

# ACCUSTEM

Building Better Oncology Tools

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## DISCLAIMER

The Company has filed a registration statement on Form S-1, as amended (Registration No.: 333- ) with the Securities and Exchange Commission for the offering to which this presentation relates. Before you invest, you should read the registration statement and other documents that we have filed with the Securities and Exchange Commission for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the Commission's website at <u>www.sec.gov</u>.

This presentation shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any of our securities nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Any offering of securities can only be made in compliance with applicable securities laws.

This prospectus contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. In some cases, you can identify these forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "depends," "estimate," "expects," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "wull," "would" or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short-term and long-term business operations and objectives and financial needs.

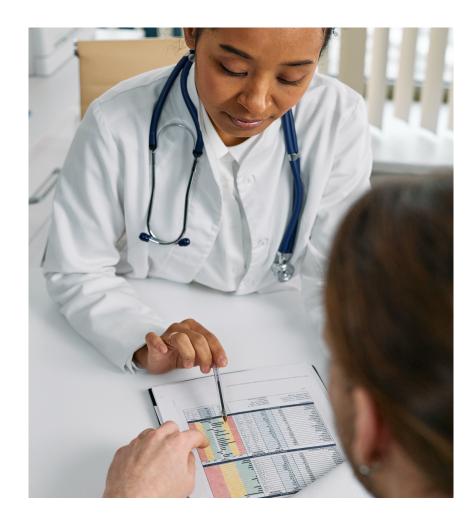
These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read carefully the factors described in the "Risk Factors" section of the Registration Statement to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. These statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements or out update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this presentation. These forward-looking statements speak only as of the date of this presentation, and we assume no obligation to update or revise these forward-looking statements for any reason.



## **COMPANY OVERVIEW**



Our mission at AccuStem is to provide novel diagnostic tools that optimize outcomes and quality of life for all patients along the continuum of oncology care, from cancer screening through treatment and monitoring.

Our focus will be the commercialization of proprietary genomic tests for patients with early stage breast cancer

# Our management team has nearly 60 years of combined oncology diagnostic experience

 Existing relationships with luminary US institutions will enable faster clinical research necessary for expediting reimbursement and commercialization



## **ACCUSTEM ROADMAP TO COMMERCIALIZATION**

Our focus will be the commercialization of a proprietary genomic test for patients with breast cancer representing an estimated market opportunity greater than \$1.3B annually

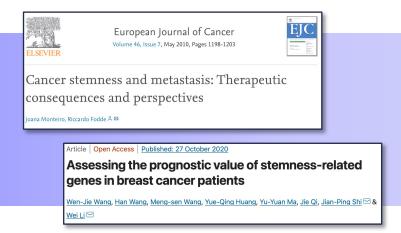
ASSET	TARGET CANCER MARKET	ANALYTICAL VALIDATION	CLINICAL VALIDATION	CLINICAL UTILITY	CMS COVERAGE
StemPrintER	Early Stage <b>Breast Cancer</b>				*may meet minimum threshold
Chara Drivet E D	Early Stage <b>Lung Cancer</b>				
StemPrintER	Localized Prostate Cancer				



## **ACCUSTEM AT A GLANCE**

BREAST CANCER PROGRAM	STEMNESS PROGRAM	EFFICIENT CORPORATE EXECUTION
<ul> <li>In-licensed StemPrintER assay from Istituto Europeo di Oncologia (IEO)</li> <li>US and EU patents approved</li> <li>Our assay has been validated in prospective cohorts</li> <li>Preparing for submission of pre- menopausal data to SABCS</li> <li>Planning to address unanswered clinical questions with our assay</li> <li>Will expand offering to include commodity testing</li> </ul>	<ul> <li>Planning to build on current research of stemness across different tumor types</li> <li>Pursuing signal seeking in lung and prostate cancers</li> <li>Clinical questions identified via work with lung and prostate KOLs</li> <li>StemPrintER evaluated in a Cancer Genome Atlas lung cancer cohort</li> <li>Where applicable, commodity testing will be offered along with StemPrintER</li> </ul>	<ul> <li>Proven leadership team with nearly 60 combined years of experience in the oncology diagnostics sector</li> <li>Opening research lab to focus on breast and stemness programs</li> <li>Planning to expand product offering to additional tumor types as resources permit</li> <li>Evaluating collaboration strategies with industry partners</li> <li>Forming SAB to support effective product development</li> </ul>
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## THE ROLE OF "STEMNESS" IN CANCER



