. The diagnostics, bioassay, and test segment has quite high multiples, reflecting its high growth and strategic importance driven by a shift towards specialist and personalized medicine. This is also a dynamic that Prostatype Genomics can take advantage of.

Relative valuation compared with regional and international peers

Company	Market Cap (SEKm)	EV/Sales	2022'e	2023'e	2024'e	2025'e
Accelerate Diagnostics	738		8,5	5,8	-	-
Biovica	1 002		23,3	12,0	4,3	1,7
bioMerieux	121 869		3,6	3,4	3,2	3,0
CareDx	18 451		4,7	4,1	3,7	-
Diasorin	79 475		6,4	5,5	4,7	4,3
Exact (USDm)	110 791		6,4	5,5	4,7	4,3
Immunovia	913		10,1	5,4	1,5	0,6
MdxHealth	1 116		2,7	2,7	2,7	2,7
Myriad Genetics	17 808		2,3	2,2	2,1	2,0
Qiagen	105 312		5,9	5,7	5,3	4,9
Q-linea	3 330		27,6	10,2	4,8	4,7
Veracyte	17 356		5,9	4,9	4,0	3,1
Average	39 847		9,0	5,6	3,4	2,6
Median	17 582		6,2	5,4	4,0	3,1
ProstaType Genomics	120		32,9	6,5	2,4	1,2
- Premium to average (%)			*268%*	*16%*	*-29%*	*-52%*
- Premium to median (%)			*433%*	*20%*	*-40%*	*-60%*
The five smaller companies						
Average	1 420		14,4	7,2	2,6	1,9
Median	1 002		10,1	5,8	3,5	2,2
- Premium to average (%)			*128%*	*-10%*	*-8%*	*-36%*
- Premium to median (%)			*225%*	*12%*	*-30%*	*-44%*

Source: Factset, Redeye Research

Relative to the overall group of 12 companies, Prostatype already receives relative value support by 2023E-2024E. We expect the company to reach break-even during 2023E, with the growth rate maturing from the initial elevated rate by 2025E-2026E.

The relative value compared with the five smaller companies is perhaps more relevant, especially as three of these companies are, like Prostatype Genomics, regional companies (Biovica, Q-linea, and Immunovia). The EV/sales multiples for this subgroup are higher for 2022E-2023E but lower for 2024E-2025E, which is also the case for Prostatype Genomics. We find support from both the relative and DCF valuations, but the key to this upside is, of course, execution and the successful rollout of Prostatype in key markets during 2022 and 2023.

Scenario Analysis

We list some of our most central value drivers. Changes in these would also provide a better understanding of the risks and uncertainties Prostatype Genomics faces over the next five years. The table is somewhat simplified. The list price filters down to changes in the net price in our sensitivity scenario. A different list price can partly be offset by a different rebate or a different distributor margin.

Our base case for the key value drivers

Redeye key value drivers	Base	Comment
Prostatype list price (USD)		
- *US*	3 625	This is an established price range for comparable tests
- *Europe and other afluent*	1 631	We expect the list price to differ between countries
- *Other relevant*	1 269	Significant variations
2030e target market		
Low risk		
- Potential private pay	50%	The rate can be expected to increase over time
- Prostatype potential market share 2030	40%	To 2030e we Prostatype achieves 20-35% in our base case
Intermediate Risk		
- *Potential private pay*	40%	The rate can be expected to increase over time
- *Prostatype potential market share 2030*	15%	To 2030e we Prostatype achieves 10-15% in our base case
US Penetration of target market		
- Low Risk	23%	With guideline and scientific support we expect this to increase
- Intermediate Risk	11%	With a larger commercial partner we expect a higher penetration
Public regulatory support		
Guideline support	Limited	This is a possitive likely trigger
Public Reimbursement support	Limited	This is a possitive potential trigger

Source: Redeye Research

During our forecast period, most or almost all sales come from private pay—either private insurance pay or private out-of-pocket pay. As a result, the proportion of new PCa patients relevant for this private market is an important variable in the acceptance of additional tests among private insurance companies. We believe the company has a good opportunity to secure additional support from guidelines and public reimbursement two to three years after the US launch or as early as from 2024-2025. The following table illustrates different scenarios based on some key value drivers.

