



Profitable Growth from Supporting Next-Generation Diagnostics

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Corporate Presentation – Summer, 2024

### **Forward-Looking Statements**

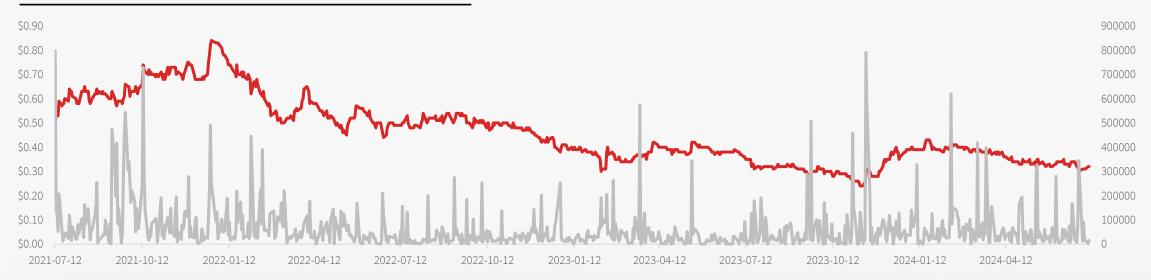


- This presentation contains forward-looking statements about trends and objectives.
- Risks and uncertainties related to such statements could cause actual outcomes to differ materially.
- Such risks include, among others, those related to operations, customers or markets, growth drivers, products or technologies, product pricing or costs, development projects, financial results, regulatory matters, and access to capital.
- Forward-looking statements represent Microbix's current judgement, and it disclaims any obligation to update them.



# **Financials – Microbix Capital Structure**





TSX: MBX	•	<b>OTC QX: MBXBF</b>
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Current Price	<b>\$0.315</b> (July 9)
Shares Outstanding (Basic)	137.4M**
(Fully Diluted)	182.5M**
52 Week High	\$0.45
52 Week Low	\$0.23

Market Capitalization	\$41.7M
Avg. Daily Volume	~60K (3 mos.)
Cash and Line of Credit	~\$14.9M**
Longer Term Debt	\$4.8M BDC & Govt.** \$4.0M debentures*

### **Analyst Coverage**



David Martin

(KRCINSIGHTS)

Bruce Krugel

<sup>\*</sup>Convertible at \$0.23 \*\* As of March 31, 2024

### **Microbix Senior Management**



#### Cameron L. Groome

CEO, President, and Director

- Has served on the MBX BoD and AC since 2012, and was appointed CEO in 2017.
- 30+ years' experience in senior life sciences and finance roles.
- Successful leader, executive, director, and advisor for public and private companies.

#### **Phil Casselli**

Senior. V.P. Business Devel., Sales, and Marketing

- Manages MBX's relationship with over 100 makers of infectious disease diagnostics across multiple regions.
- He holds a Bachelor of Applied Science in Chemical Engineering and has more than 30 years' experience in the biotech and pharmaceutical industries.

#### Jim Currie, CPA

Chief Financial Officer

- Joined MBX as CFO in 2016 after several CFO roles and a VP of Finance role at MDS SCIEX, a global leader in life science and analytical technologies.
- Jim holds a Bachelor of Commerce and holds a CPA and a CMA.

#### Mark Luscher, Ph.D.

Senior Vice President, Scientific Affairs

- Responsible for scientific programs, he is a specialist in cell biology, immunovirology, and cytometry.
- He is an inventor on numerous patents and patent applications and oversees scientific and technological programs and initiatives related to MBX's products.

### Ken Hughes, Ph.D.

Chief Operating Officer

- Executive and biomedical scientist with 25 years of experience in biotech and pharma.
- Previously was CEO of iTP Biomedica, VP of Sci. & Reg. Affairs at Innovative Medicines Canada, and Co-founder and Advisory Board member of PlantForm Corporation.

# >20 Other Skilled Directors & Managers, and total of >120 Staff

Including but not limited to: Steven Hagerman –
 Senior Director of Operations, Amer Alagic –
 Director of R&D, Daniel Costa – Director of
 Manufacturing, Bo Hollas – Director, QA &
 Compliance, Lucy Lin – Director of QC, and Pavel
 Zhelev – Director, Product Management.

