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Antonia Borovina PhD
Analyst
416-640-7582
aborovina@bloomburton.com

David Martin PhD MBA
Analyst
416-642-8865
dmartin@bloomburton.com

Microbix Biosystems Inc. (TSX:MBX; $0.55)

Microbix Initiation: Steady Cash Flow and Significant Growth Potential

Unlike many small cap "COVID" stocks, Microbix was breakeven before the pandemic and is expected to experience substantial organic growth post-COVID. It is a developer and manufacturer of products that are used for in vitro diagnostic (IVD) testing of infectious diseases, including antigens used as components of third-party IVD tests, quality assessment products (QAPs) that ensure IVD test accuracy, and viral transport media (DxTM) used for the collection of patient samples (e.g., for SARS-CoV-2).

Large and rapidly growing market. The global infectious disease IVD market is expected to grow from US$54.6B in 2021 at a CAGR of 6.9%, reaching US$81.5B in 2027 (Research & Markets, 2022). Growth is expected to be driven by several factors including the increased demand for point-of-care and multiplex IVD testing (particularly for respiratory pathogens), higher regulatory scrutiny on IVD tests, and as health systems seek to utilize the testing capacity that was built up during COVID-19 for other applications.

Leveraging quality, reputation and relationships into new, but related areas. We expect Microbix to achieve better than market growth due to its reputation for quality infectious disease antigens (2021 global market: $100M) and its recent expansion into related product lines: QAPs (2021 global market: US$20B for infectious disease controls) and DxTM (2021 global market: $100M for viral transport media in Canada). Across its product segments, we forecast that Microbix's revenues will grow from $22.8M in 2022 to $44.3M in 2025, representing a 25% CAGR.

COVID-19 related sales contributed about 1/3 of Microbix's 2021 revenues. As the pandemic wanes, we expect that some of Microbix's products will decline moderately (e.g., DxTM from $7.0M in 2022E to $6.0M in 2025E, supported by use for other viruses; some COVID-19-specific QAPs transitioning to multiplexed respiratory testing applications), but that the opportunities post-COVID significantly outweigh the risks (e.g., rebound of antigens and growth of new QAPs).

Future growth is fully funded. Microbix is making significant investments in the scale up and automation of production, upgrades to support infrastructure and expanding headcount – all fully funded with cash on hand. With these upgrades, the company believes it can support up to $100M in potential revenues.

We initiate coverage of Microbix with a $1.00* target price and a BUY rating, Above Average risk. The stock has declined 35% since its peak in December 2021, due to the general weakness in biotech, and in particular, COVID stocks. However, we believe the company is well-positioned for the future, as one of a small number of Canadian life sciences companies that is both a growth company and cash flow positive (with 6 consecutive profitable quarters).

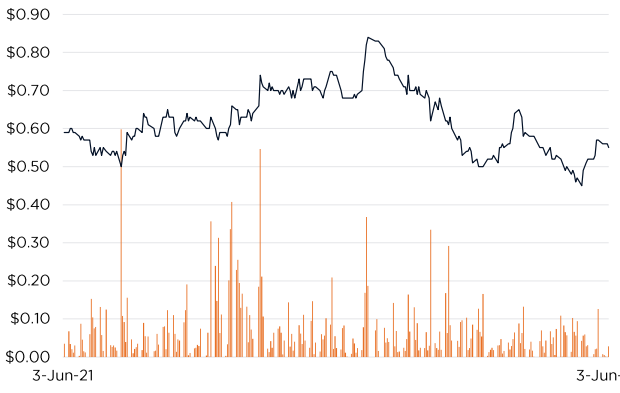
**Our $0.99 target, which we round up to $1.00, is based on an average of DCF analysis ($1.20/share; 8% discount rate; 4% terminal growth rate), 20.2x 2023E EBITDA ($0.87/share) and 4.7x 2023E revenues ($0.88/share).*

Rating:	BUY
Risk:	Above Average
12 Month Price Target:	$1.00

Price	$0.55
Implied Return	81.8%
Fiscal Year End	30-September
52 Week Range	$0.43-$0.87
Shares Outstanding (M)	136.9
Market Cap. (M)	$75.3
Book Value	0.17
Avg. Daily Volume (M)	0.07

C$	2021A	2022E	2023E	2024E
Total Revenue (M)	$18.6	$22.8	$29.8	$37.1
EBITDA (M)	$4.8	$4.6	$6.9	$8.8
EV/EBITDA	14.4	15.2	10.1	7.9
EPS (f.d.)	$0.03	$0.03	$0.04	$0.06
P/E	21.2	20.9	12.9	10.0

2022	1QA	2QA	3QE	4QE
Total Revenue (M)	$4.9	$4.9	$5.5	$7.6
EBITDA (M)	$1.1	$0.9	$0.6	$1.9
EPS (f.d.)	$0.01	$0.01	$0.00	$0.01



This report is priced as of prior trading day's close. All values in C$, unless otherwise noted.

Company Overview

Microbix Biosystems Inc. is a developer and manufacturer of products that are used for diagnostic testing of infectious diseases. Its products include reagent components of third party in vitro diagnostic (IVD) tests, as well as standalone items: quality assessment controls/products (QAPs), that ensure IVD test accuracy; and viral transport media (DxTM) used for the collection of patient samples to test for viral pathogens, including the SARS CoV-2 virus.