The impact of some different scenarios on our Base Case

		Test Price variations %		
	WW	-10%	Base	+10%
Private pay acceptance Low Risk Pca %	+15%	20	28	38
	Base	14	22	24
	-15%	8	12	15

		Prostatype LR Market Share %		
	US	-10%	Base	+10%
Prostatype IR Market Share %	+10%	19	24	28
	Base	16	22	25
	-8%	14	18	23

Source: Redeye Research

The Prostatype test's future market sensitivity above is probably understated in this illustration. This is probably true for both the positive and the negative scenarios. The main reason is that our illustrative opex cost does not fully reflect the changed top line above. If the future Prostatype price diverges considerably, a larger part of the change would impact the cash flow and the bottom line than the percentage of top-line change. It would be more difficult to accommodate a reduced top line and opex would increase by a smaller percentage in the event of a more positive top line. In short, opex is likely to be less flexible, resulting in increased sensitivity in both the short- and medium-term outlooks.

Bear Case: SEK 5

We assume a slow gradual sales launch in Europe and the US. We also assume that a small proportion of PCa patients will be prepared to finance the Prostatype test privately. In this scenario we also assume that professional urologists will require more scientific support before committing to Prostatype. We use a WACC of 14 percent.

Base Case: SEK 22

We assume sales potential of almost near SEK 400m through 2030E and a volume launch in 2022E-2023E. We assume a growth capital injection of SEK 30m (net) and a US launch in 2023E. We apply a WACC of 12.3 percent. In this scenario, Prostatype Genomics could be acquired within three to four years.

Bull Case: SEK 54

We assume early support from urologists and a high acceptance of private pay. We also assume early guideline support and public reimbursement. In this scenario, we assume increased support from PCa patients initially staged with intermediate-risk PCa. We use a WACC of 11 percent. In this scenario, Prostatype Genomics will probably be acquired within two to three years.

Financial Forecasts for 2021E – 2030E

P&L through 2025E

Income Statement	2021	2022E	2023E	2024E	2025E
Sales	2,5	8,1	31,5	77,9	129,1
Growth (%)		224%	287%	147%	66%
Cost of Revenues	-0,3	-0,9	-3,1	-7,0	-10,3
Gross Profit*	2,2	7,2	28,3	70,9	118,8
Gross Profit Margin (%)	88%	89%	90%	91%	92%
Research and Development	-1,5	-3,1	-4,9	-8,3	-12,7
Staff Cost	-8,0	-13,9	-21,7	-34,9	-40,8
Other External cost	-8,5	-9,8	-13,1	-17,8	-24,1
Other Op. Expense / (Income)	0,0	0,0	-1,2	-1,8	-2,4
EBITDA	-15,5	-19,2	-12,6	6,9	36,1
EBITDA Margin (%)		-236%	-40%	9%	28%
Amortization	-0,1	-0,5	-2,1	-3,0	-4,1
EBIT	-15,6	-19,7	-14,7	4,0	32,0
EBIT Margin (%)	-620%	-242%	-47%	5%	25%
Interest Income	0,0	0,0	0,0	0,1	0,2
Interest Expenses	-0,1	-0,1	-0,3	-0,4	-0,4
EBT	-15,6	-19,8	-15,0	3,6	31,8
Income Tax Expenses	0,0	0,0	0,0	0,0	-6,5
Effective Tax Rate (%)	0,0%	0,0%	0,0%	-20,6%	-20,6%
Net Income	-15,6	-19,8	-15,0	2,9	25,2
Recurring Net Income	-15,6	-19,8	-15,0	2,9	25,2
Net Income Margin (%)	-623%	-243%	-48%	4%	20%
EPS	-1,0	-0,9	-0,7	0,1	1,2