## The cancer stem cell hypothesis is a fundamental concept in cancer biology

- Essentially, all tumors arise from precursor cells that are similar to stem cells; these cancer stem cells are highly adaptable and have the ability to grow indefinitely
- This hypothesis and tumor "stemness" have been widely studied across a multitude of tumor types

## "Stemness" indicates how much a tumor behaves like stem cells

- "High stemness" in tumors is considered a primary rationale for disease recurrence and/or lack of response to chemotherapy and radiation
- Surgery may be the only way to effectively kill cancer stem cells or "high stemness" tumors

## The Role of Cancer Stem Cells in Radiation Resistance

Christoph Reinhold Arnold  $^{\rm 1\star}$ , Julian Mangesius  $^{\rm 1}$ , Ira-Ida Skvortsova  $^{\rm 1,2}$  and Ute Ganswindt  $^{\rm 1}$ 

#### Novel and Alternative Targets Against Breast Cancer Stemness to Combat Chemoresistance

Sangita Sridharan<sup>1†</sup>, Cory M. Howard<sup>1†</sup>, Augustus M. C. Tilley<sup>1†</sup>, Boopathi Subramaniyan<sup>1†</sup>, Amit K. Tiwari<sup>2</sup>, Randall J. Ruch<sup>1</sup> and Dayanidhi Raman<sup>1\*</sup>

While the medical community recognizes the potential utility of measuring tumor "stemness," existing diagnostic approaches have not been able to accurately assess it in patients



## **POTENTIAL UTILITY OF STEMPRINT TECHNOLOGY**

We believe StemPrintER is the only multigene assay able to accurately assess "stemness" which may lead to enhanced patient-physician discussions and more effective treatment interventions that will improve patient outcomes

## "STEMNESS" AND STEMPRINTER COULD INFLUENCE PATIENT MANAGEMENT DECISIONS

 Across all cancers, tumor "stemness" could determine the roles of systemic therapy, surgery and radiation in patient care



## HANNAH GILMORE, MD Chief, Division of Anatomic Pathology University Hospitals

The Science of Health. The Art of Compassion.

"The role of 'stemness' in cancer is an interesting topic and could have big implications for how we treat patients."

"There is clear potential for a "stemness" test in breast cancer but it doesn't stop there- in fact, there may be even more utility in other solid tumors such as **lung, prostate** and head & neck cancers."



## 2M+ new breast cancer diagnoses annually

• No genomic tests to inform surgical approach, benefit of radiation

## StemPrintER is a novel 20-gene test designed to measure the "stemness" of tumors

• By evaluating the underlying "stem" biology of tumors, we believe our test will address unanswered clinical questions

## StemPrintER is highly prognostic in patients with ER+/HER2- breast cancer

• High Risk patients are up to 4x more likely to experience a distant recurrence compared to Low Risk patients<sup>1,2</sup>