The company is based in Mississauga, Ontario, where it manages three sites that house the company's headquarters, as well as R&D and manufacturing facilities.

Microbix is a revenue generating company, with fiscal year (FY) 2021 sales of $18.6M (FY ends September 30), and profitable, with FY 2021 EBITDA of $4.8M (EBITDA margin of 26%). The business is also rapidly growing (revenue +77% FY 2021/2020), as the company adds new, higher margin products to its offering and pursues new customers and markets.

The stock has been listed on the TSX since 1990 (went public via RTO transaction) under the symbol MBX.

Historical Context

Microbix has a long history, spanning several decades. The company was founded in 1984 by William Gastle, a virologist by training, who started by spinning down bovine plasma and selling serum to Ontario public health authorities. Microbix then expanded into performing culturing work for public health and eventually into the production of viral and bacterial antigens for global IVD test makers (added in 1995), which has historically been what the company was best known for, until it recently moved into the manufacturing of more complex products used for IVD tests, namely QAPs and DxTM.

Although still more of a niche player in the global IVD market, which is dominated by large multinational companies, Microbix has developed a reputation for having high quality products, with particular expertise in pathogenic strain selection, reliable and efficient organism culture at scale, purification and pathogen inactivation. Microbix's current catalogue includes products used for the detection of a range of pathogens that are implicated in respiratory diseases including COVID-19, and also a wide range of other maternal, pediatric, childhood, sexually transmitted and insect-borne diseases.

Outside of its core business segment, Microbix also has rights to Kinlytic urokinase, a thrombolytic drug used to treat blood clots, that it acquired rights to in 2007 and which the company is looking to partner to return the drug back to the market. Bloom Burton ascribes no value for Kinlytic in its valuation of Microbix and view a partnership as potential upside.

As the company expanded its product offering, it also grew and expanded its footprint, acquiring its flagship antigen manufacturing facility at 265 Watline Ave. in 2008, which it has since been complemented by the recent addition of two new facilities to produce QAPs and DxTM.

Current CEO of Microbix, Cameron Groome, was appointed in 2017, after William Gastle stepped away from the position. Cameron Groome is a 30+ year veteran of the life sciences and finance industries and during his tenure at Microbix, has been able to grow the business from just over $10M in FY 2017 to over $18M in FY 2021. Mr. Groome also oversaw the launch of Microbix's key new product categories, QAPs and DxTM, which the company sees as its major drivers of long-term growth.

The company is now aiming to enter the next phase of its evolution with an ambitious plan to support $100M in annual revenues over the next several years. The shift began in FY 2021 when the company was able to demonstrate strong sales growth (+77% Y/Y), through the launch of new products and the pursuit of new markets, as well as the improvement in gross margin (59% vs 44% in FY 2020), due to the greater contribution of higher margin Microbix-branded medical devices.

To support further growth, Microbix is making significant investments the scaleup and automation of production, upgrades to support infrastructure and expanding headcount.

Key Product Categories

Antigens

Antigens are glycoproteins that are purified from inactivated bacteria and viruses, or recombinant versions, that are critical test ingredients in the production of immunoassays testing exposure to, or immunity from, the pathogens. Microbix has one

the world's largest collection of antigens produced at commercial scale which it sells to more than 100 customers worldwide, primarily multinational diagnostics companies.

From 2017 until the emergence of the COVID-19 pandemic, growth in end-customer demand for Microbix's antigens had been stronger in both established and emerging markets (FY 2019 sales of $13.1M), but was depressed in FY 2020 and 2021 (sales of $8.7M and $9.1M respectively) due to fewer patients seeking diagnosis for diseases other than COVID-19, reducing demand for non-COVID-19 IVD tests.

We expect future antigen sales to grow due to the resumption of immunological testing for non-COVID-19 diseases, the increase in respiratory pathogen testing for differential diagnosis (e.g., distinguish between COVID-19, flu and other respiratory pathogens) and growth in Asia Pacific, as certain IVD tests become more widely used in the region.

We forecast that Microbix's antigen business will grow at a CAGR of 7% from $8.2M in FY 2022 to $10.0M in 2025.

QAPs

Quality Assessment Products (QAPs) are inactivated and stabilized samples of a pathogen (or an analogue of a pathogen) that are designed to look like patient samples and are used as controls for:

1) Proficiency testing of clinical labs by lab accreditation organizations (QAPs usually unbranded "white label");

2) Test development, instrument validation and technician training by large global original equipment manufacturers (OEMs) developing point of care (POC) IVD tests (QAPs branded as PROCEEDx); and

3) The quality management of patient test-workflows by clinical labs (QAPs branded REDx).

QAPs ensure the accuracy of IVD tests by catching systemic errors and can be used for antigen, immunoassay and nucleic acid (PCR) tests. They come in over 80 discrete SKUs (primarily for respiratory and sexually transmitted diseases) and include both liquid vial and FLOQSwab formats (technology licensed from Copan Italia; private).