** Adjusted for capitalized development cost*

Source: Prostatype Genomics & Redeye Research

Balance Sheet through 2025E

Balance Sheet	2021	2022E	2023E	2024E	2025E
Current Assets					
Cash & Equivalents	9,8	17,3	1,6	4,6	27,6
Inventories	0,2	0,3	1,9	5,2	8,3
Accounts Receivable	1,1	0,7	4,1	10,3	16,3
Other Current Assets	10,5	0,5	2,7	7,4	12,1
Total Current Assets	21,6	18,8	10,4	27,4	64,4
Non-Current Assets					
Property, Plant & Equipment, Net	0,0	0,1	0,4	1,0	1,6
Goodwill	0,0	0,0	0,0	0,0	0,0
Intangible Assets	18,6	21,5	23,8	25,9	26,8
Right-of-Use Assets	0,0	-0,1	-0,3	-0,7	-1,4
Shares in Associates	0,0	0,0	0,0	0,0	0,0
Other Long-Term Assets	0,0	10,2	10,2	10,2	10,2
Total Non-Current Assets	18,6	31,7	34,1	36,4	37,2
Total Assets	40,2	50,5	44,5	63,8	101,6
Current Liabilities					
Short-Term Debt	0,4	0,9	4,9	7,9	6,9
Short-Term Lease Liabilities	0,0	0,0	0,0	0,0	0,0
Accounts Payable	1,2	0,6	3,3	8,1	12,5
Advances From Customers	0,0	0,0	0,0	0,0	0,0
Prepaid Income	1,5	1,5	1,5	1,5	1,5
Accrued Expenses	0,4	0,5	2,7	7,4	12,5
Other Current Liabilities	0,4	0,5	2,7	7,4	12,5
Total Current Liabilities	3,4	3,4	12,4	24,8	33,4
Non-Current Liabilities					
Long-Term Debt	0,9	0,9	0,9	0,9	0,9
Long-Term Lease Liabilities	0,0	0,0	0,0	0,0	0,0
Other Long-Term Liabilities	0,0	0,0	0,0	0,0	0,0
Other Long-Term Liabilities, % of Rev.	0,0	0,0	0,0	0,0	0,0
Total Non-current Liabilities	0,9	0,9	0,9	0,9	0,9
Non-Controlling Interest	0,0	0,0	0,0	0,0	0,0
Shareholder's Equity	35,9	46,2	31,2	38,1	67,3
Book Value Per Share	2,4	2,9	1,5	1,8	3,2
Total Liabilities & Equity	40,2	50,5	44,5	63,8	101,6
Net Debt	-19,1	-16,0	1,4	-3,2	-32,0
Net Gearing (%)	-53%	-35%	5%	-8%	-48%

Source: Prostatype Genomics & Redeye Research

Cash Flow through 2025E

Cash Flow Statement	2021	2022E	2023E	2024E	2025E
Operating Activities					
Net Income	-15,6	-19,8	-15,0	3,6	31,8
Non cash adjustments	0,1	0,5	2,1	3,0	4,1
Tax	0,0	0,0	0,0	-0,8	-6,5
Other	0,0	0,0	0,0	4,0	4,0
CF before WC	-15,6	-19,2	-12,9	9,9	33,3
Change in WC/Other	-0,8	-0,5	-2,3	-4,6	-4,4
Operating Cash Flow	-16,3	-19,7	-15,1	5,2	29,0
Cash EPS	-1,1	-1,2	-0,7	0,3	1,4
Investing Activities					
Investments in fixed assets	0,0	-0,1	-0,5	-1,0	-1,0
Investments in development/intangibles	-2,5	-3,3	-4,0	-4,2	-3,9
Acquisitions	0,0	0,0	0,0	0,0	0,0
Other	0,0	0,0	0,0	0,0	0,0
Investing Cash Flow	-2,5	-3,4	-4,5	-5,2	-4,9
Financing Activites					
Equity issue	0,0	30,1	0,0	0,0	0,0
Change in loan	0,0	0,5	4,0	3,0	-1,0
Dividend	0,0	0,0	0,0	0,0	0,0
Other	0,0	0,0	0,0	0,0	0,0
Financing Cash Flow	0,0	30,6	4,0	3,0	-1,0
Net Cash Flow	-18,8	7,4	-15,7	3,0	23,1
Cash Balance	9,8	17,3	1,6	4,6	27,6

