Corporate Overview

NASDAQ New Ticker Symbol: **ONCO**

January 2024

Dr. Ralph Schiess

Interim CEO

FORWARD LOOKING STATEMENTS

The Presentation (the "Presentation") has been prepared by Onconetix™(the "Company"). Certain information contained herein has been derived from sources prepared by third parties. While such information is believed to be reliable for the purposes used herein, the Company makes no representation or warranty with respect to the accuracy of such information.

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Certain statements in this presentation and associated discussions relating to this presentation are considered to be forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Onconetix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements.

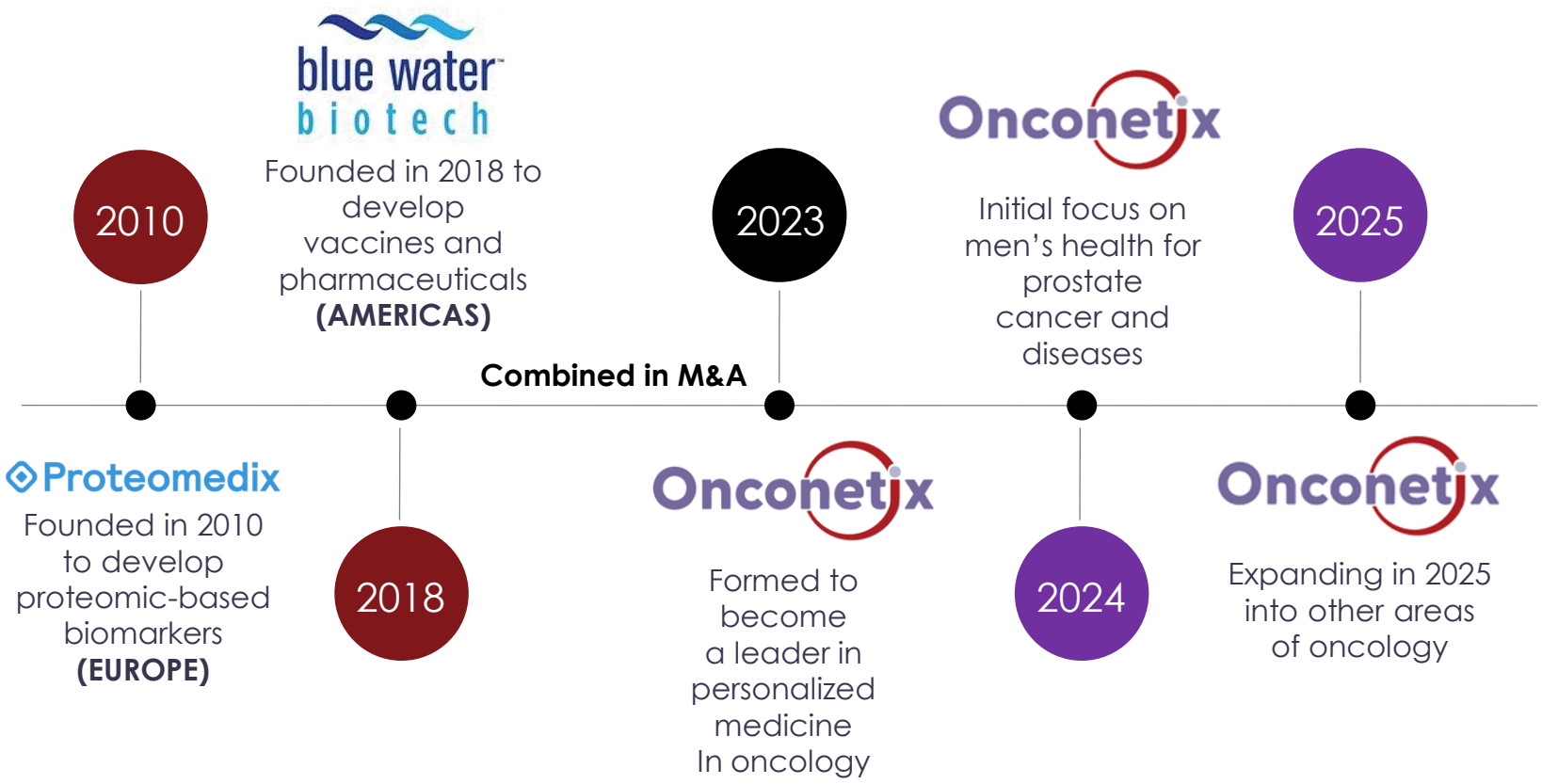
These factors include, but are not limited to, risks related to risks related to Onconetix's ability to commercialize ENTADFI® and Proclarix® described herein; risks related to Onconetix's ability to expand its business scope and integrate the assets and commercial operations acquired from Proteomedix into Onconetix's business; risks related to Onconetix's ability to attract, hire and retain skilled personnel necessary to commercialize and operate the company's commercial products; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates in oncology; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. Onconetix does not undertake an obligation to update or revise any forward-looking statement.

Investors should read the risk factors set forth in Onconetix's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 9, 2023, and periodic reports filed with the SEC on or after the date thereof. All of Onconetix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

Table of Contents

Oncoentix™

Building a World Class Oncology Company



CORPORATE PROFILE

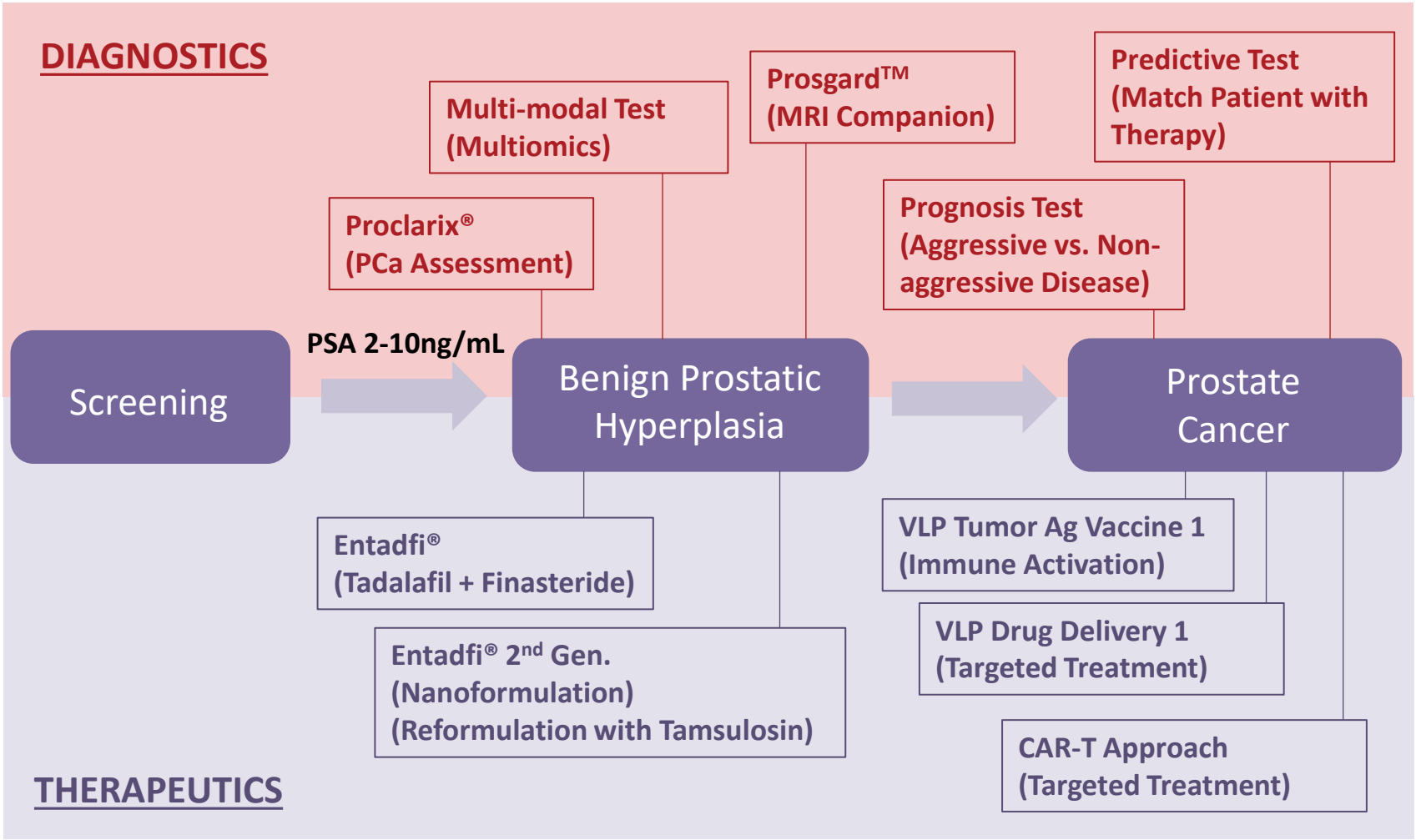
Onconetix™, Inc. is the new name of the combined company from the assets of Blue Water Biotech, Inc. (BWV) and Proteomedix AG.