### **Microbix Board of Directors**



#### **Martin Marino**

**Board Chairman** 

- Mr. Marino has more than 30 years' experience in corporate legal roles and executive management functions, with emphasis on transaction-based corporate development.
- He also has considerable experience in conflict resolution and litigation management.

#### **Vaughn C. Embro-Pantalony** AC Chair

- Mr. Embro-Pantalony has held multiple executive roles in life sciences, with responsibility for licensing, business development, and strategic planning.
- His experience includes executive roles with Bayer, Novopharm and Terra International. He is a Chartered Director and Audit Committee Certified through McMaster University.

- Dr. Blecher worked as an Emergency Room physician for ~25 years.
- He is a Medical Director of NeuPath Centres for Pain & Spine and is a credentialed pain practitioner with both the American and Canadian Academies of Pain Medicine.
- Dr. Blecher is a co-founder and CMO of both Entourage Health and FH Health.

**Joe Renner** 

Director

• He has enjoyed a successful career

approvals in the United States.

leading businesses with many drug

years' experience in the pharmaceutical industry.

#### Dr. Peter M. Blecher

Director

#### **Jennifer Stewart**

Director

- Mr. Renner, Chairman of Zydus • Ms. Stewart is founder, President, and CEO of Syntax Strategic, a leading Pharmaceuticals, of Pennington, New Jersey, has more than 30 firm in the sector of advocacy and communication for the public and private sectors in Canada.
  - She is a renowned expert in this field, and is actively involved with media, business, and the community.

#### Mark A. Cochran, Ph.D.

HRGC Chair

- Dr. Cochran was Executive Director of Johns Hopkins Medicine.
- His experience spans all levels of the drug discovery and development value chain, including operational and executive roles in the healthcare, venture capital, pharmaceutical, and biotech industries.

#### **Cameron Groome**

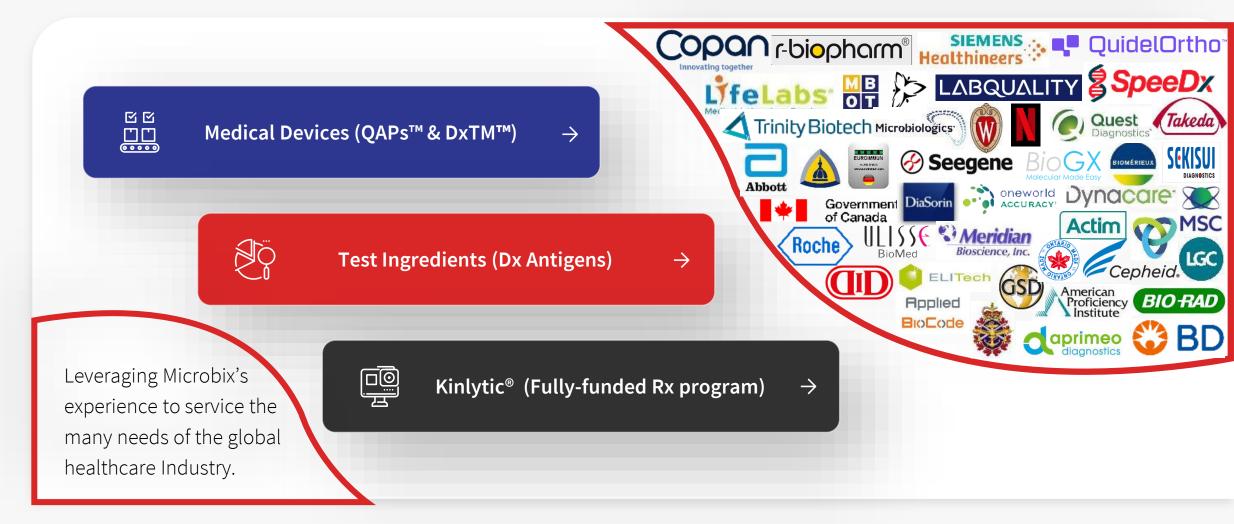
Director

 Mr. Groome is CEO and President of Microbix.