Source: Prostatype Genomics & Redeye Research

Appendix 1. Some Internationally Established PCa Risk-Grading Systems

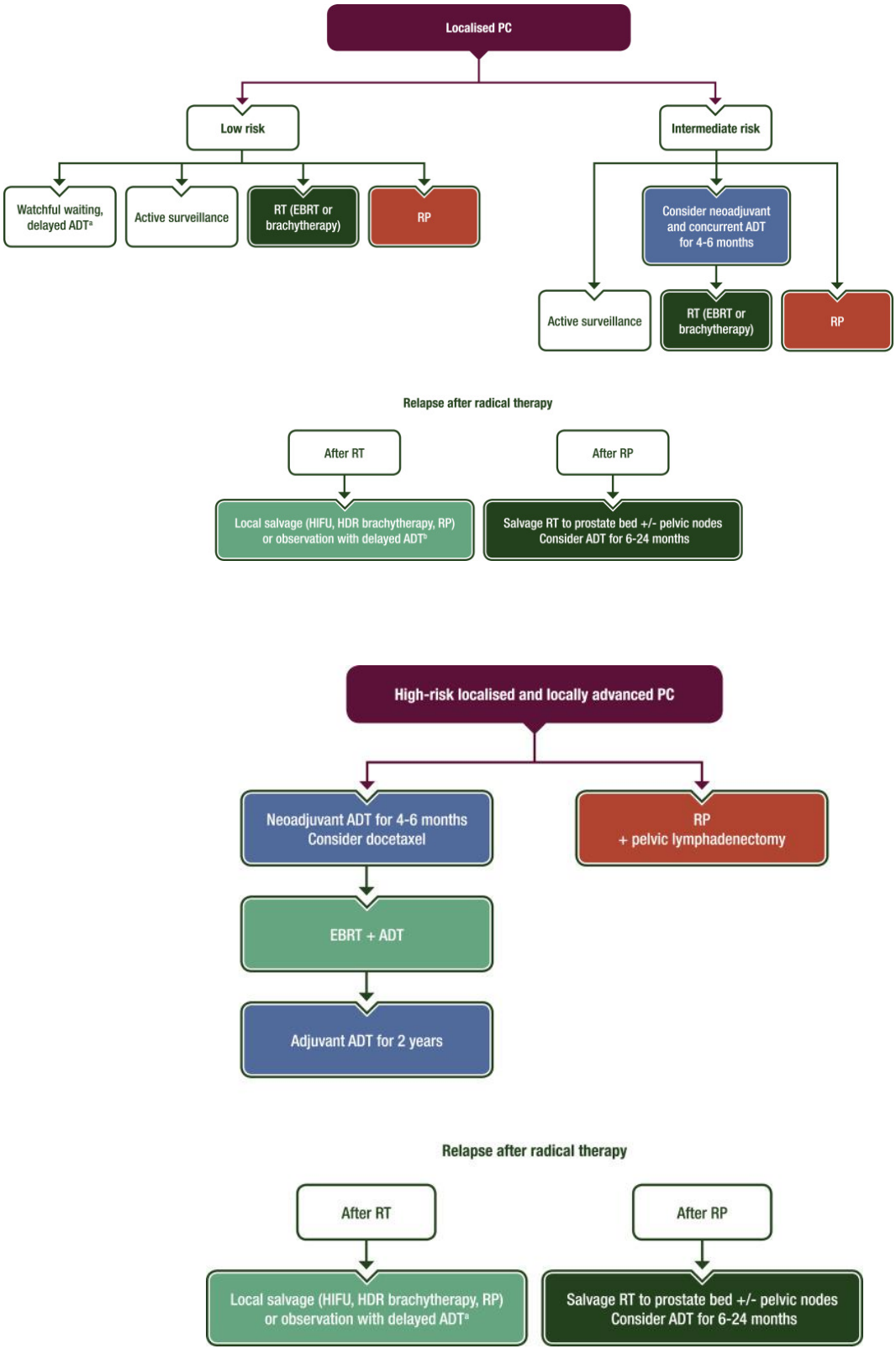
Grading System	Very Low Risk	Low risk	Intermediate Favorable
D'Amico		PSA <10ng/ml and Gleason Grade < 6 and cT = T1c to 2a	PSA 10-20 ng/ml or Gleason Grade = Score 7 or cT = T2b
EAU		PSA <10ng/ml and Gleason Grade < 6 and cT = T1c to 2a	PSA 10-20 ng/ml or Gleason Score = (ISUP 2-3) or cT = T2b
NICE		PSA <10ng/ml and Gleason Grade < 6 and TSN = T1c to 2a	PSA 10-20 ng/ml or Gleason Grade = Score 7 or cT = T2b
AUA	PSA <10ng/ml and ISUP 1 and cT = T1c to 2a and <34% positive core and No core with >50% cancer and PSA density < 0.15	PSA <10ng/ml and Gleason Grade < 6 and cT = T1c to 2a PSA <10ng/ml Gleason Grade < 6 (ISUP 1) and cT = T1c to 2a	PSA 10-20 ng/ml or Gleason Grade = ISUP 2-3 or cT = T2b to 2c
NCCN	PSA <10ng/ml ISUP 1 and cT = T1c and < 3 positive cores No core with ≤ 50% cancer and PSA density < 0.15	PSA <10ng/ml and Gleason Grade < 6 and cT = T1c to 2a	PSA 10-20 ng/ml or Gleason Group = 3 to 4 (ISUP 2) or cT = T2b to 2c and No core with ≤ 50% cancer