Onconetix is a Nasdaq commercial-stage biotechnology company focused on the research, development, and commercialization of proprietary science and technologies for therapeutics, diagnostics, and services for the treatment of cancer.

Therapeutically, the Company currently has **Entadfi®**, an FDA-approved, once-daily oral therapeutic for the treatment of benign prostatic hyperplasia (BPH), a disorder of the prostate. **Diagnostically**, we have **Proclarix®**, a European CE IVD approved test for prostate diagnostics and a lab developed test (LDT) currently in the U.S.

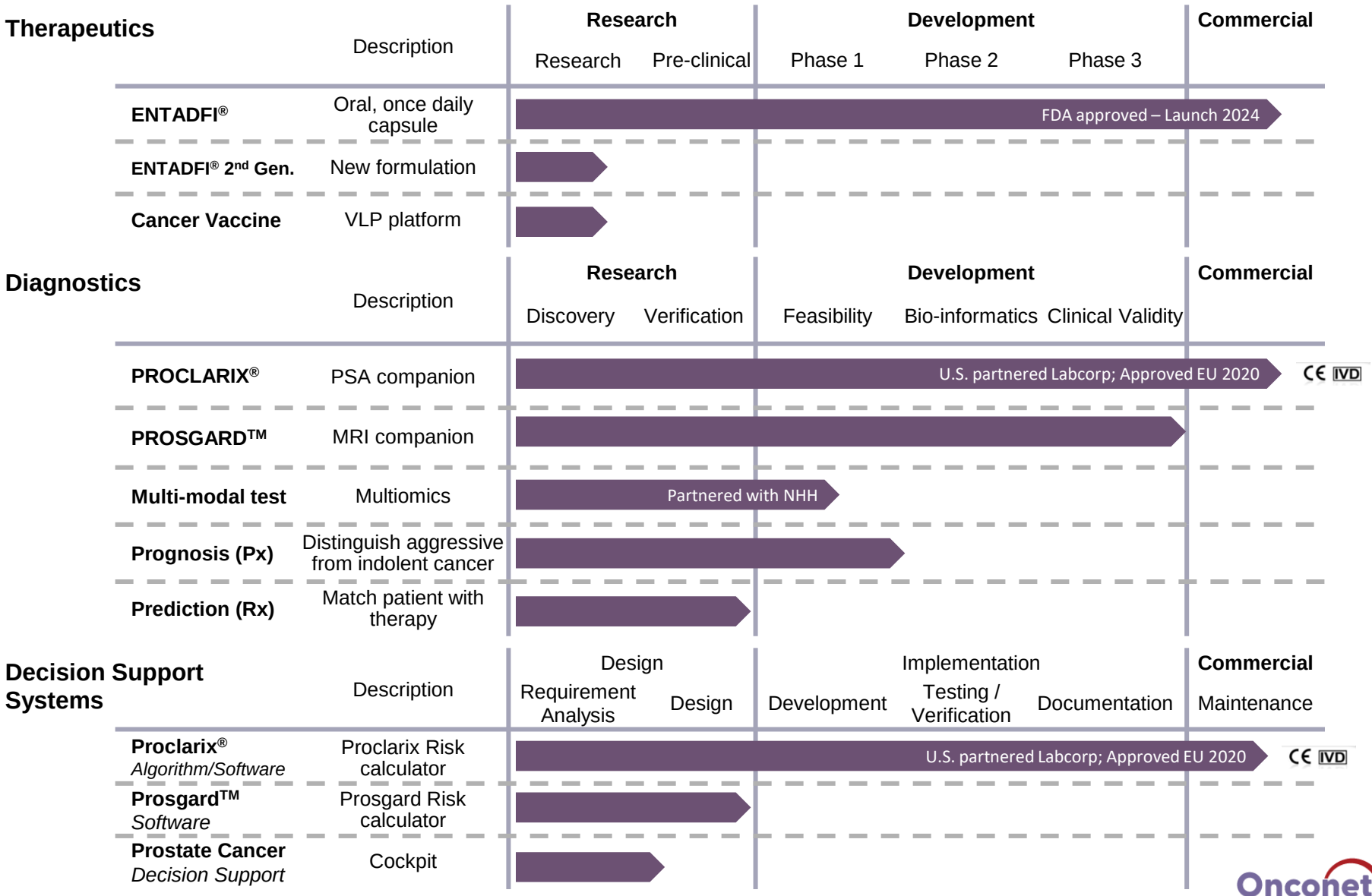
The Prostate Cancer "Journey"

Onconetix's Diagnostic and Therapeutic Product Line



Onconetix™

Onconetix™ Product Pipeline



Experienced Management Team

Proven, successful life science commercialization experience

Dr. Ralph Schiess
Interim CEO
Chief Science Officer

Mr. Bruce Harmon
Chief Financial Officer

Dr. Don Very
SVP, Commercial Research & Development

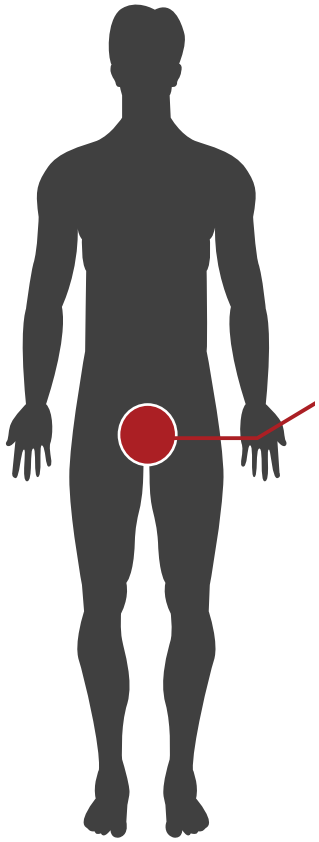
Mr. Christian Brühlmann
Chief Strategy Officer
General Manager, Europe

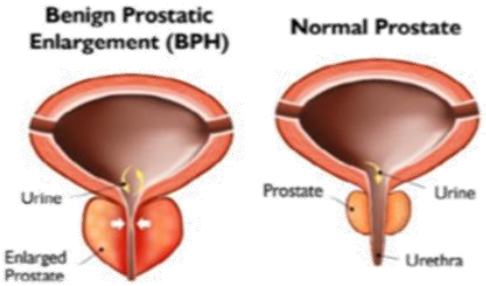
Onconetix

ENTADFI®

Launch 2024

Significant Health Burden of Prostate Disease





Benign Prostatic Hyperplasia (BPH)

- Also known as benign prostatic hypertrophy, BPH is a **histologic diagnosis** characterized by proliferation of the cellular elements of the prostate, leading to an **enlarged prostate gland**
- **Chronic bladder outlet obstruction** (BOO) secondary to BPH may lead to urinary retention, impaired kidney function, recurrent urinary tract infections, gross hematuria, and bladder calculi
- Common problem that affects the quality of life in approximately **one third of men >50 years**
- Histologically evident in up to **90% of men by age 85 years**
- As many as **55.1 million men in the US have symptoms** and worldwide, **approximately 94 million men have prevalent cases** related to BPH

References: 1. Yale Medicine (https://www.yalemedicine,org/conditions/enlarged-prostate-benign-prostatic-hyperplesia-bph); 2. Oelke M, Bachmann A, Descazeaud A, Emberton M, Gravas S, Michael MC, et al. EAU Guidelines on treatment and follow up of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. *Eur Urol*. 2013;64:118-40. 3. Resident Population of the US by sex and age as of July 1, 2021 (https://www.statista.com/statistics/241488/population-of-the-us-by-sex-and-age/).