### **Products & Customers Across the Healthcare Industry**



• Supporting diagnostics makers, clinical labs, and lab-proficiency/accreditation agencies worldwide

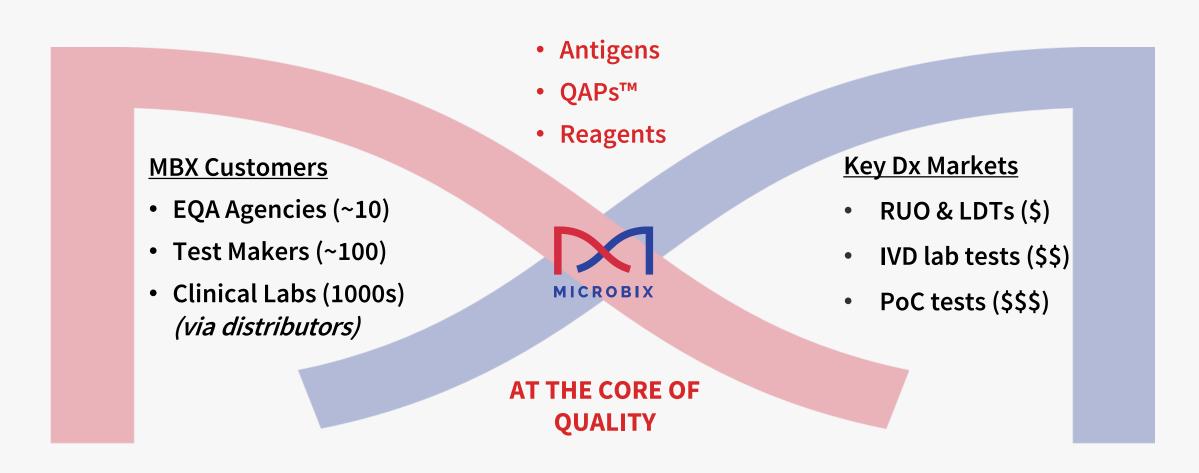


# Makers, Regulators, Users, & Payors Must Be Certain Dx Tests Really Work





Microbix makes essential products that enable diagnostic tests to be made and sold. Many next generation Dx assays need Microbix products for approval & reimbursement.

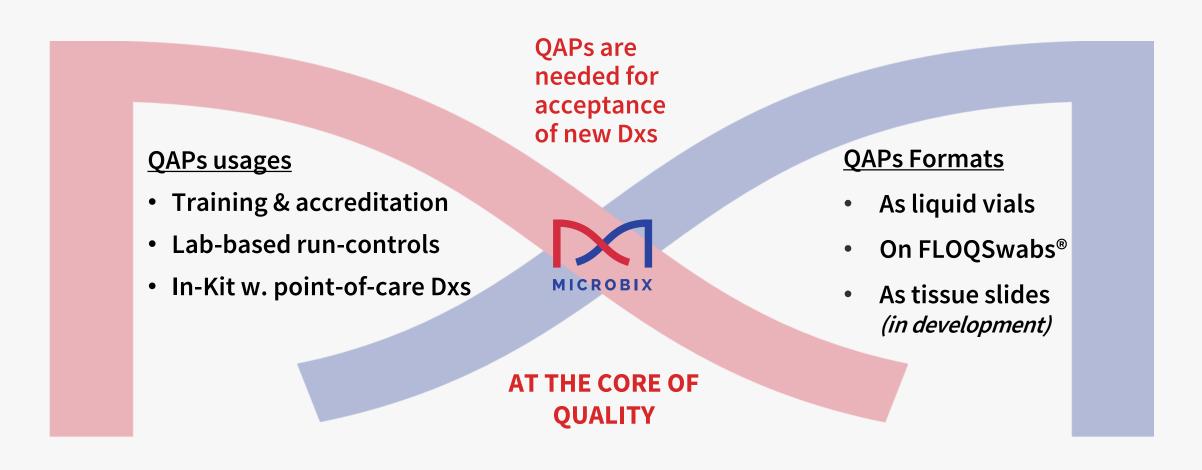


### Microbix Quality Assessment Products (QAPs<sup>™</sup>) Validate Dx Tests



**①** 

Microbix creates mimics of patient samples to challenge tests and thereby avoid systemic errors. Use of QAPs prevents the bad consequences of false-negative or false-positive test results.