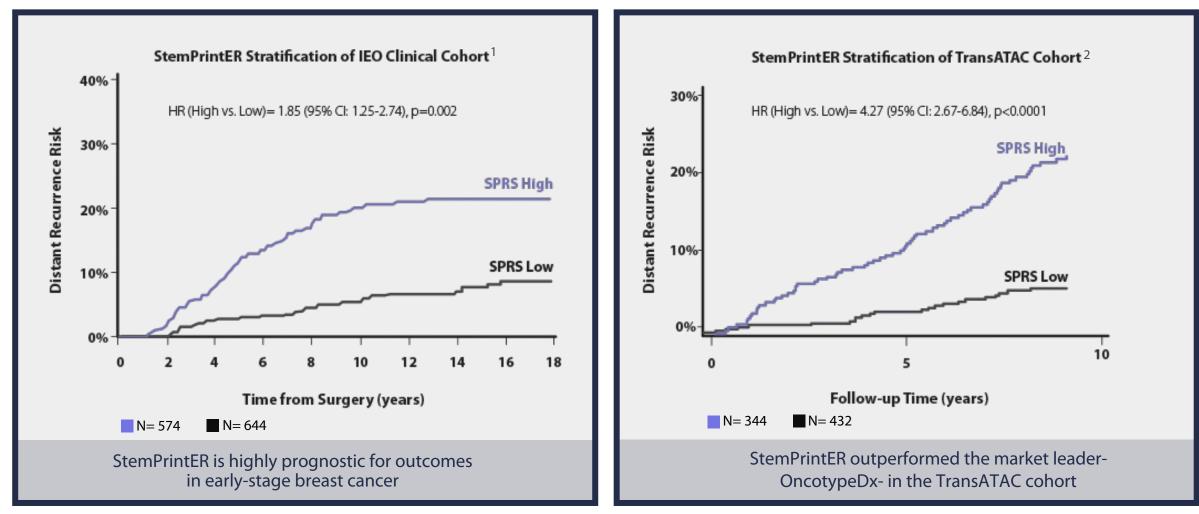
"Understanding the prognosis of a patient's cancer is critical to effective treatment planning and patient counseling."

-Peter Beitsch, MD

1. Pece, et al. Ebiomedicine. 2019; 2. Pece, et al. Eur J Cancer. 2022



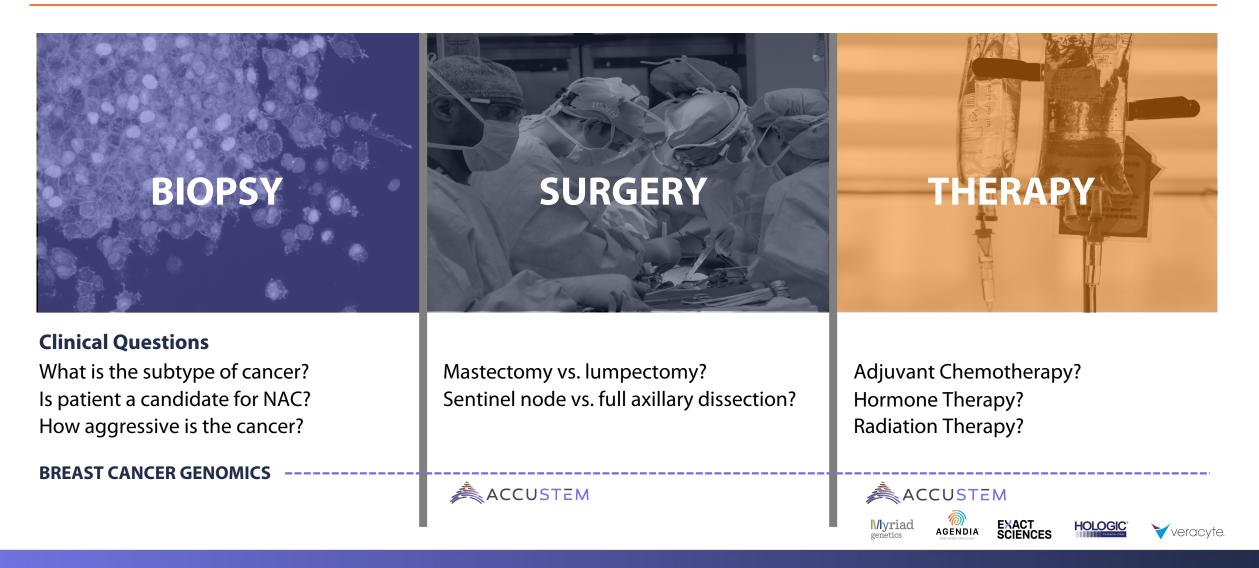
## **VALIDATION OF STEMPRINTER IN BREAST CANCER**