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Treatment of LUTS-BPH Remains Problematic

Approximate Medicare annual in-office and outpatient BPH service costs[1]:

$1.5 BILLION

23% of all urologic office visits attributed to BPH

BPH treatment and diagnosis make up the largest segment of urologic practice[2]

41.2% of privately insured BPH patients

41.2% of privately insured BPH patients filled at least one BPH-related prescription[1]

12.2M actively managed with BPH treatment

54.8% of 12.2M actively managed BPH patients are managed with pharmacological therapy[2]

Source: 1. Feinstein L., Matlaga B. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2018; NIH Publication No. 12–7865 [pp. 78–81]. 2. Vuichoud, C. Canadian Journal of Urology 22.Suppl 1 (2015): 1-6.

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The ENTADFI® Opportunity

ENTADFI® has the potential to be first-line treatment for BPH symptoms, both reducing prostate size and managing ED

- **Current BPH treatment can take up to 6-12 months for significant symptom relief**, contributing to adherence concerns[1]
- **Men with moderate-to-severe LUTS are at increased risk for sexual dysfunction**, including erectile dysfunction, ejaculatory dysfunction, and hypoactive desire[2]
- LUTS/BPH severity and number of medications influence adherence rates
  - Men with less severe symptoms have poorer adherence[3]
  - **Men taking multiple BPH treatments concurrently had an adherence rate of 9%**[4]
- Several **BPH treatments significantly increased the risk of ED, ejaculatory dysfunction, and hypoactive sexual desire** in subjects with BPH[3,4]
- AEs related to sexual/ejaculatory dysfunction appear to increase with 5-ARI/ a-blocker coadministration[1]

Lower urinary tract symptom improvement is not observed with finasteride monotherapy for 6 to 12 months and a-blockers are not indicated to reduce prostate size[1]

5-ARI – 5-alpha reductase inhibitor; AE – adverse events; BPH – benign prostatic hyperplasia; ED – erectile dysfunction; LUTS – lower urinary tract symptoms.

References: 1. Casabé A et al. *Journal of Urology*. 191:727-733 2014. 2. Rosen RC, et al. *European Urology*. 2005;47(6):824-837. 3. Zabkowski T, Saracyn M. *J Physiol Pharmacol*. 2018;69(4):10.26402/jpp.2018.4.14. 4. Cindolo L, et al. *European Urology*. 2015;68(3):418-425. 5. Shin YS, et al. *World Journal of Men's Health*. 2019;37(2):157-165. 6. Corona G, et al. *Andrology*. 2017;5(4):671-678.

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Patients Usually Present to PCP or Urologists When Lower Urinary Tract Symptoms (LUTS) Become Bothersome

PATIENTS

Medical History/Comorbidities

- Men aged ≥40
- Other comorbidities: cardiovascular (hypertension, CHF), diabetes, hyperlipidemia, obesity
- Patients will likely take other medications concurrently, with 65.2% of men ages 40-79 taking at least one prescription drug, and 21.1% taking 5 or more[1]

SYMPTOMS

Bothersome Lower Urinary Tract Symptoms

- Increased urinary frequency
- Urgency
- Nocturia
- Decreased and intermittent force of stream
- Sensation of incomplete bladder emptying
- Small voided volumes
- Partial or complete urinary retention

EXAMS & TESTS

Physical Examination/Laboratory Testing

- Digital rectal examination (DRE)
- I-PSS (International Prostate Symptom Score)
- Urination observation
- Prostate-specific antigen (PSA)
- Urinalysis
- Serum creatinine

I-PSS[2]

(INTERNATIONAL PROSTATE SYMPTOM SCORE)

A validated, self-administered questionnaire to assess BPH and severity of symptoms and quality of life

A tool used to screen for, rapidly diagnose, track the symptoms of, and suggest management of BPH symptoms

Scores range from:

- Mild (symptom score ≤7)
- Moderate (symptom score 8-19)
- Severe (symptom score 20-35)

PCP – primary care provider; CHF – congestive heart failure.

Sources: 1. Hales CM, Servais J, Martin CB, Kohen D. Prescription drug use among adults aged 40–79 in the United States and Canada. NCHS Data Brief, no 347. Hyattsville, MD: National Center for Health Statistics. 2019. 2. Lee K, Weiss J. International prostate symptom score - an overview: science direct topics. https://www.sciencedirect.com/topics/medicine-and-dentistry/international-prostate-symptom-score. Accessed June 10, 2022.

ENTADFI® is The First and Only FDA-Approved Combination Therapy for Benign Prostatic Hyperplasia

ENTADFI®
(tadalafil and finasteride)
capsules

INDICATION AND USAGE

ENTADFI® is a combination of finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, and is indicated to initiate treatment for the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.[1]

Key Differentiators

- **Dual MOA**
- **Faster & improved LUTS**
- **Significant 1° & 2° endpoints** (at all time points)
- **Greater relief of LUTS**
- **Sustained over 26 weeks**
- **> Treatment satisfaction at week 26**

FDA – U.S. Food and Drug Administration.

Source: 1. Entadfi™. Prescribing Information. Blue Water Biotech; 2023.

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ENTADFI® Significantly Improves Early BPH Symptoms

International Prostate Symptom Score (IPSS): an eight-question self-administered survey used to screen for, diagnose, track, and manage the symptoms of BPH. Higher scores correlate with more severe symptoms and decreased QoL.

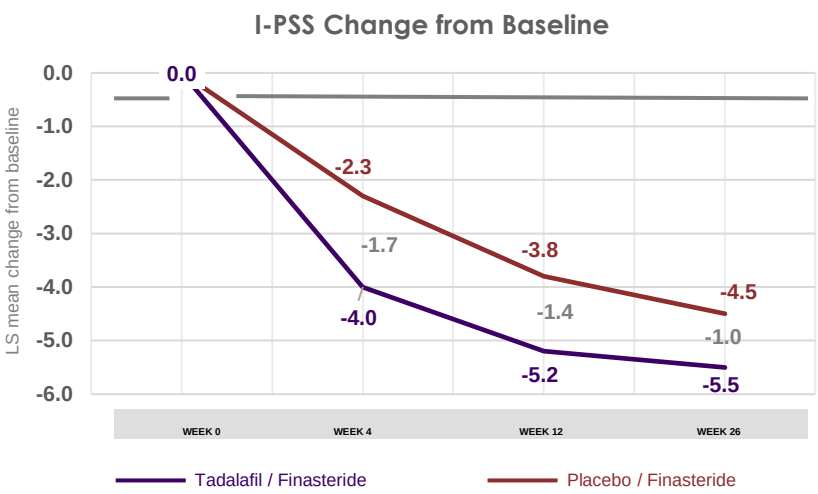
Primary Endpoint Achieved

- LS mean change from baseline with TAD/FIN at 12 weeks was -5.2 vs -3.8 for PBO/FIN (LSTD of -1.4 [95% CI -2.3, -0.6; p ≤0.001])

Key Secondary Endpoints Were Statistically Significant

- Significant LUTS improvements were observed with TAD/FIN at 4 and 26 weeks after baseline
- LS mean change in I-PSS total score
  - Week 4: TAD/FIN was -4.0 vs -2.3 for PBO/FIN (p <0.001)
  - Week 26: TAD/FIN was -5.5 vs -4.5 for PBO/FIN (p = 0.022)

Time course of LS mean change from baseline in I-PSS total score



TAD/FIN Led to a **74% Greater Reduction than Finasteride Alone** Within the First 4 Weeks and a **22% Greater Reduction** at Week 26

I-PSS – International Prostate Symptom Score; TAD – tadalafil; FIN – finasteride; PBO – placebo; IIEE-EF - International Index of Erectile Function – Erectile Function; Qmax - peak or maximum flow rate; ED – erectile dysfunction.