The first QAPs were launched in early 2020, with sales increasing from $1.5M in FY 2020 to $4.7M in FY 2021, driven by growth in new and existing products, including the launch of QAPs for COVID-19 antigen and PCR tests, despite the pandemic disrupting the demand many QAPs geared for other diseases.

While Microbix has made significant inroads with lab accreditation organizations, the two largest customer segments for QAPs are OEMs and clinical labs, which are at earlier stages of market penetration. In addition to increasing market share in these segments, QAPs sales growth is expected to be driven by the creation of new proprietary products for different disease applications, including multiplexed tests (e.g., running a single control for multiple viral pathogens).

Sector tailwinds include the expectation that public health authorities will seek to utilize excess testing capacity that was developed during the pandemic to perform IVD testing for many other diseases, as well as increasing quality management regulation of clinical labs in the U.S. and Europe (e.g., stricter CLIA regulations, EU IVD-D and IVD-R regulations and ISO 15189 standards).

We forecast that Microbix's QAPs business will grow from $8.3M in FY 2022 to $28.0M in FY 2025, representing a CAGR of 49%.

DxTM

While Antigens and QAPs are global businesses, Microbix has focused on local (Canada – primarily Ontario to date) need with its viral transport media, branded DxTM. DxTM is used for the storage and transport of patient samples from the site of collection to the clinical testing lab. The product was designed to support PCR testing for the detection of the SARS-CoV-2 virus, but it can be used for the transport of any virus.

Microbix began work on the product in early 2020 and in October 2020, it was announced that the project was awarded an Ontario Together Fund grant of $1.5M (fund to help businesses pivot their typical manufacturing operations to focus on producing health solutions to combat COVID-19 by covering 50% of the cost to scale-up production). DxTM is now one of 3 viral transport medias qualified by the province, but is the only one that is domestically produced, a desirable quality given the current supply chain disruptions and geopolitical tensions.

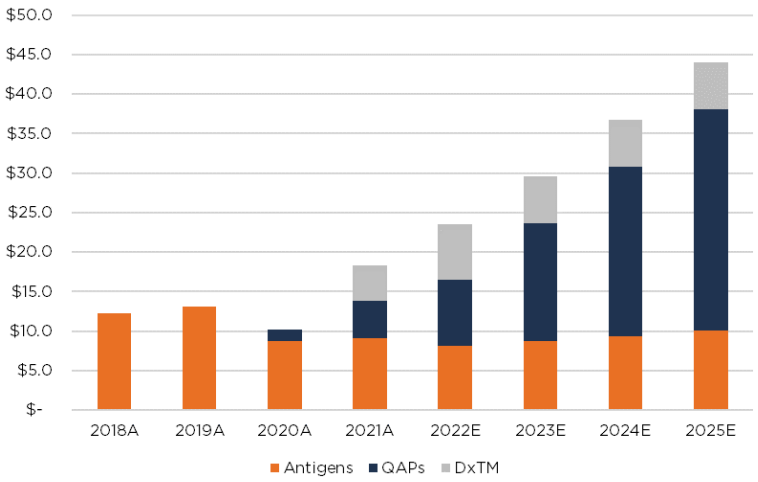
In April 2021, the Ontario government placed a $4.3M order for DxTM (recognized in fiscal 3Q and 4Q-2021), followed by a $4.7M reorder in December 2021 ($1.8M recognized in fiscal 1Q-2022). Microbix also has some smaller private sector orders but the Ontario government accounts for >90% of current DxTM, which the company is looking to de-risk by securing a long-term contract with Ontario and pursuing contracts with other Canadian provinces.

The DxTM business is expected to grow in other provinces, enabled by the company's investments in automated production, which will scale its output from 50K vials per week (100K when double shifting) to 500-600K per week (upgrades expected to be completed by the end of the summer), but this is expected to be offset by an overall decrease in COVID-19 PCR testing volumes, due to the pandemic waning.

We forecast that Microbix's DxTM business to stay relatively stable from $6.1M in FY 2022 to $6.0M in FY 2025.

While Microbix does not break out its revenues by individual products, management noted that in 2021, approximately 1/3 of its revenues were attributed to products geared towards COVID-19, including QAPs for COVID-19 testing and DxTM. Going forward, we expect revenues from COVID-19-specific products to decrease as a proportion of revenues, however, predicting the exact proportion is challenging since some of the newer QAPs will be used for tests of COVID-19, as well as other respiratory viruses (e.g., multiplexed respiratory tests).

Exhibit 1. Microbix's product sales by product category.



Source: Company documents and Bloom Burton estimates

Operations

Microbix currently operates 3 buildings in Mississauga, with a total 34,000 square feet on its campus: 265, 235 and 275 Watline Avenue. Each building houses a mixture of warehousing, office, and manufacturing space, with over 100 staff employed across the 3 facilities.

Its sales infrastructure includes some internal sales capabilities, as well as a network of distributors providing end-user access and sales support in over 30 countries.

Balance Sheet and Capital Structure

Microbix had $12.2M in cash and $6.4M in debt at March 31, 2022 (end of fiscal 2Q-2022). The company's debt includes $3.1M in long term debt ($1.8M BDC loan and a $2.2M FedDev loan), $1.6M of convertible debentures (have a face value of $4.5M and 9% converts at $0.23/share), $0.5M of non-convertible debentures (face value of $2.5M) and $1.1M of operating lease liability. The company is operating cash flow positive, with some quarterly variability ($2.1M in FY 2021 and $8.5M in FY 2020).