1. Pece, et al. Ebiomedicine. 2019; 2. Pece, et al. Eur J Cancer. 2022



## **CLINICAL DECISION MAKING IN BREAST CANCER**





## **VOICE OF BREAST CANCER KEY OPINION LEADER**



PAT WHITWORTH, MD Breast Surgical Oncology



"Beyond clinical factors and patient preference, we do not currently possess tools to determine the most appropriate surgical interventions, especially the need for and extent of lymph node dissection"

"Knowing that patients with 'high stemness tumors' have elevated risk for local recurrence would certainly influence treatment decisions"



## **BREAST CANCER GENOMICS INDUSTRY**

	AccuStem	Exact Sciences	Agendia	Hologic	Myriad Genetics	Veracyte
Product	StemPrintER	OncotypeDX	MammaPrint	Breast Cancer Index	Endopredict	Prosigna
Global Serviceable Market	798,000	562,000	562,000	562,000	562,000	562,000
Reimbursement (CMS)	N/A	\$3873	\$3873	\$3873	\$3873	\$3873
2021 Revenue	N/A	\$600M <sup>1</sup>	\$60M	\$37M	~\$16M <sup>2</sup>	~\$12M³
Market Cap	\$16.44M	\$12.27B	N/A (private)	\$19.16B	\$2.02B	\$1.97B
<b>Risk of Recurrence</b>	Yes	Yes	Yes	Yes	Yes	Yes
Adjuvant Chemo	Yes	Yes	Yes	Yes	Yes	Yes
Surgery Type	Yes	Νο	No	Νο	No	No

1. Estimated global serviceable market based on 2015 data; 2. Full precision medicine division revenue (many products, not just OncotypeDX); EndoPredict revenue was \$4.1M for Q1 2021; Prosigna revenue was \$3.1M for Q1 2021



## **ACCUSTEM AT A GLANCE**

BREAST CANCER PROGRAM	STEMNESS PROGRAM	EFFICIENT CORPORATE EXECUTION
In-licensed StemPrintER assay from Istituto Europeo di Oncologia (IEO)	<ul> <li>Planning to build on current research of stemness across different tumor types</li> </ul>	<ul> <li>Proven leadership team with nearl 60 combined years of experience i the oncology diagnostics sector</li> </ul>
	<ul> <li>Pursuing signal seeking in lung and prostate cancers</li> </ul>	<ul> <li>Opening research lab to focus on breast and stemness programs</li> </ul>
	<ul> <li>Clinical questions identified via work with lung and prostate KOLs</li> </ul>	
	• StemPrintER evaluated in a Cancer Genome Atlas lung cancer cohort	
	<ul> <li>Where applicable, commodity testing will be offered along with StemPrintER</li> </ul>	



#### 2M+ new lung cancer diagnoses annually

• No genomic tests to inform surgical approach, benefit of radiation

#### StemPrintER may inform treatment planning in patients with early stage lung cancer

• By evaluating the underlying "stem" biology of tumors, we believe our test will address unanswered clinical questions

	AccuStem	Oncocyte
Product	StemPrintER	DetermaRx
Global Serviceable Market	416,000	416,000
Reimbursement (CMS)	N/A	\$3150
Risk of Recurrence	Yes	Yes
Surgery vs. Stereotactic Body Radiotherapy (SBRT)	Yes	Νο



## 1.4M+ new prostate cancer diagnoses annually

• No genomic tests to inform approach to definitive treatment (e.g., surgery, radiation, ablation)

#### StemPrintER may inform treatment planning in patients with localized prostate cancer

• By evaluating the underlying "stem" biology of tumors, we believe our test will address unanswered clinical questions