Source: 1. Casabé A et al. Journal of Urology. 191:727-733 2014.

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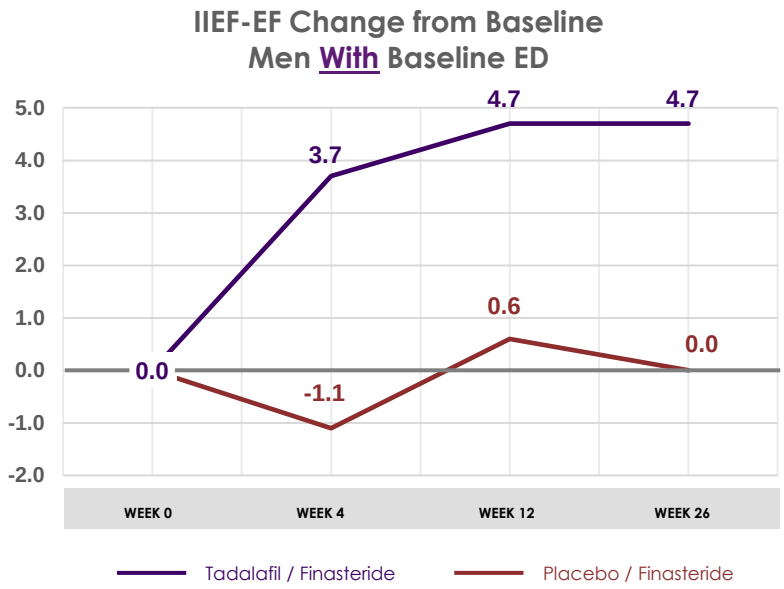
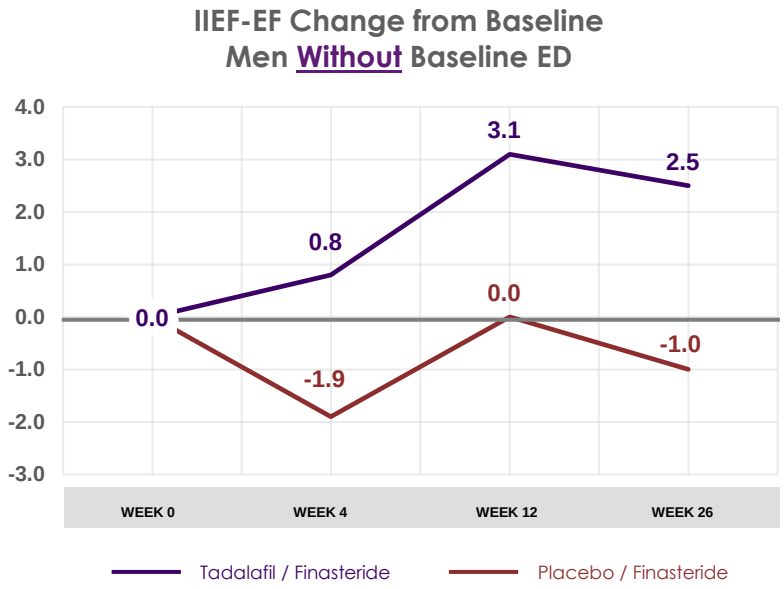
ENTADFI® Significantly Improves Sexual Function

Among Sexually Active Men With and Without Baseline ED Treated with TAD/FIN, Significant Improvements Were Observed in Scores at All Three Postbaseline Timepoints that were Significantly Greater than Patients Treated with PBO/FIN[1,2]

The International Index of Erectile Function (IIEF): a widely-used multidimensional evaluation for male sexual function. A self-administered questionnaire that reliably assesses sexual function & satisfaction to help inform HCPs of sexual symptoms associated with BPH





BPH – benign prostatic hyperplasia; ED – erectile dysfunction; FIN – finasteride; HCP – healthcare provider; IIEF – International Index of Erectile Function; LS – least square;; PBO – placebo; TAD – tadalafil.

Source: 1. Casabé A et al. *Journal of Urology*. 191:727-733 2014. **2.** Glina et al. *J Sex Med*. 2015;12:129–138.

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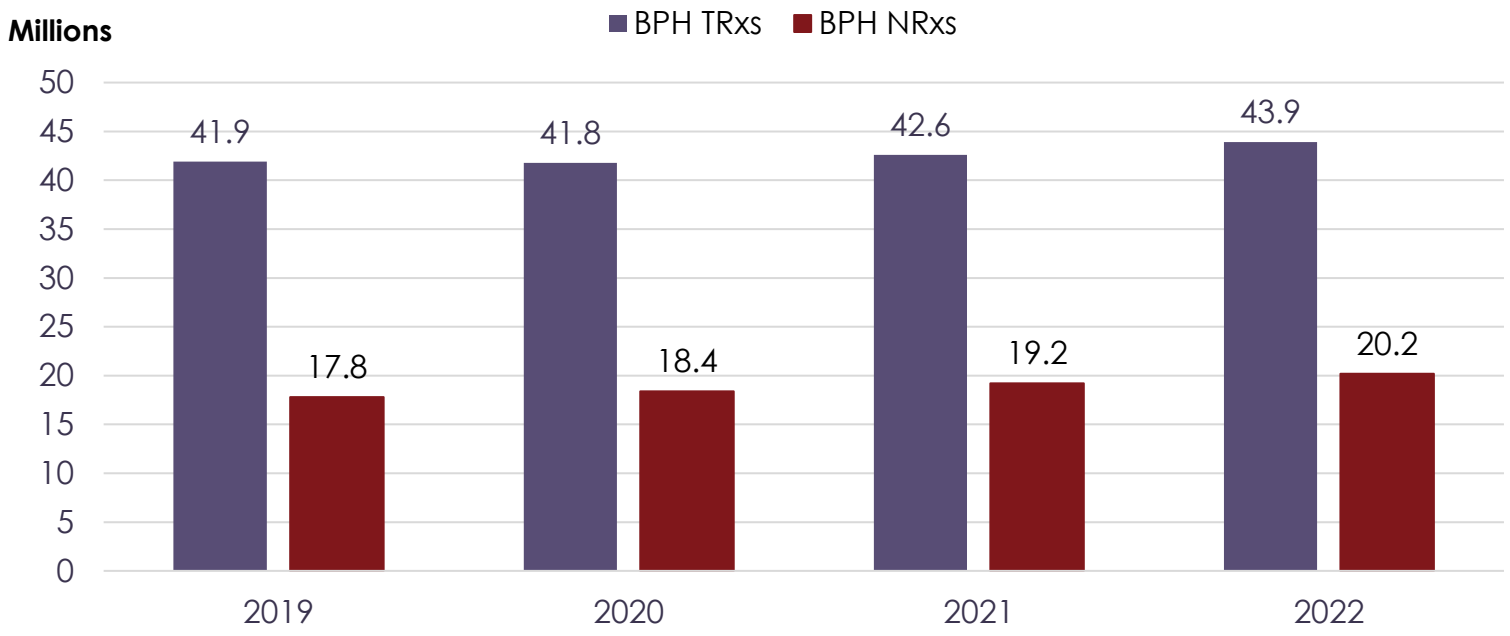
BPH Market is Large and Growing

Expected Increases in Both Total Prescriptions and New Prescriptions within BPH Based on Historical Data

Annual BPH TRx & NRx Prescription Market[1]



NOTE: Figures for 2022 are annualized based on 11 months of information available from IQVIA at the time of development

References: 1. IQVIA Annual BPH Market – January'23.