At the end of 2Q-2022, Microbix's current ratio (current assets divided by current liabilities) was 6.49 and its debt-to-equity ratio (total debt over shareholders' equity) was 0.38.

The company has 136.9M in shares outstanding as of March 31, 2022, 182.0M fully diluted (includes 16.0 warrants with a weighted average exercise price of $0.52/share, 11.7M options with a weighted average exercise price of $0.41/share and 17.4M of convertible debentures with a conversion price of $0.23/share).

In May 2021, Microbix raised $6.9M through a public offering to fund the scaling of its manufacturing capacity (raised 11.5M shares at $0.60/share; with one-half of one common share purchase warrant exercisable at $0.80/warrant share for 24 months). Its balance sheet is expected to be sufficient to fund all current growth plans.

Catalysts

We believe the potential near term catalysts that could be positive drivers for the stock include:

- Additional industry alliances for its products, most notably QAPs;
- The successful completion of manufacturing scaling and automation;
- Announcing a strategic alliance for Kinlytic (although we believe this is a low probability and would not be a significant driver of the stock);
- Increasing DxTM sales outside of Ontario.

Valuation

We value Microbix based on an average of 3 different valuation methodologies:

- DCF analysis of 2022 to 2035E free cash flow which comes out to $1.20/share. Our DCF uses a discount rate of 8% (Microbix's current WACC of 6%, adjusted for expected interest rate hikes) and a terminal growth rate of 4% (to account for long term inflation and population growth);
- EBITDA multiple method which comes out to $0.87/share. We multiply 2023E adjusted EBITDA of $6.9M by 20.2 (multiple based on comps; Exhibit 12);
- Revenue multiple method which comes out to $0.88/share. We multiply 2023E revenues of $29.8M by 4.7 (multiple based on comps; Exhibit 12);

Using an average of the 3 different valuation methodologies we arrive at our 12-month target price of $0.99/share, which we round up to $1.00/share.

Risks

The key risks to our valuation of Microbix are: aggressive growth assumptions based on market dynamics that are expected to gain momentum, but are as yet, in early stages; limited visibility into customer plans that would validate Microbix's above industry growth expectations; the company's high customer concentration where the top 5 customers (includes Ontario and multinational diagnostic companies) account for 63% of all revenues and Ontario accounts for >90% of DxTM sales; and the uncertainty surrounding the future impact of the COVID-19 pandemic on IVD testing volumes.

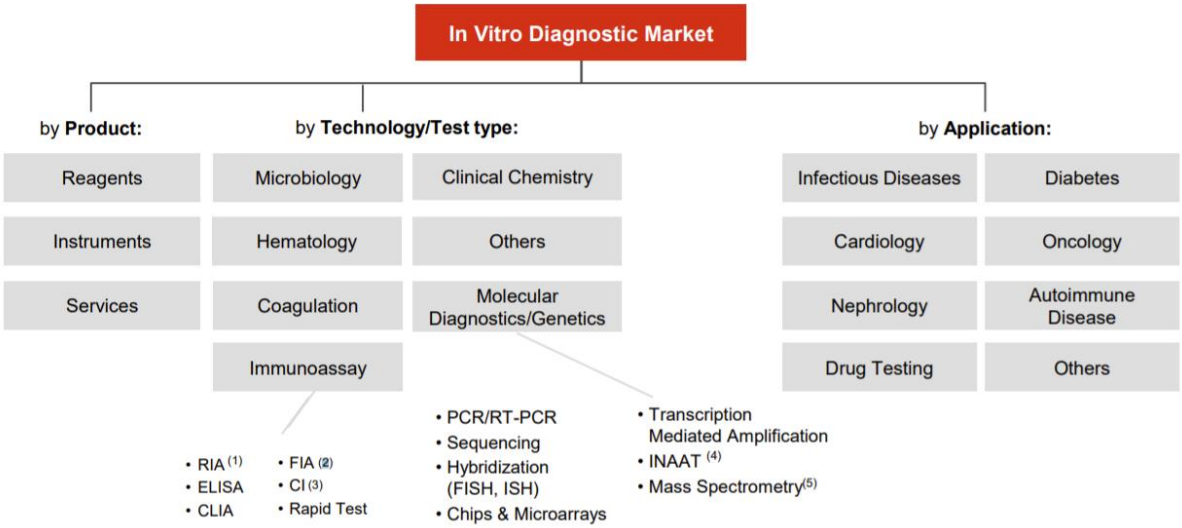
In Vitro Diagnostics Market Overview

Microbix participates in the IVD market, which broadly includes all reagents and assays used to diagnose and monitor a medical condition, by analyzing bodily fluids and tissues of patients.