# Test Controls - Quality Assessment Products (QAPs™)

### **QAPs** Competitive Advantages



#### Performance

Full-genome & whole-workflow, to best prevent systemic errors across all platforms



#### **Formats**

Vial & FLOQSwab® formats to enable support of both lab-based & point-of-care testing



#### Stability

Proven stability at room temp (swabs) or 2-8°C (vials) for up to two years







#### Multiplexing

Multiple pathogens in one QAP to support next-gen multiplex test-platforms



#### Resistance/Variants

Supporting tests for viral variants and for antimicrobial resistant strains



#### **Intellectual Property**

Defended by issued or pending patents of both Microbix and Copan







# **QAPs™** – Ensuring Test and Test-Workflow Accuracy

Example: QAPs Human Papillomavirus (HPV) Panel needed for MDx test acceptance For use in laboratory-based testing & referenced by Abbott, Becton Dickinson, Roche, & Others

MBX is the sole provider of quality control materials for HPV "extended genotyping panel" PCR tests

HPV molecular diagnostics market is ~US\$ 800M (YE 2022), with ~5% of that \$# becoming accessible to MBX.

MBX supporting launch & ongoing QMS for HPV assays of leading Dx systems (e.g., Abbott Alinity, BD COR, Roche cobas) Providing quality control materials for lab-based assay verification/validation, site onboarding, etc.

Securing contracts to supply HPV quality control materials for cervical cancer screening

National-level programs being secured (e.g., cervical cancer screening use in The Netherlands & Ireland) and supporting further MDx testing rollouts worldwide.







# **QAPs™** – Ensuring Test and Test-Workflow Accuracy

Example: QAPs Supporting Point-of-Care Tests (PoCTs) across multiple pathogens & settings, such as on the QuidelOrtho "Savanna" and the Cepheid "GeneXpert" PCR-based instrument systems.

MBX uniquely able to provide FLOQswab® format control materials, particularly for "in-kit" PoCT support

Replicates the sample-collection workflow and provides consistent sample uptake and elution.

A MBX triplex STI swab QAPs supporting PoCT for C. trachomatis, N. gonorrhea, & T. vaginalis

Australia's GeneXpert-based PoCT program successful in reducing rural community re-transmission of STIs.

MBX QAPs handling stability enables lab-level QMS in a wide range of settings

Validated stability ≥2 years at temperatures of up to 30°C – eliminating need for QMS cold-chain.





# Medical Devices – DxTM<sup>™</sup> (VTM) & Other Testing-related Reagents

Sample Collection Devices (SCDs), Sample or Control Elution Buffers (CEBs)

Sales Potential for SCD & CEB testing reagents

Most lab-based PCR tests conducted require sample-collection or elution reagents, for which security and quality of supply is often questionable. Microbix has secured such business during the pandemic and is now working to secure a broader range of customers for such products & services.

Microbix can now produce at 100,000 vials/week and pending full-process automation increases that 5-10x for support of multiple products.

Two orders from Ontario Govt. totaling C\$ 8.9 million were delivered across FY2021 & FY2022.

Price per-vial depends on formulae & if MBX product or contract filling. Has typically been in C\$ 4-6 range.

Multiple SCD product opportunities to develop. DxTM sales to continue.



Gross margins from reagents production are favourable and other clients are now being pursued. SCDs & CEBs therefore represent another large and sustainable value-creation opportunity.

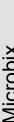


### Test Ingredients - Antigens

Grows, purifies, and inactivates native bacteria and viruses for use as antigens for more than 100 leading international diagnostic companies. Microbix provides antigens on a large scale for major international diagnostic manufacturers, most often as a critical sole-source supplier.

- ToRCH Antigens Worldwide commercial leader
- Respiratory Antigens Broad range of pathogens
- Childhood Disease Antigens Unique offerings
- Sexually Transmitted Infections Full range
- Tropical Disease Antigens Insect-borne pathogens







### Test Ingredients - Antigens

Growth Outlook for this Business Area

In FY2024, Antigens comprise ~50% of revenues, down from 90% historically due to growth of other segments.