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ENTADFI®'s Three-Pronged Commercial Strategy

Decile	Total Rx's	Total URO	Rx per HCP
10	1,046,034	229	4,568
9	1,044,673	327	3,195
8	1,044,958	402	2,599
7	1,043,744	470	2,221
6	1,049,786	553	1,898
5	1,045,625	648	1,614
4	1,040,716	766	1,359
3	1,043,213	960	1,087
2	1,043,741	1,334	782
1	1,043,245	7,069	148

~2,600 HCP's fall into Urology Deciles 5-10

* 2023 Deciling, IQVia LRx claims

Source: Integrated Insights Consulting ENTADFI™ Messaging Research; *n*=25; July 2022

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Healthcare Provider – Patient Focus

Targeting 3 channels directed to top decile urologists & patients

DTP
Direct-to-Physician

DTC
Direct-to-Consumer

Telehealth
Consumer Health

Patient awareness Patient demand

Inquire Qualify

Transact Ship

T.B.A

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Onconetix

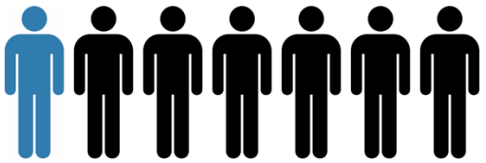
Proclarix®

Partnered with Labcorp in U.S.

Available in Europe

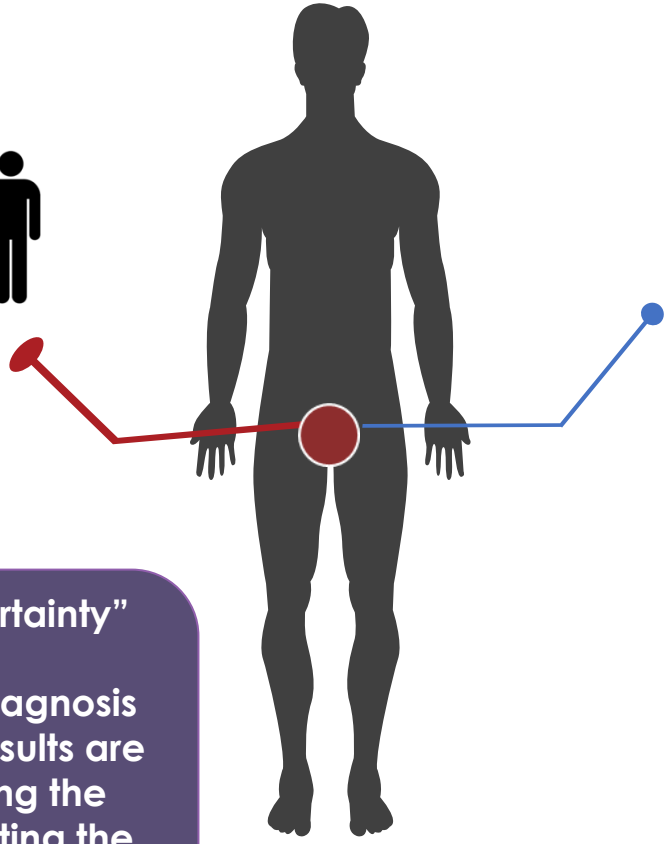
Public Health Burden of Prostate Cancer

Driven by longevity, increased awareness, and more personalized treatment options



1 in 7

Men diagnosed with prostate cancer

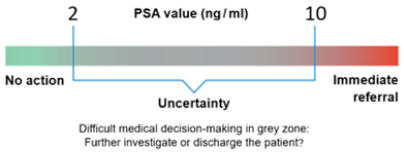


106 million

PSA tests for prostate cancer performed every year for screening purposes

15 million tests

with high PSA levels (2-10ng/ml)



3 million

Biopsies performed every year

1.5 million

Negative or clinically insignificant biopsies representing significant costs and risk/discomfort for patients

Proclarix® addresses "Uncertainty" limitation of the PSA test by improving the NPV of the diagnosis when Proclarix® and PSA results are combined thereby improving the patient experience (by limiting the use of Digital Rectal Exams and preventing unnecessary biopsies)

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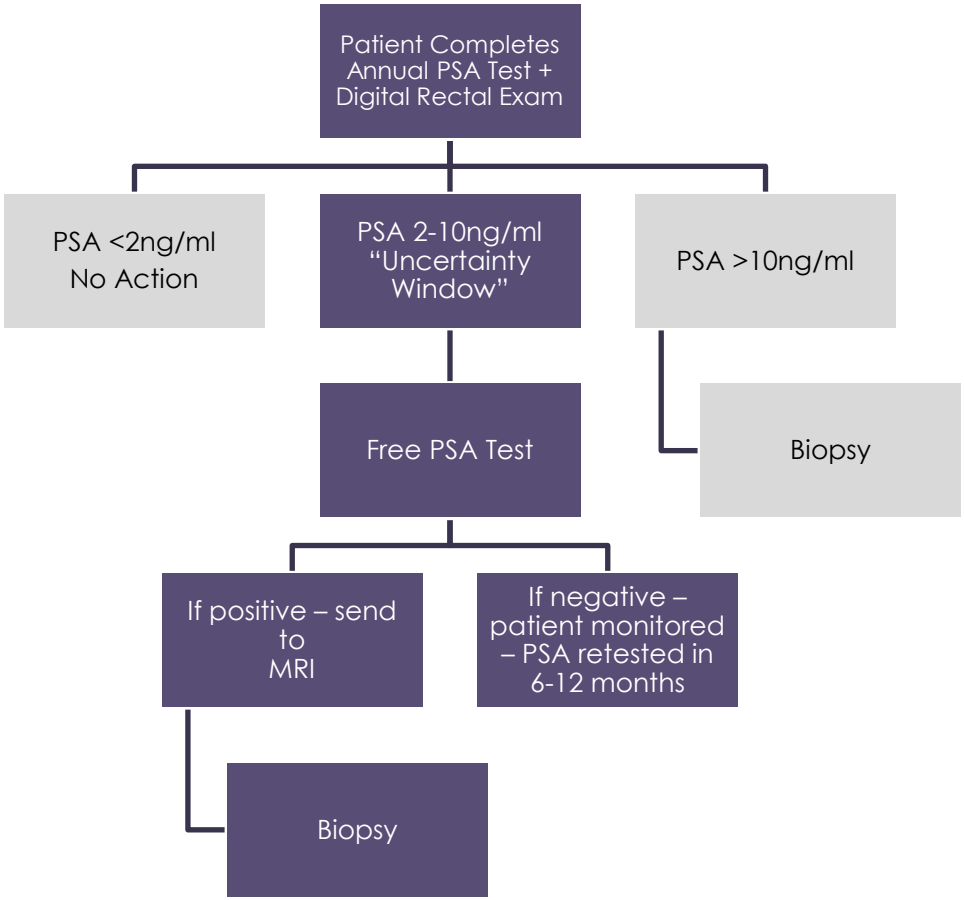
Current Prostate Cancer Diagnosis Patient Journey



Current First Line Testing Performance Metrics*

- PSA Test + DRE: specificity 10%, sensitivity 97%, NPV 86%
- PSA Test + DRE + Free PSA: specificity 20%, sensitivity 93%, NPV 86%
- Low specificity with current testing resulting in unneeded biopsies, 5/10 biopsies today are negative after being recommended to biopsy as a result from PSA Test + DRE + Free PSA Test