The IVD market can be segmented in various ways (Exhibit 2), including by:

- **Product** – This includes reagents used to develop and run IVD tests (like the reagents and products Microbix sells), instruments and testing services;
- **Test type** – This includes microbiology, hematology, coagulation, immunoassay, clinical chemistry and molecular diagnostics and other types of tests (Microbix's products are generally used for immunoassays and molecular tests);
- **Application** – This includes tests for infectious diseases (Microbix's focus), cardiology, nephrology, drug testing, diabetes, oncology, autoimmune diseases and others.

Exhibit 2. IVD market segmentation.



Sources: PwC Analysis
Notes: (1) RIA stands for Radioimmunoassay; (2) FIA stands for Fluorescence Immunoassay; (3) CI stands for Colorimetric Immunoassay; (4) Isothermal Nucleic Acid Amplification Technology; (5) Within the Molecular Diagnostics/Genetics segment, is adopted as accessory technology to perform specific analysis

Source: PwC – IVD Market Trends, 2021

Across the various segments, a recent PwC report estimated that the combined IVD market was valued at €80.2B in 2020 ($116B), growing to €104.8B in 2024 ($151B), representing a 6.9% CAGR (PwC – IVD Market Trends, 2021).

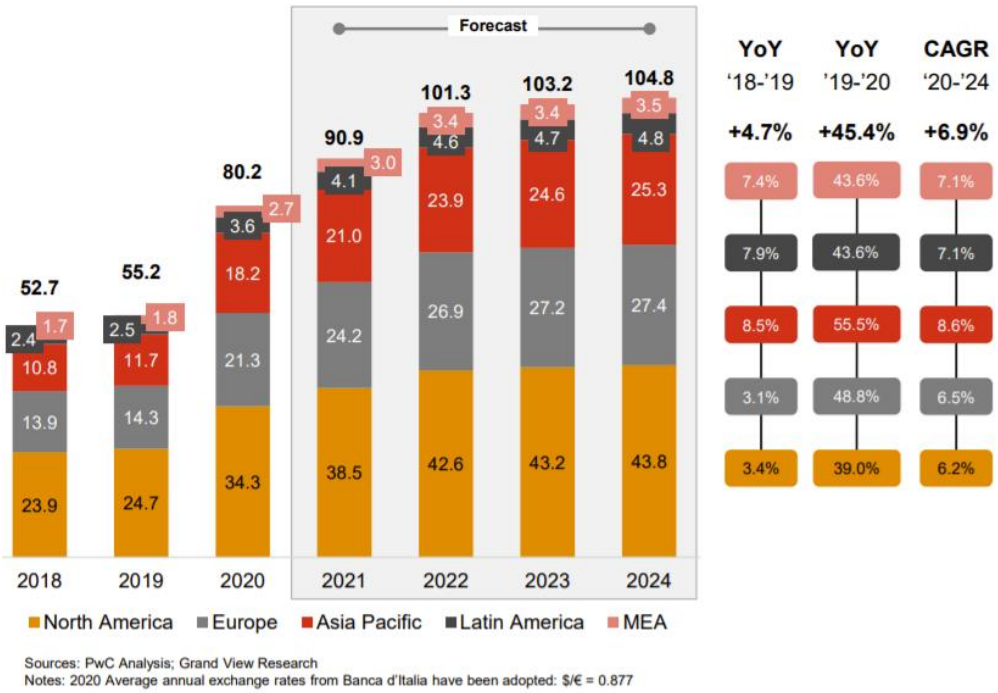
The largest and most established IVD market is in North America, which was valued at €34.3B in 2020 ($48.8B) and is expected to grow at a 6.2% CAGR to €43.8B in 2024 ($62.3B). The fastest growing market is Asia Pacific, which was valued at €18.2B in 2020 ($25.9B) and is expected to grow at a 7.1% CAGR to €25.3B in 2024 ($36.0B), fueled by an improving regulatory environment, increased prevalence of chronic diseases and the increased adoption of IVD tests (Exhibit 3).

Globally, growth in the IVD market is expected to be fueled by a combination of factors, including:

- Demographic shifts (aging populations) and life expectancy lengthening;
- Increase in chronic diseases related to lifestyles (e.g., cancer and diabetes);
- Increased utilization of personalized medicine and a greater focus on disease prevention;
- Healthcare spending growth, particularly in emerging markets;
- Increased demand for rapid and POC diagnostic testing.

Headwinds for the industry include increased regulatory scrutiny (which may be an opportunity for certain players like Microbix) and poorly defined or inadequate reimbursement in some markets.

Exhibit 3. The global IVD market by geography (2018-2024; €B, %).

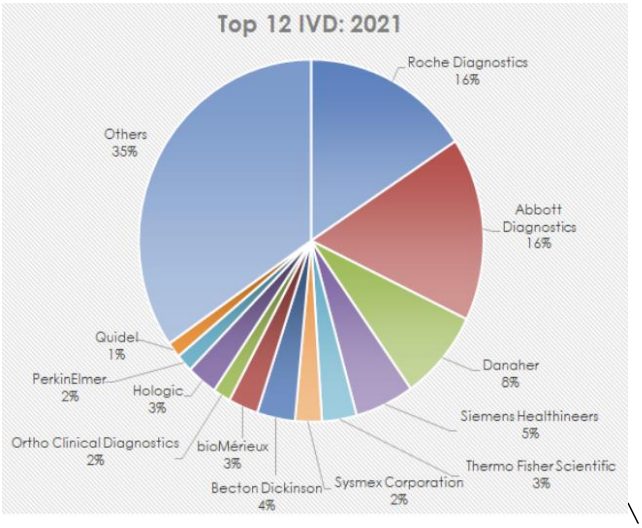


Source: PwC – IVD Market Trends, 2021

While there are more than 500 major participants in the global IVD market, ranging from narrowly focused firms that specialize in one product to large, diversified multinationals, the market is dominated by 20 multinationals that account for nearly 2/3 of the market and have worldwide sales ranging from US$1B to nearly US$30B. Roche and Abbott are currently tied for the #1 spot, each with 16% market share (Exhibit 4).