During the pandemic, Antigen sales suffered due to reduced testing for nonpandemic diseases.

In FY2023, antigen sales returned to pre-pandemic levels and have again become a growth area for Microbix.



- As healthcare continues to re-stabilize, Antigen sales should benefit from greater global attention to respiratory and infectious disease testing following the COVID-19 pandemic.
- In the more mature markets of the USA and Europe, growth can be derived from expanding relationships with established diagnostics company clients.
- Further sales growth likely from adoption of public-health oriented immunoassays in new regions, such as Asia-Pacific nations.
- Microbix antigens are already being incorporated into dozens of tests seeking approval for use in China – for a large new market opportunity.
- Improvements to processes, including the use of bioreactor technologies for production of multiple antigens, promise to enhance realizable gross margins for this segment.



# Kinlytic® Urokinase – An FDA-Approved Thrombolytic

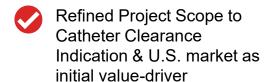
Partnered with Sequel Pharma, LLC for re-launch of a LMW cell-culture derived urokinase

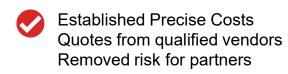
### Kinlytic® Urokinase

Microbix's expertise in biologicals led to its securing rights to this clot-buster drug, that is approved in the U.S. and Canada for two clinical indications (clearing catheters & pulmonary emboli).

- To resume sales, production at a new site must be validated as equivalent to past batches.
- A path to market settled with U.S. FDA, with CDMOs to make drug substance & drug product.
- The U.S. monopoly market for tPA is ~US\$ 350 M for the catheter clearance sub-indication.

Microbix's Kinlytic-Specific Accomplishments:





- Prepared Due Diligence
  Data Room & detailed project
  Plans ~ 3 years to market
  post-funding
- Secured pre-launch funding of ~US\$ 35M to fully underwrite project cost & risk

Sequel Pharma, LLC has the funding and technical expertise to help return Kinlytic to market, which represents a massive opportunity via sBLA, sales-driven milestone payments of up to US\$ 30 million, and ongoing royalties targeted to be a double-digit percentage of net sales.



# Kinlytic - Microbix Agreement With Sequel Pharma, LLC

Via its agreement with Sequel Pharma, LLC, MBX is developing Kinlytic for market re-entry, initially into the U.S. market for the venous catheter-clearance sub-indication.

- In May 2023, MBX announced program to return Kinlytic to the U.S. market under an agreement intended to provide an estimated C\$ 50 million in pre-launch project-related funding from Sequel and its backers.
- Sequel specializes in developing and commercializing drugs for the U.S. market and is fully backed by a leading global life sciences private equity firm (U.S.-based).
- Kinlytic will initially be returned to market to dissolve blood clots in venous catheters in the U.S. (via sBLA), however, it is intended for its use to expand to other geographies and clinical indications.
- Sequel and Microbix undertook new consultations with the U.S. Food and Drug Administration ("FDA") and received updated guidance on the process for filing the supplemental Biologics Licensing Application ("sBLA").
- Microbix has received US \$ 4.0 million thus far and, in March 2024, Sequel executed a multi-million-dollar contract for production of new "Drug Substance" with a leading contract development and manufacturing organization (CDMO). In approximately three years, we are targeting FDA re-approval, sales-driven milestone payments of US\$ 30 million, and ongoing royalties targeted to be a double-digit percentage of net sales.