Reference *Roche documentation as specified in instructions for use for total PSA and free PSA assays.*

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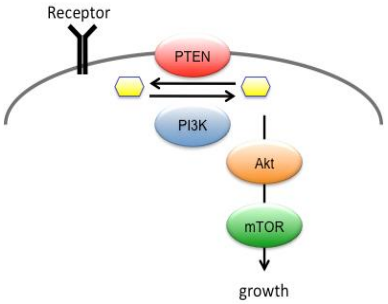
Targeted Biomarker Approach

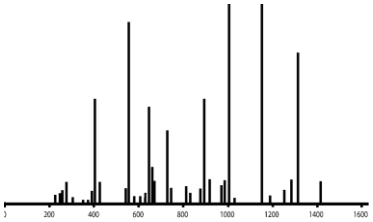
Proteomedix discovered prostate cancer-related biomarkers (THBS1/CTSD) through a genetics-guided approach

1. Molecular cause of Prostate Cancer…



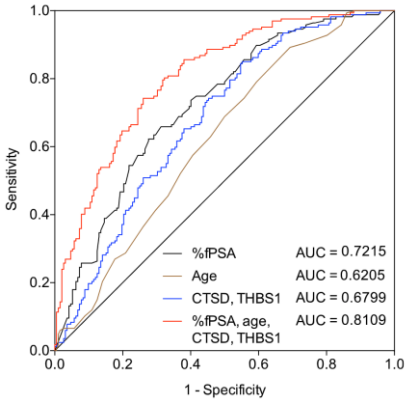
…studied in PTEN KO mouse models[1]

2. Mass spectrometry-based discovery…



…of protein biomarkers in serum (CTSD/THBS1)

3. Biomarker signatures…



…generated from blood-based proteins[2]

Diagnosis
Reduce false-positive results[2] = Proclarix®

Prognosis
Assess Aggressiveness of disease

Prediction
Stratify patients for response to therapy

References: 1. Cima I., *et al. PNAS* (2011), 2. Endt K., *et al. PLoS ONE* (2017)

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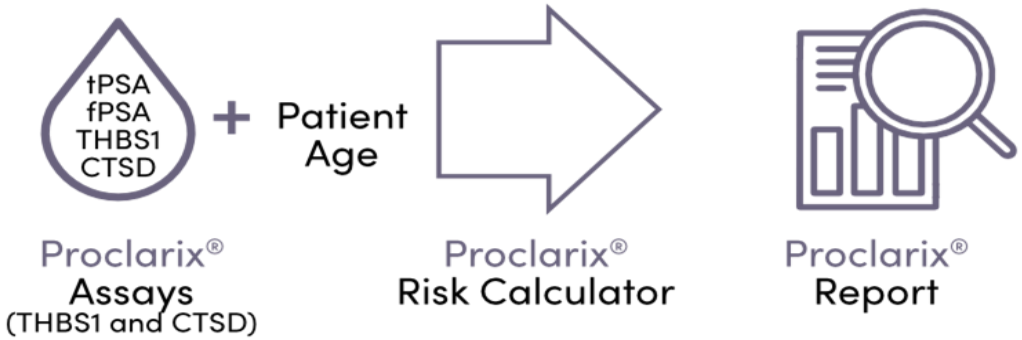
Proclarix® Value Proposition

Proclarix® Improves Patient Experience and Provides a More Accurate Diagnosis



NON-INVASIVE
Blood-based

FAST
Single sample

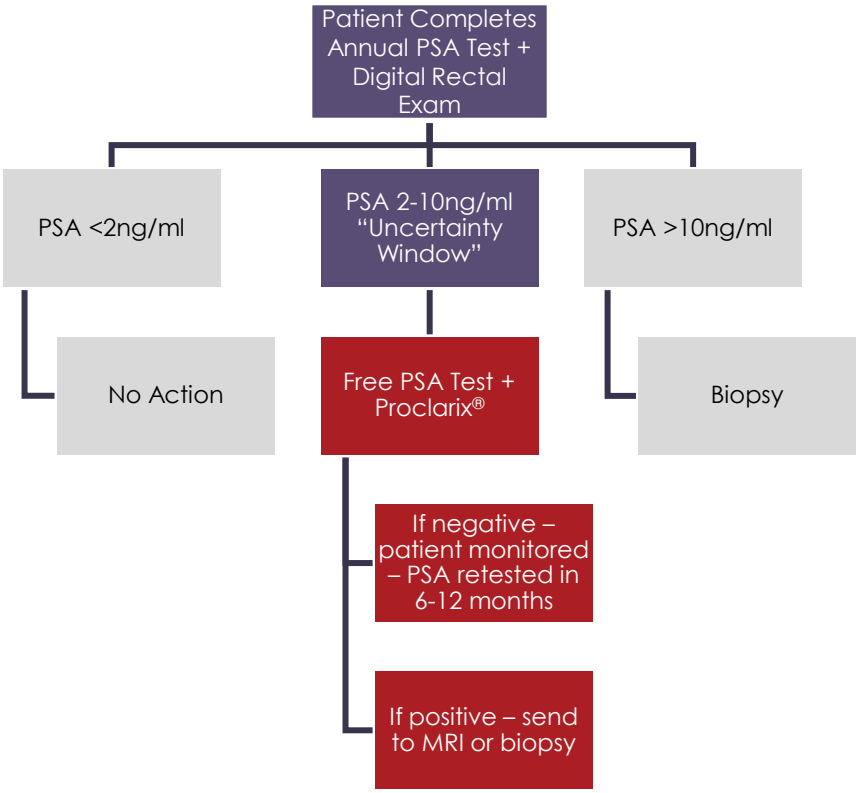
PRECISE
Accurate & reliable

ACCESSIBLE
Local laboratory

COMPLEMENTARY
Proclarix & MRI

Oncnetix™

Proclarix® PC Diagnosis Patient Journey



In the "Uncertainty Window"

- PSA Test + DRE: specificity **18%**, sensitivity 90%, NPV 89%
- PSA Test + DRE + Free PSA Test: specificity **17%**, sensitivity 90%, NPV 89%
- PSA Test + DRE + Free PSA Test + Proclarix®: specificity **43%**, sensitivity 90%, NPV **95%**

Improved specificity and NPV, reducing need for MRI and leading to prevention of unnecessary biopsies = better patient experience

Reference *Klocker, H. et al. Development and validation of a novel multivariate risk score to guide biopsy decision for the diagnosis of clinically significant prostate cancer. BJUI Compass 2020 1(1), 15-20.*

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Proclarix® - Proven Clinical Performance and Benefit

CE validation study (retrospective)

955 patients / 2 centers (AT/DE)
Klocker et al. 2020 BJUI Compass

Clinical Performance

- 90% sensitivity
- 43% specificity
- 95% negative predictive value (NPV)
- Reduction of unnecessary biopsies by 43%

PROPOSe: Clinical benefit study (prospective)

457 patients / 10 centers (EU)
Steuber et al. 2021 Eur Urol Oncol

Clinical Benefit

- Prospectively evaluated, Multicenter setting
- Rule-out test verified (97% sensitivity, 96% NPV)
- Reduction of unnecessary biopsies by 26% vs 7% for fPSA)

Guide use of MRI (retrospective)

721 patients / 2 centers (UK, Spain)
Morote et al. 2023 BJU International

MRI Companion

- Proclarix-MRI combination (90% sensitivity, 68% specificity)
- A large reduction of two thirds of unneeded biopsies demonstrated

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Proclarix® Guideline Inclusion

Proclarix included in the 2023 European and in the American Association of Urology Guidelines

- Guidelines assist clinicians in making informed treatment decisions, taking into account the available scientific data.
- The inclusion of Proclarix in the guidelines is an important recognition of the clinical value of Proclarix.
- It serves as a validation for the clinical utility and importance of using Proclarix in the detection of prostate cancer.