While IVD test makers generally compete on innovation, test accuracy and technological differentiation, overall success in the industry requires an effective balancing of R&D, manufacturing, marketing, distribution and customer service functions.

Exhibit 4. The top 12 players in the global IVD market.



Source: Kalorama Information, 2022

Microbix's Specific Market Segments

Microbix operates in niche subsegments of the IVD market for which it is difficult to determine accurate market sizes. While our forecasts are primarily driven by broader industry trends for IVD testing volumes (discussed later), below we summarize Microbix's key markets and management's internal estimates for the size of its markets. Since Microbix's markets are niche subsegments of the broader IVD market, the size and dynamics of these subsegments are largely opaque and challenging to externally validate.

Global Antigens Market

The global antigens market can be broken into two broad segments – native antigens (made from inactivated organisms) and recombinant antigens (made in recombinant expression systems). While Microbix offers both types, it primarily specializes in native antigens, which are generally believed to be superior as IVD test reagents since they enable broader antibody binding, and therefore greater test specificity and sensitivity (discussed later).

Management estimates that the market for the third party supply of native antigens is approximately $20M annually, which it splits evenly with Meridien Bioscience (NASDAQ:VIVO; unrated). Additionally, there are some large diagnostic companies like Roche that tend to retain most or all of their antigen manufacturing in-house, as well as some other smaller players in the market that can supply significantly lower quantities of product (micrograms or milligrams vs multi-gram quantities supplied by Microbix, with high purity and reproducibility between batches).

The recombinant antigens market is most often dominated by lower priced products that are used in less expensive tests, with less specificity and sensitivity. Key players in the recombinant antigen market include The Native Antigen Company (private), which does not make native antigens as its name implies, but rather recombinant antigens with more native resembling glycosylation sites, as well as Fapon Biotech (private).

Combined, Microbix estimates that the global antigen market is valued at $100M, with about half of the market available to third party suppliers like Microbix, and about $20M of that subset being truly native antigens.

Prior to the emergence of COVID-19, the antigens market had been growing in overall size and in terms of the proportion being outsourced (market growth rate was 5-7% annually), but antigen consumption declined when the pandemic hit due to the reduction in testing for other diseases. Our forecasts assume a resumption in growth past FY2022, growing 7% annually (discussed later).

Global IVD Controls Market

IVD controls are liquids which contain known concentrations of molecules (e.g., proteins, microbes, etc.) which are run on clinical analyzers to ensure they are functioning correctly prior to analyzing patient samples. The global market for IVD controls is broad and includes controls for various types of IVD tests, with the market dynamics and players involved varying depending on the type of IVD test. Currently, Microbix only operates in the infectious disease subsegment of the IVD market and its QAPs products are controls used to ensure the accuracy of molecular tests and immunoassays.

Management estimates that the current infectious disease test markets that its QAPs plays in total approximately US$20B globally, with COVID-19 testing accounting for up to 50% of that, with the rest being split between hospital-acquired infections (~20%), non-COVID-19 respiratory pathogens (~10%), as well as gastrointestinal, high-risk HPV, vector-borne and STI multiplex (all at or below 10%).

Future growth opportunities for Microbix's QAPs include multiplexed POC tests and antimicrobial resistance testing. Outside of single-channel COVID-19 testing, management expects the testing market will experience double-digit growth, a view that is shared by us and with the company's customers.

Within the infectious disease IVD controls market, Microbix's key customer segments include lab accreditation agencies, where the company has a solid foothold (double-digit percent market share), as well as its newer markets of supplying diagnostic manufacturers of POC IVD tests and clinical labs. In aggregate, the spend on test controls is on the order of 5-10% of the test market.

Viral Transport Media Market

Microbix's DxTM business is focused exclusively on the Canadian market since this is where the product is most differentiated as a domestically produced product. The company's primary customer for this segment remains Ontario, with plans to target federal procurement, other provinces and private buyers as greater capacity comes on-line this summer.

Management estimates that prior to the pandemic the Canadian viral transport market was valued at $50M annually (40% of the market is in Ontario, based on population share), with usage peaking at $150M during the most severe COVID-19 waves, and currently trending at approximately $100M ($40M in Ontario). Usage will likely fluctuate as the COVID-19 pandemic wanes and testing capacity begins to be used for testing of other viral pathogens.

Microbix is supplying about 1/3 of the viral transport media of Ontario public health (there are three suppliers, of which Microbix is one). There are other parties supplying themselves (e.g., McMaster University's home-brew) or selling to commercial entities (e.g., Norgen Biotek or Salus Scientific), and most viral transport media used in Canada remains imported.