Grading System	Intermediate Unfavorable	High Risk	Very High Risk
D'Amico		PSA >20ng/ml or Gleason Grade 8-10 or cT =T2c to T3a	
EAU		PSA >20ng/ml or Gleason Grade at least 8 or cT =T2c to T3a	
NICE		PSA >20ng/ml or Gleason Grade 8-10 or cT > T2c	
AUA		PSA >20ng/ml ISUP 4-5 or cT ≥ T3	
NCCN	PSA 10-20 ng/ml or Gleason Group 3, 4/4, 5 (ISUP 2-3) or TSN = T2b to 2c	PSA >20ng/ml Gleason Group 4, 4+4, 5 (ISUP 4-5) or TSN = T3a	GG1 5 or >4 cores + GS 8-10 (ISUP 4-5) or TSN = T3b-4

D'Amico	D'Amico Risk Classification System
EAU	European Association of Urology
NICE	The National Institute for Health and Care Excellence
AUA	American Urological Association
NCCN	National Comprehencive Cancer Network
ISUP	International Society of Urological Pathology
cT	Clinical Tumor stage

D'Amico is probably the most traditional and well-recognized risk grading system for prostate cancer. There are other systems and variances of the above, but when assessing the different guidelines or standards, it is also obvious that the differences between them are minor. We can probably expect most updates and changes to be to the intermediate-risk PCa grading systems, where some standards are more detailed and distinguish between favorable and unfavorable intermediate-risk PCa.

Appendix 2. PCa Treatment Guidelines (ESMO)



Source: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up

Appendix 3. PCa Tumour Stage

Stage	Criteria	Description
Stage 1	cT1, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA less than 10 or cT2a, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA less than 10 or pT2, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA less than 10	The doctor can't feel the tumor or see it with an imaging test such as transrectal ultrasound (it was either found during a transurethral resection of the prostate (TURP) or was diagnosed by needle biopsy done for a high PSA) [cT1]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1, and the PSA level is less than 10. The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound and is in one half or less of only one side (left or right) of the prostate [cT2a]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1, and the PSA level is less than 10. The prostate has been removed with surgery, and the tumor was still only in the prostate [pT2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1, and the PSA level is less than 10.
Stage 2a	cT1, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA 10-20 or cT2a or pT2, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA 10-20 or cT2b or cT2c, N0, M0 Grade Group 1 (Gleason score 6 or less) PSA less than 20	The doctor can't feel the tumor or see it with imaging such as transrectal ultrasound (it was either found during a transurethral resection of the prostate (TURP) or was diagnosed by needle biopsy done for a high PSA level) [cT1]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1. The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound and is in one half or less of only one side (left or right) of the prostate [cT2a]. OR the prostate has been removed with surgery, and the tumor was still only in the prostate [pT2].The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1. The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound. It is in more than half of one side of the prostate [cT2b] or it is in both sides of the prostate [cT2c]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1. The PSA level is less than 20.
Stage 2b	T1 or T2, N0, M0 Grade Group 2 (Gleason score 3+4=7) PSA less than 20	The cancer has not yet spread outside the prostate. It might (or might not) be felt by digital rectal exam or seen with imaging such as transrectal ultrasound [T1 or T2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 2. The PSA level is > 20
Stage 2c	T1 or T2, N0, M0 Grade Group 3 or 4 (Gleason score 4+3=7) or 8 PSA less than 20	The cancer has not yet spread outside the prostate. It might (or might not) be felt by digital rectal exam or seen with imaging such as transrectal ultrasound [T1 or T2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 3 or 4. The PSA level is less than 20.
Stage 3a	T1 or T2, N0, M0 Grade Group 1 or 4 (Gleason score 8 or less) PSA > 20	The cancer has not yet spread outside the prostate. It might (or might not) be felt by digital rectal exam or seen with imaging such as transrectal ultrasound [T1 or T2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1 to 4. The PSA level is at least 20.
Stage 3b	T3 or T4, N0, M0 Grade Group 1 or 4 (Gleason score 8 or less) Any PSA	The cancer has grown outside the prostate and might have spread to the seminal vesicles [T3], or it has spread into other tissues next to the prostate, such as the urethral sphincter (muscle that helps control urination), rectum, bladder, and/or the wall of the pelvis [T4]. It has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 1 to 4, and the PSA can be any value.
Stage 3c	Any T, N0, M0 Grade Group 5 (Gleason score 9-10) Any PSA	The cancer might or might not be growing outside the prostate and into nearby tissues [any T]. It has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Grade Group is 5. The PSA can be any value.
Stage 4a	Any T, N1, M0 Any Grade Group Any PSA	The tumor might or might not be growing into tissues near the prostate [any T]. The cancer has spread to nearby lymph nodes [N1] but has not spread elsewhere in the body [M0]. The Grade Group can be any value, and the PSA can be any value.
Stage 4b	Any T, any N, M1 Any Grade Group Any PSA	The cancer might or might not be growing into tissues near the prostate [any T] and might or might not have spread to nearby lymph nodes [any N]. It has spread to other parts of the body, such as distant lymph nodes, bones, or other organs [M1]. The Grade Group can be any value, and the PSA can be any value.