### **Operations - Capabilities and Highlights**





- Microbix now has over <u>120 staff</u> across <u>3 adjacent sites</u>
- CE Mark and/or FDA Registrations for over <u>50 IVD "REDx" Molecular Test Controls</u>
- 265 Watline (building 1) fully-licensed CL2+ Dx biologicals manfacturing facility
  - Culturing of a wide range organisms at industrial scale
  - Full capabilities for production, QC, and QA of antigens and QAPs materials
- <u>235 Watline</u> (building 2) built-out fully completed and operational
  - Semi-auto liquid-vial format QAPs Mfg. suite 150,000/month capacity
  - Semi-auto dried-swab format QAPs Mfg. suite 200,000 swabs/month capacity
- <u>275 Watline</u> (building 3) now finishing build-out
  - Fully-automated line for reagents production installed
  - Further 2,000 ft<sup>2</sup> Product Development & QC Lab Space completed
- Evolving Organizational Infrastructure
  - Expanding R&D, Customer Service, IT, & Synthetic Biology Capabilities
  - Electronic QMS (MasterControl) & new ERP (NetSuite) being fully implemented





# **Operations - Developing Many New Products & Increasing Revenue Base**



- Hicrobix's product line is rapidly expanding, as is our base of customers. Just In the past 12 months...
  - July 2023 **Netherlands' HPV Screening Program** QAPs supporting <u>BD</u> "COR®" system
  - July 2023 **Bacterial STI Test Support** Using fourplex QAPs on <u>Copan</u> FLOQSwabs®
  - September 2023 **C\$ 1.0+ Million in QAPs orders** From <u>QuidelOrtho</u> for support of "Savanna™" systems
  - October 2023 Ireland's HPV Screening Program QAPs supporting Roche "cobas®" system
  - Hovember 2023 **HPV testing collaboration** with <u>Ulisse Biomed</u> on "Hyris bCUBE™" systems
  - December 2023 **PoCT syndromic testing –** with <u>BioGX</u> on pixl<sup>™</sup> platform
  - December 2023 **Lab-based multiplex testing** with <u>Seegene USA</u> on Novaplex™ & Allplex™
  - January 2024 C\$ 1.0+ Million in QAPs orders From a leading Clinical-Lab Proficiency-Testing & Accreditation <u>"EQA" Agency</u>
  - February 2024 **Novel Test Control for Gastric Ulcer Disease Testing** Needed FLOQSwab-formatted QAP for *H. pylori* assays
  - March 2024 Novel Test Control for Head & Neck Cancer Testing Extending QAPs sales into oncology & histology
  - 4 April 2024 New Lab Accreditation Program for AMR STIs Extending QAPs sales into antibiotic resistance profiling
  - March 2024 Advance in Test-Ingredient Manufacturing Capabilities Increased use of bioreactors for antigens

### **Financials – The Past Several Years**

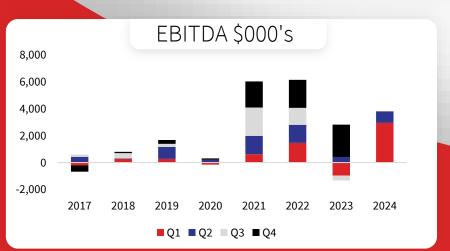


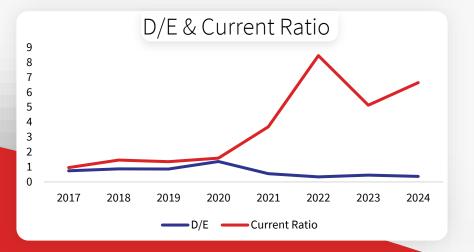
Financial Results – 2017 to 2024 YTD











### Microbix's Business Objectives – The Next Few Years



Attain Dx-Related Revenues of ≥ C\$ 100 million per year by way of:



**1. Cross-Selling** – Sell every product category across existing customerbase of >100 Dx industry firms .



2. New Clients – Identify & secure new Dx industry clients with over C\$ 1 million per year sales potential.





**3. New Product Classes** – Creating or acquiring new product lines, across both user and test categories.



**4. MDx & PoCTs** – Support growth of Molecular and point-of-care-testing via value-added product lines.





**5. Multiplex Tests** – Support industry's move into multi-analyte tests for "syndromic" diagnoses.



**6. Resistance/Variant Tests** – Supporting tests for viral variants and for antimicrobial resistance.



### **Key Takeaways about Microbix**





Microbix has become a "go-to" partner regarding next-generation diagnostic tests. Its QAPs are often essential for approval/adoption of new lab-based and PoC tests.





# **THANK YOU**

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Corporate Presentation – Summer, 2024

### **Cameron Groome**

CEO, President, and Director cameron.groome@microbix.com