In Vitro Diagnostics Market Trends

COVID-19 Impacts

Following the emergence of the COVID-19 pandemic, the global IVD market saw a strong increase in sales (45.4% growth in 2020/2019), largely fueled by the demand for COVID-19 diagnostic tests (namely, molecular PCR and antigen tests for the exposure to the SARS-CoV-2 virus, but also antibody tests for previous infection). While the 2021 IVD market size numbers have yet to be published, the continued impacts of the COVID-19 pandemic were expected to contribute to further strong growth in 2021.

However, these COVID-19 gains were partially offset by the negative impact that lockdowns had on other routine medical testing, as patients shied away from doctor's visits and many hospitals diverted resources away from diagnosing and treating other diseases to treating COVID-19. The pandemic has also disrupted supply chains, which has negatively impacted the development and running of some IVD tests.

When separated by IVD segment, COVID-19 has boosted the sales of immunoassays (like antigen tests; +49.9% in 2020/2019) and molecular tests (like PCR tests; +230.9% in 2020/2019), while negatively impacting other segments (3-5% declines) due to the decline in the routine testing. When segmented by application, COVID-19 negatively impacted all other disease applications except infectious disease testing (+166.2% 2020/2019), with the others impacted negatively.

Changing Regulatory Oversight of IVD Tests

A potential growth opportunity for companies like Microbix, that supply controls for IVD tests, is the apparent shift towards greater surveillance of clinical labs in the U.S. and Europe.

In the U.S., clinical labs are regulated by Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which governs their accreditation, inspection and certification (e.g., ensures the analytical validity of tests through lab surveys every 2 years, although it does not assess clinical validity of tests).

Recently, various proposals have been introduced to modernize CLIA oversight of clinical labs, including the lab inspection process, quality control recommendations and proficiency testing requirements, and most proposals are in favor of greater oversight. The American Association of Clinical Chemistry (AACC) has made recommendations for ensuring the quality of laboratory developed tests, including updating CMS guidelines on design controls and establishing test reliability, as well as expanding quality control and third party proficiency testing (https://www.aacc.org/advocacy-and-outreach/position-statements/archived-position-statements/modernization-of-clia).

Clinical labs are also governed by ISO15189 standards which require the independent assessment of the labs by accreditation organizations, including the examination of personal qualifications and competence, equipment, reagents and supplies, quality assurance (QA), as well as analytical, preanalytical and postanalytical factors. Part of the standards require clinical labs to use third party controls as part of their quality management systems, although adherence to this by clinical labs has historically been mixed.

Furthermore, many IVD POC tests (described in the subsequent section) that were authorized for COVID-19 during the pandemic, as well as other multiplexed tests, were granted market access under Emergency-Use-Authorization (EUA), whereby the normal rules requiring CLIA-compliant in-kit controls were waived and labs were also working under emergency conditions. With the sunsetting of EUAs, there could also be a boost to demand for IVD controls to be included with these tests.

In Europe, new regulations for IVD tests, IVD-R, come into full effect in May 2022 (after a 5-year transition period) which are a major overhaul of the entire IVD supply chain, forcing more stringent requirements for the certification of IVD tests. IVD-R requires the reclassification and recertification of all IVD devices registered in the EU, where manufacturers and suppliers of IVD tests will need to provide analytical performance data, scientific validity, peer-reviewed literature, and clinical performance data to support more stringent standards for clinical evidence. This will also include external quality assessment to support post-market surveillance of IVD test performance to ensure accuracy in real world settings.

The COVID-19 pandemic has also shone a light on the risks of clinical lab error, exemplified by a high profile case in the UK, where a lab falsely reported 43,000 COVID-19 positive patients as being uninfected by PCR testing. The issue appears to have

been with the lab testing protocols and procedures, and not the PCR reagents and tests (https://www.reuters.com/world/uk/uk-lab-suspended-after-false-negative-covid-tests-2021-10-15/).

The regular usage of products such as Microbix's QAPs helps labs avoid systemic errors, which we believe will be increasingly in demand as the scrutiny faced by clinical labs increases and they are encouraged to use quality assessment products from qualified third parties.

Increasing Infectious Disease Testing Outside of COVID-19 (Longer-Term)

While infectious disease IVD testing saw a boom in 2020 and 2021 due to the surge in diagnostic testing for COVID-19 and is expected to decline in the near term as COVID-19 transitions to an endemic disease, longer term, infectious disease IVD testing is expected to benefit from several trends (discussed below), although with differential impacts depending on the subsegment.

POC tests are performed outside of central clinical and hospital labs and are instead conducted in doctor offices and hospital ambulatory and emergency departments (considered professional POC tests), as well as those implemented directly by patients. The professional infectious disease POC market is expected to decline 8.0% annually from its peak in 2021 (US$9.2B) to 2026 (US$6.0B; but up from US$5.9B in 2022; Kalorama Information), due to the endemic transition of COVID-19. However, this disguises more modest growth in the subsector, which is expected to be driven by the analysis of other disease-resistant pathogens and the increasing utilization of these tests in Asia, Africa, and Central and South America.