Source: AJCC TNM (2018)

Appendix 4. PCa Grading

Grade Group	Gleason Score	Related Risk Group	Pca differentiation
1	Up to 6	Low to Very Low	The cells look similar to healthy cells = well differentiated
2	7 (3+4)	Intermediate	Most cells still look similar to normal prostate cells
3	7 (4+3)	(Favourable & Unfavorable)	The cells look less like normal prostate cells
4	8	High	Some cells look abnormal
5	9-10	Very High	The cells look very abnormal

Source: Company data

Catalysts

Prostatype is now in a position where it has established a sales network. Its transitions towards establishing volume sales represent both a major challenge and a major opportunity that can trigger a significant positive revaluation.

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Moderate	Unlikely	Major	Likely	Short

US commercial progress

Prostatype is now building a presence in the south-west of the US, an area that has many PCa centers (as does the south-east). Its next step is to secure a CLIA-certified lab and conclude a validation test. The US launch is likely to follow in 2023, and by 2024-2025, it will be clear whether if Prostatype Genomics can secure volume support from the largest and most dynamic market for Prostatype.

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Moderate	Unlikely	Major	Possible	Mid

Private pay and private insurance support

The willingness of individual PCa patients to pay out of pocket will depend on the support from professional urologists and the level of scientific support. Prostatype has a strong case already, but its future success will depend on its ability to confirm and expand the level of scientific support. Prostatype has a substantial opportunity to secure support from private insurance cover by 2023-2024.

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Significant	Possible	Major	Possible	Mid

Summary Redeye Rating

People: 4

Prostatype is led by an experienced and close-knit team. Senior management led by CEO Fredrik Persson provides experience and a network in related areas such as diagnostics, kit and tissue marketing, and logistics, as well as a clear vision regarding the future use of the Prostatype test. We believe the board is well balanced and includes members with different and complementary experience.

Business: 3

The business is scalable, with high gross margins for disposable kits. Prostatype Genomics has secured sourcing and is well underway to securing regulatory clearance in both Europe (completed) and US (approaching). There is a clear clinical and cost rationale for using the Prostatype test. In order to secure larger volumes, the company needs to secure support from more commercial partners, extended scientific support, and expanded KOL support.

Financials: 1

The company's financial position reflects the early stage of the commercial launch, with limited sales and limited growth capital. We expect the company to secure expanded growth capital of SEK 30m later in 2022 or in early 2023.