The Proclarix® test is a blood-based test that estimates the likelihood of csPCa according to measurement results for thrombospondin-1, cathepsin D, total PSA, percentage free PSA and patient age. This test has been correlated with the detection of significant PCa, notably in case of equivocal MRI (PI-RADS 3 lesions).

European Association of Urology

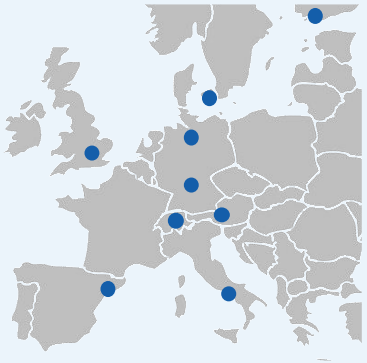
European Guidelines: *Link*

American Urological Association

American Guidelines: *Link*

Proclarix® Commercialization Status

Europe



CAMBRIDGE CLINICAL LABORATORIES

UNIVERSITÄTS KLINIKUM FRANKFURT GOETHE-UNIVERSITÄT

REGION Rigshospitalet

Vall d'Hebron Hospital

Martini-Klinik Prostatakrebszentrum

ZENTRUM FÜR LABORMEDIZIN

DIAGNOSTICA MEDICA

Kantonsspital Aarau

UCL

MEDICAL UNIVERSITY INNSBRUCK

- Pilots with laboratories (lab-chains, private labs and hospital labs) in EU, Switzerland, Germany, Italy & UK
- Broad clinical data/ scientific publications with several top tier cancer centers from Europe
- IVDR certification for Proclarix® assays & software

US

Proteomedix Agrees to Issue Labcorp Exclusive License for Proclarix® Blood Test to Detect Prostate Cancer

Labcorp Plans to Develop and Commercialize the Innovative Prostate Cancer Liquid Biopsy Test in the U.S.

labcorp

May 22, 2023 01:00 AM Eastern Daylight Time

ZURICH-SCHLIEREN, Switzerland--(BUSINESS WIRE)--Proteomedix, a Swiss diagnostics company committed to advancing prostate cancer care, announced today that it entered into an agreement for Labcorp, a leading global life sciences company, to be the only laboratory to develop and commercialize the Proclarix® Prostate Specific Antigen (PSA) test in the U.S.. Proclarix is performed using the same blood sample as a PSA test, and is designed to help determine the risk of clinically significant prostate cancer for men with an elevated total PSA and a digital rectal examination that indicates elevated prostate volume, but who are not suspected of having cancer. In appropriate cases, the test provides a non-invasive alternative to a prostate biopsy, which can have significant side effects.

"This test will give patients and providers clear answers to help them make more informed decisions about the most appropriate monitoring and treatment plan for each patient."

Tweet this

"We are extremely proud of our new collaboration with Labcorp," said Helge Lubenow, CEO of Proteomedix, and added: "About 1 in 7 men will be diagnosed with prostate cancer during their lifetimes, and this type of cancer is the most frequent in men and the second deadliest. There is an important unmet medical need for an accurate diagnosis of clinically significant prostate cancer by employing an innovative, simple blood test. The future commercialization of this assay in the U.S. will significantly impact how care and treatment for men with elevated PSAs is managed. We are pleased to work with Labcorp to make this test available to improve care for more men in the U.S."

"Labcorp is focused on expanding access to innovative diagnostic options like Proclarix," said Dr. Prasanth Reddy, M.D., MPH, FACP, senior vice president and oncology head at Labcorp. "This test will give patients and providers clear answers to help them make more informed decisions about the most appropriate monitoring and treatment plan for each patient."

Tungsten Advisors served as the exclusive financial advisor to Proteomedix. Brown Rudnick served as legal counsel to Proteomedix.

- Labcorp Exclusive Commercial Partner for Proclarix® in the US
- All necessary clinical studies and clinical utility studies will be completed by Labcorp
- Labcorp will commercialize Proclarix® in the US

Oncotix™

Proclarix® vs Leading Prostate Cancer Diagnostics

	Old generation		New generation		Next generation
	Beckman Coulter	OPKO	BioTechne	MDxHealth	Oncnetix
	PHI score	4Kscore	Epi	SelectMDX	**Proclarix™**
Description of the test	Combining PSA, %free PSA, and p2PSA into a score from proprietary algorithm	Combining 4 protein biomarkers and other clinical information into score for aggressive cancer risk from algorithm	Measuring the concentration of 3 RNA cancer biomarkers in urine to score cancer likelihood	Measuring the concentration of 2 cancer biomarkers in urine with other factors to score cancer likelihood	**Measuring the concentration of 2 cancer biomarkers in blood with PSA and age to score cancer risk**
Additional cancer-specific biomarker	No	No	Yes	Yes	**Yes**
Test Type	IVD	LDT	LDT	LDT	**CE-IVDR in E.U./ LDT in US**
Logistics	Complex: Serum to be deeply-frozen for transport	Complex: Samples to be centrifuged and shipped frozen on dry ice	Complex: Relatively unstable samples requiring processing within days	Complex: Relatively unstable samples requiring processing within 5 days	**Blood-based test, using same sample as PSA test and easier shipment**
Cost	EUR 150-180	USD 500	USD 760	USD 300	**USD ~760/EUR ~250**
Reimbursement	Not generally reimbursed anywhere	Not reimbursed in Europe Reimbursed in the US	Not reimbursed in Europe Reimbursed in the US	Not reimbursed in Europe	**Targeting reimbursement**
Ease of use	Need to be run by labs on Beckman equipment	Blood-based test, no prostate massage required	Urine-based test, no prostate massage required	Less patient-friendly – prostate massage required prior to sample collection	**Adaptable to clinical routine, fast time to result, no prostate massage required**

Oncnetix™

Proclarix® Market, Reimb. and Drivers for Adoption

Proclarix's current addressable revenue opportunity in the US and EU is ~$5B (at a retail price of $760 per test in the US and $250 per test in the EU)

US Market $4.25B revenue opportunity:

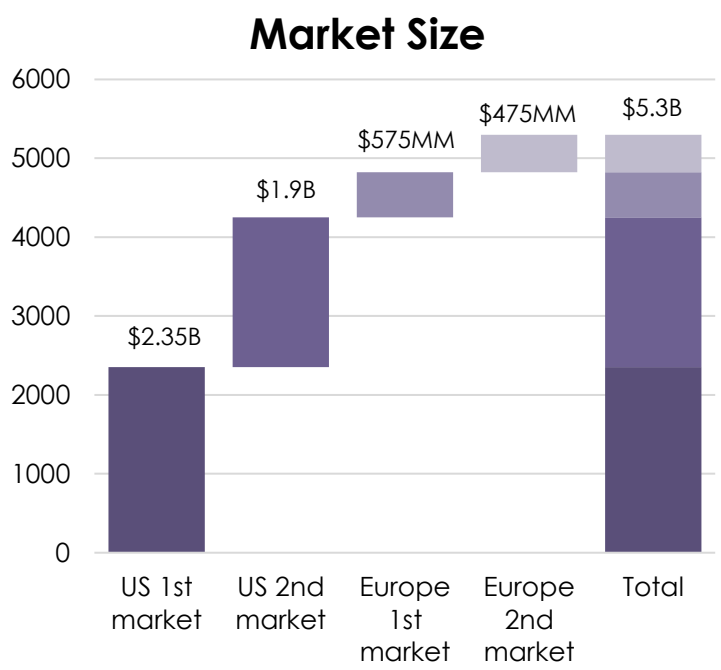
- First market of 3.1MM PSA Tests that fall into the "Uncertainty" window + enlarged prostate + negative DRE
- Second market of an additional 2.5MM PSA Tests if volume and DRE restrictions are removed based on newly generated data