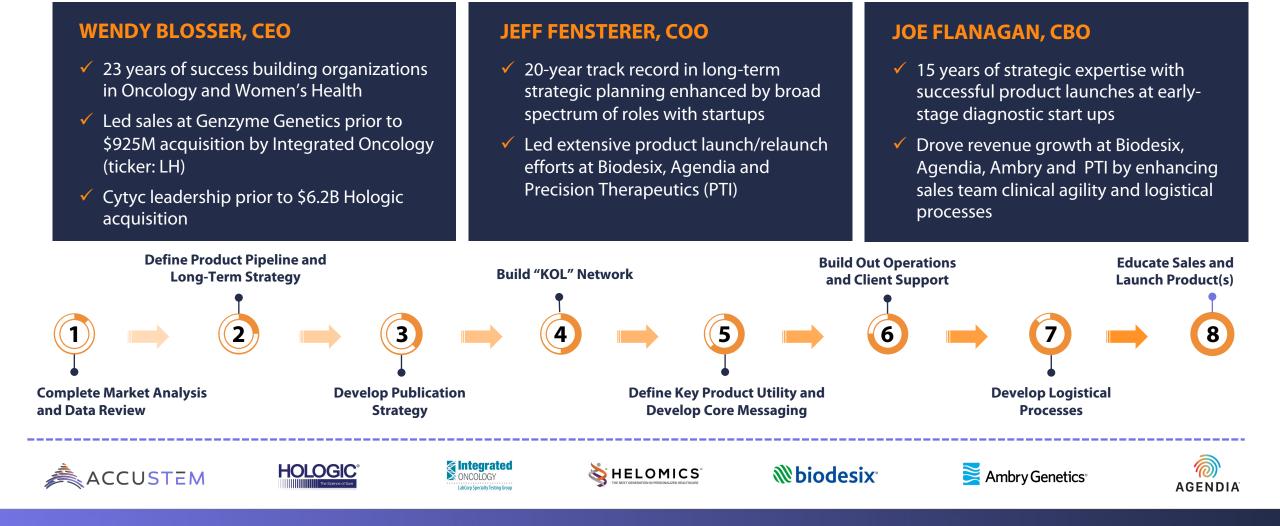
	AccuStem	MDxHealth	Myriad Genetics	Veracyte
Product	MSC Test	OncotypeDX	Prolaris	Decipher Prostate Biopsy
Global Serviceable Market	427,000	54,000	1,570,000	314,000
Reimbursement (CMS)	N/A	\$4000	\$3400	\$3800
Risk of Recurrence	Yes	Yes	Yes	Yes
Active Surveillance vs. Definitive Treatment	Yes	Yes	Yes	Yes
Type of Definitive Treatment	Yes	Νο	Νο	Νο



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#### **GABRIELE CERRONE**

#### Executive chairman

- Chairman and founder of TIZIANA Life Sciences TLSA and OKYO Pharma
- Inhibitex sale for \$2.5B
- Prior experience at Synergy, Cardiff
   Oncology, Gensignia, Rasna, Hepion, and
   Siga Technologies
- Co-founded NASDAQ: HEPA, CLSP, RASP, CRDF, SIGA

**SYNERG** 

inhibitex

#### WENDY BLOSSER

#### Director

- 25 years of success launching, relaunching and building organizations in diagnostic, surgical and capital sales, with a focus in Oncology
- Prior experience at Cytyc (HOLX), Laboratory Corporation of America (Integrated Oncology), Biodesix
  - and Agendia

**TIZIANA** 

SIGA



#### JOHN BRANCACCIO

#### Director

- Over 35 years financial experience in pharmaceuticals, biotechnology and medical devices with over 15 years experience with multiple public companies
- Management and SEC reporting
- Private and public fundraising experience

Sintegrated

abCorn Specialty Testing Group

ONCOLOGY

#### **SEAN MCDONALD**

#### Director

- Experienced technology and healthcare executive who has built multiple companies from startup to over \$150M in revenue
- Founder, President and CEO of Ocugenix
- Past Director Respironics (PHG), Precision Therapeutics and Aethon

HEPION

### **WILLY SIMON**

#### Director

- Career as an executive in the banking and corporate finance sector
- Previous work at Kredietbank N.V., Citibank, Generale Bank NL; Past CEO of Fortis Investment Management
- Past chairman of Bank
   Oyens & van Eeghen;
   Chairman of Rasna
   Therapeutics



citibank

**KB** KREDIETBANK



## THANK YOU FOR YOUR CONSIDERATION



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