Abbreviations

Active surveillance	No active treatment but involving regular active tests that can include biopsies.
ADT	Hormone therapy for PCa that lowers male hormones
ASCO	American Society of Clinical Oncology, a very influential organization
AUA	American Urological Association, often referred to in respect of guidelines
Biopsy	Typically, a urologist performs a core needle biopsy that is used to set the PCa diagnose.
Brachytherapy	An internal radiation therapy typically performed at very close range
Chemotherapy	The use of drugs to destroy cancer cells
CLIA	Clinical Laboratory Improvement Amendments (1988) is a FED regulatory standard for laboratory testing
CCL	Prostatype's UK partner, Cambridge Clinical Laboratories
cT	Clinical Tumor stage
EAU	European Association of Urology, often referred to in respect of guidelines
EBRT	External Beam Radiation
ET	Another term for hormone therapy
D'Amico	D'Amico Risk Classification System
Decipher test	A 22-feature RNA biomarker assay that was developed to predict metastasis following prostatectomy
DRE (digital rectal examination)	An internal examination of the rectum performed by a healthcare provider
Gleason Grade	A PCa grading system based on the histological pattern of the biopsy
ISUP	International Society of Urological Pathology
LDT	A laboratory-developed test (LDT) is a type of in-vitro diagnostic test that is designed, manufactured, and used within a single laboratory
MRI	Magnetic field and computer-generated radio waves to create detailed images
mpMRI	A multiparametric MRI producing more detailed images than a standard MRI scan
NICE	UK National Institute for Health and Care Excellence, often referred to in respect of guidelines
NCCN	National Comprehensive Cancer Network (NCCN) is a non-profit alliance of 31 US cancer centers, often referred to in respect of guidelines
Prolaris	Prolaris is a genetic test developed by Myriad to provide a risk score to help predict the likelihood of disease progression in men with localized prostate cancer
ProMark	A proteomic test based on an eight-protein signature prognostic test for localized PCa
Prostate cancer (PCa)	Cancer of the prostate gland
PSA	Prostate-specific antigen test
Oncotype DX Prostate	A clinically validated 17-gene genomic assay that provides a genomic prostate score
Radical Prostatectomy	A surgical procedure that removes the prostate gland and attaches seminal vesicles
Robot-Assisted Prostatectomy	Robot-assisted radical prostatectomy; robot-assisted surgical removal of the prostate
Prostate Health Index (PHI)	A test based on PSA can be seen as an improved PSA test, mainly used for diagnostics

4K Score	Largely an improved PSA test that aims to reduce the number of unnecessary biopsies
Select MDx	A urine-based mRNA biomarker intended to detect high-risk PCa
PCA3	Prostate cancer antigen 3, a urine-based diagnostic PCa biomarker
Confirm MDx	DNA-based test using the biopsy to support diagnostics
ExoDx Intelliscore (EPI)	A urine-based test assessing the risk of high-grade or more advanced PCa
Prolaris	A multi-gene assay (RNA) test designed to predict the aggressiveness (growth and spread) of PCa from Myriad
Prostatype P-Score	The P-Score indicates the aggressiveness of the tumor. The prostate-cancer-specific mortality risk at ten years for a patient with a low P-Score (green) is below 3.4 percent, while for an intermediate P-Score (yellow) it is below 10.8 percent
Urologist	A specialist surgeon who treats men, women, and children for problems of the kidneys, bladder, prostate, and male reproductive organs
Ultrasound	An imaging method that uses high-frequency sound waves to produce images
Watchful waiting	Observing PCa without active treatment
Low Risk PCa	Local PCa with low PSA, small amount of tissue changes, and low Gleason score
Intermediate-risk PCa	The largest group of local PCa with considerable biological and clinical heterogeneity
High-risk PCa	Local but aggressive PCa measured by PSA, T stage, and Gleason score
(U) Favorable intermediate risk	In contrast to unfavorable PCa—two groups of intermediate-risk PCa (Gleason Score 3+4 vs 4+3)
Metastatic PCa (mPCa)	Regional or distant mPCa at diagnosis, some 13 percent have cancer that has spread to regional lymph nodes, and six percent have distant metastasis
Regional PCa	Regional or distant mPCa at diagnosis, some 13 percent have cancer that has spread to regional lymph nodes, and six percent have distant metastasis
Local PCa	By far the most common type of PCa, where the cancer has not spread beyond the prostate
AUC	The area under (a ROC) curve is a measure of the accuracy of a quantitative diagnostic test
Positive Predictive Value	The ratio of patients truly diagnosed as positive of all those who had positive test results
Negative Predictive Value	The ratio of subjects truly diagnosed as negative of all those who had negative test results
False positive	A test indicating that a person has a condition when this not the case
False negative	A test indicating that a person does not have a condition when they do
Sensitivity	The ability of a test to correctly identify patients with a disease
Specificity	The ability of a test to correctly identify people without the disease
HR (Hazard Ratio)	The ratio of the hazard rates corresponding to the conditions described by two levels of an explanatory variable
p-value	A statistical measurement used to validate a hypothesis against observed data (>0.05 is statisit5ically insignificant)