European Market $1.05B revenue opportunity:

- First market of 2.3MM PSA Tests that fall into the "Uncertainty" window + enlarged prostate + negative DRE
- Second market of an additional 1.9MM PSA Tests if volume and DRE restrictions are removed based on newly generated data

Key Benefits when PSA is combined with Proclarix®:

- 2.5x better specificity when PSA and Proclarix are combined vs PSA alone
- Proclarix + PSA – fixed sensitivity of 90% for significant disease resulted in a specificity of 43% and a NPV of 95%
- fPSA alone – fixed sensitivity of 90% for significant disease resulted in a specificity of 17% and NPV of 89%
- Reduction of unnecessary biopsies by 43%



Above figures are management calculations based on number of PSA tests in first and second markets, multiplied by Proclarix retail prices for each addressable market. Estimated number of tests in first market: Steuber et al. 2021 *Eur Urol Oncol* and second market: Morote, J. et al. 2022 *World J Mens Health*

Onconetix™

Proclarix® Risk Report

Proclarix® Report

Clinical Information

Patient ID:	Test Report	Software Version:	2.2.1
CTSD:	268 µg/L	Configuration Version:	3
THBS1:	27874 µg/L	PSA Test Manufacturer:	Roche Systems
Total PSA:	4.74 µg/L	Report ID:	1356
Free PSA:	1.74 µg/L	Report Date:	04.09.2023 12:09:01
Calculated %fPSA:	37%		
Age:	55 years		

Risk of High-Grade Prostate Cancer (Proclarix Risk Score)

Low 3.3%

Low Risk | Cut-off | High Risk

0% 5% 10% 25% 50% 75% 100%

Result Interpretation

Proclarix returns a Risk Score corresponding to the probability of detecting high-grade prostate cancer (defined as Gleason score 7 or higher, i.e. ISUP grade group 2 or above based on a prostate biopsy).

The risk for high-grade prostate cancer is low in men with a Proclarix Risk Score below the cut-off value of 10% and high with a Proclarix Risk Score above the cut-off value. Given the high negative predictive value of 95%, the risk of missing high-grade cancer below the Proclarix Risk Score cut-off is less than 5% [1].

Due to systemic and assay variability, test results between 6.7% and 12.3% should be interpreted with caution. Test results should be interpreted in conjunction with other laboratory and clinical data and consultation of the relevant guidelines on the decision for biopsy. Prostate biopsy is required for diagnosis of prostate cancer. Use outside of the indication has not been validated.

Proclarix Description

Prostate cancer is the second most frequent cancer diagnosis made in men [2]. Proclarix is an aid in prostate cancer diagnosis for patients with elevated PSA values. The Proclarix Risk Score provides physicians and patients with actionable information to confidently take decisions when considering a prostate biopsy that is required for final diagnosis.

Proclarix is comprised of two quantitative immunoassays that measure the concentration of thrombospondin 1 (THBS1) and cathepsin D (CTSD) in human serum [3, 4]. The Proclarix Risk Calculator integrates the values for THBS1 and CTSD, age, total and free PSA (normalized values from third party instruments) to calculate a Risk Score.

The Proclarix cut-off value has been established in a multicenter study with two European clinical centers including 955 men matching the intended use. The cut-off value was set to 10%, referring to a sensitivity of 90% (95% CI: 84-94%) and a negative predictive value of 95% (95% CI: 92-97%) for high grade prostate cancer using transrectal prostate biopsy. The specificity is 43% (95% CI: 39-46%) [1]. Proclarix was further evaluated in multiple clinical studies [5-8].

Proclarix is indicated in men with elevated total PSA (2.0 to 10.0 µg/L), a digital rectal examination finding consistent with elevated prostate volume (35 mL or higher) and not suspicious for cancer. Proclarix is intended for professional use only.

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[2] Bray et al. CA Cancer J Clin. 2018;68(6):394-424;
[3] Steuber et al. BJU Int. 2019. 123(5):826-833;
[4] Macagno et al. PLoS One. 2020;15(5):e0233442;
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[6] Morote et al. World J Men's Heal. 2021;40: 0;
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[8] Morote et al. Int J Biological Markers. 2022.

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CE IVD

General information contains anonymized patient data relevant for risk calculation

The **test result** section reports an individualized risk score between 0 and 100% indicating the risk of high-grade prostate cancer

This section highlights the **result interpretation** by explaining the cut-off chosen

This section contains the **test description** including the parameters, the validation cohort and the intended use

References with peer-review publications

Oncotix™

Proteomedix Accreditation

Quality Management System (QMS):

- ISO 13485:2016 certified for the "Design and development, production and distribution of in-vitro diagnostics and software-based decision aids for improving prostate cancer management".
- Audited by TÜV SÜD Product Service GmbH, an internationally recognized notified body headquartered in Germany.

Proclarix CE-marked according to IVDR:

- Proclarix is classified in the second highest risk class (class C).
- CE-certification of Proclarix under IVDR was accomplished in 2022. A Declaration of Conformity was submitted to Swissmedic. The product can be placed on the European market.
- Authorized representative (Emergo/UL) for EU and UK were engaged.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 097102 0002 Rev. 04

Holder of Certificate: **Proteomedix AG**
Wagistrasse 23
8952 Schlieren
SWITZERLAND

Facility(ies): **Proteomedix AG**
Wagistrasse 23, 8952 Schlieren, SWITZERLAND

See Scope of Certificate

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of in-vitro diagnostic reagents and stand-alone software for prostate cancer management**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 097102 0002 Rev. 04

Report No.: 713272330

Valid from: 2023-01-04
Valid until: 2026-01-03

Date, 2022-12-23

Christoph Dicks
Head of Certification/Notified Body

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Onconetix™

Publications and Patents

Research, Development and Technical Performance

- Cima I, Schiess R, et al. Cancer genetics-guided discovery of serum biomarker signatures for diagnosis and, Hubprognosis of prostate cancer. Proceedings of the National Academy of Sciences. 2011.
- Endt K, et al. Development and clinical testing of individual immunoassays for the quantification of serum glycoproteins to diagnose prostate cancer. Pizzo SV, editor. Plos One. 2017.
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Proclarix in Combination with Imaging (mpMRI)

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Proteomedix Patent Portfolio

- WO2009138392 (licensed). Use of prostate cancer biomarkers for diagnosis and monitoring. Priority date: 14.05.2008. Status: Granted in US, Japan, China, Europe
- WO2018011212. Method of detecting proteins in human samples (Proclarix). Priority date: 15.07.2016. Status: Granted in US, Europe, Japan, China, South Korea, India, Australia. Pending in Canada.
- WO03102018 (licensed). Glycocapture technology. Priority date: 03.06.2002. Status: Granted in US, Europe, Japan.
- WO2023274741. Proclarix and MRI. Priority date: 29.06.2021. Status: Filed in US, China
- WO2023274742. Prognosis biomarkers. Priority date: 29.06.2021. Status: Filed in US, China, Europe

Onconetix™ Summary

- Onconetix (Nasdaq: ONCO) personalized medicine theranostic company in oncology.
- Corporate headquarters: Cincinnati, Ohio
- Initial focus is men's health: BPH and prostate cancer.
- Commercial: **Therapeutically**, The Company currently has **Entadfi®**, an FDA-approved, once-daily oral therapeutic for the treatment of benign prostatic hyperplasia (BPH), a disorder of the prostate.
- Commercial: **Diagnostically**, we have **Proclarix®**, a European CE IVD approved test for prostate diagnostics and a lab developed test (LDT) currently in the U.S.
- Targeted pre-market pipeline of therapeutic, diagnostic, and computational services platform for oncology.
- Deeply experienced, successful commercialization management team.

Thank you!

Dr. Ralph Schiess

Interim CEO

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