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	2021	2022E	2023E	2024E
INCOME STATEMENT				
Net sales	0	5	27	74
Cost of Revenues	-2	-3	-1	4
Gross Profit	3	8	28	70
Operating Expenses	18	27	41	63
EBITDA	-15	-19	-13	7
Depreciation & Amortization	0	1	2	3
EBIT	-16	-20	-15	4
Net Financial Items	0	0	0	0
EBT	-16	-20	-15	4
Income Tax Expenses	0	0	0	1
Non-Controlling Interest	0	0	0	0
Net Income	-16	-20	-15	7
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	10	17	2	5
Inventories	0	0	2	5
Accounts Receivable	1	1	4	10
Other Current Assets	11	0	3	7
Total Current Assets	22	19	10	27
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	1
Goodwill	0	0	0	0
Intangible Assets	19	22	24	26
Right-of-Use Assets	0	0	0	-1
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	10	10	10
Total Non-Current Assets	19	32	34	36
Total Assets	40	50	44	64
Liabilities				
Current liabilities				
Short-Term Debt	0	1	5	8
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	1	1	3	8
Other Current Liabilities	2	2	4	9
Total Current Liabilities	3	3	12	25
Non-current liabilities				
Long-Term Debt	1	1	1	1
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	0	0	0	0
Total Non-current Liabilities	1	1	1	1
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	36	46	31	38
Total Liabilities & Equity	40	50	44	64
CASH FLOW				
NOPAT	-16	-20	-15	3
Change in Working Capital	-11	10	-2	-5
Operating Cash Flow	-16	-20	-15	5
Capital Expenditures	0	0	-1	-1
Investment in Intangible Assets	-2	-3	-4	-4
Investing Cash Flow	-2	-3	-5	-5
Financing Cash Flow	0	31	4	3
Free Cash Flow	-19	-23	-20	0

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2022–2025)	-14
Momentum Period (2026–2029)	215
Stable Period (2030–)	749
Firm Value	0
Net Debt (last quarter)	-496
Equity Value	496
Fair Value per Share	27

	2021	2022E	2023E	2024E
CAPITAL STRUCTURE				
Equity Ratio	0,9	0,9	0,7	0,6
Debt to equity	0,0	0,0	0,2	0,2
Net Debt	-9	-15	4	4
Capital Employed	37	47	32	39
Working Capital Turnover	0,0	-4,9	21,4	12,5
GROWTH				
Revenue Growth	-97%	48232%	469%	168%
Basic EPS Growth	-6%	-9%	-24%	-146%
Adjusted Basic EPS Growth	-6%	-9%	-24%	-119%
PROFITABILITY				
ROE	-49%	-48%	-39%	20%
ROCE	-42%	-42%	-46%	10%
ROIC	-75%	-82%	-64%	11%
EBITDA Margin (%)	-154720%	-396%	-46%	9%
EBIT Margin (%)	-155605%	-408%	-53%	5%
Net Income Margin (%)	-156419%	-409%	-54%	9%
VALUATION				
Basic EPS	na	-0,9	-0,7	0,3
Adjusted Basic EPS	na	-0,9	-0,7	0,1
P/E	na	neg	neg	60,3
EV/Revenue	na	24,2	6,5	2,4
EV/EBITDA	na	neg	neg	25,7
EV/EBIT	na	neg	neg	44,9
P/B	na	2,9	5,6	4,6

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Creathor Venture	20,4%	20,4%
Nordnet Pensionsförsäkring	7,0%	7,0%
Håkan Englund	4,9%	4,9%
Anders Liljeblad	4,5%	4,5%
Staffan Ek	3,6%	3,6%

SHARE INFORMATION	
Reuters code	PROGEN.SE
List	First North
Share price	9,26
Total shares, million	15,81182

MANAGEMENT & BOARD	
CEO	Fredrik Persson
CFO	Mikael af Winklerfelt
Chairman	Anders Lundberg

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Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.
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Redeye Rating (2022-04-11)

Rating	People	Business	Financials
5p	32	16	4
3p - 4p	130	115	42
0p - 2p	5	36	121
Total	167	167	167

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CONFLICT OF INTERESTS

Johan Unnerus owns shares in the company : No
Erik Nordström owns shares in the company : No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.