Molecular tests for bacteria and viruses utilize DNA and RNA primers to recognize genetic signatures, offering superior sensitivity and specificity to immunoassays that detect proteins and antibodies. The molecular infectious disease market is expected to decrease 4.1% annually from 2021 (US$17.5B) to 2026 (US$14.2B). The market is expected to decline from 2021-2023, due to a reduction in COVID-19 PCR testing, and then resume a growth trajectory (bottoming at US$13.6B in 2023) due to increased demand for respiratory testing, particularly multiplexing to distinguish the type of respiratory pathogen (have similar symptoms and are difficult to differentiate from one another through immunoassays and conventional microbiology methods), efforts to combat bacterial resistance and hospital acquired infections, as well as the periodic emergence of pathogenic threats.

The market for infectious disease immunoassays is expected to stay flat from 2021 to 2026 (valued at US$6.7B), with growth coming from the introduction of new products, as well as efforts to reduce microbial resistance and healthcare-associated infections, offset by increasing competition from new, advanced molecular tests.

Microbix's IVD Products

Microbix has established a reputation for having high quality and reliable products, which has enabled it to assemble a mix of well-known customers and collaborators (Exhibit 5; represents only half of Microbix's customer/collaborator relationships), primarily global IVD manufacturers, in a market that is growing and generally quite sticky with respect to customer retention.

Microbix's product catalogue includes over 100 SKUs, that it manufactures at commercial scale, and sells to more than 100 customers worldwide. Its products can be broadly classified into three business segments: antigens, QAPs and DxTM. Combined, Microbix's products generated $18.6M in revenues in FY 2021, up from $10.5M in FY 2020 (+ 77% Y/Y), as the company has added new proprietary products and pursued new customers and markets.

Exhibit 5. Microbix's three business divisions and select customers and collaborators across those segments.

Source: Company documents

Antigens (FY 2021 sales of $9.1M)

Microbix's legacy product segment is its line of antigens relating to pathogens (any part of a virus, bacteria or parasite that elicits an immune response), for which the company has the world's largest collection that can be produced at commercial scale, including native and recombinant forms, although its specialty is the production of native antigens.

These antigens are primarily sold to manufacturers of IVD clinical tests, where they are used as controls in immunoassays (tests that use antibodies to detect antigens in the blood and other bodily fluids), including ELISA, chemiluminescent automated immunoassays, immunohistochemistry, immunofluorescence, latex agglutination, rapid tests, and flow cytometry. In addition to clinical diagnostic assays, these antigens can also be used in basic and applied research in microbiology, as well as vaccine and antiviral treatment development.

Microbix' key antigen categories include:

- ToRCH antigens – ToRCH is an acronym for toxoplasmosis, rubella, cytomegalovirus and herpes simplex virus. Infection with these parasites and viruses are some of the most common causes of congenital defects, since they can be transmitted across the placenta during pregnancy and lead to fetal complications. Routine testing for the presence

of antibodies against ToRCH antigens during pregnancy enables the early detection and treatment of these pathogens, thus preventing serious complications.

Microbix has been developing ToRCH antigens for over 20 years, which it sells to makers of ToRCH screening immunoassays. Microbix isolates highly sensitive, specific and stable native antigens using whole viruses produced in cell culture, that are subsequently purified and inactivated.

- **Respiratory pathogens** – Microbix' respiratory disease antigens cover adenoviruses, respiratory syncytial virus (RSV), influenzas, *Mycoplasma pneumoniae* and *Chlamydophila pneumoniae*.

  Microbix cultures and purifies native antigens against these pathogens (then inactivates them), enabling improved immunoassay detection (vs recombinant antigens), a competitive advantage for diagnostic companies that compete on test speed, accuracy and technological innovation.

- **Childhood diseases** – Microbix develops native antigens for test developers specializing in immunoassays for childhood communicable diseases, including mumps, measles, rubella, Epstein Barr virus and varicella zoster.

- **Sexually transmitted infections** – Microbix develops native antigens for sexually transmitted infections like *Chlamydia trachomatis* and herpes simplex-1 and -2 viruses.

- **Other antigens** – Microbix also produces native antigens from the dengue virus (type 1-4), *Borrelia burgdorferi* and rotavirus.

A key differentiation for Microbix is its ability to produce native pathogenic antigens reliably and at large scale, due to the internal knowhow and protocols it has established over its decades in the business. Key steps in Microbix's antigen production process where the company believes it has best-in-class capabilities include:

- Growing mammalian cells at large scale, with consistent and reliable methods;

- Infecting and growing mammalian cell lines with a pathogen (usually a virus) to get max yields of the pathogen (instead of monolater cell cultures, Microbix has moved some of its production to a bioreactor culture method to improve yields, most notably for rubella antigen);

- Separating pathogen from cell culture and purification of the pathogen;

- Inactivation of the pathogen without impacting the genetic material and protein structure (essential for subsequent testing);

Native antigens are generally considered superior to recombinant antigens because they retain all their antibody recognition sites, enabling a polyclonal binding response (heterogenous antibodies binding to different epitopes on a single antigen) and therefore greater IVD test sensitivity and specificity (vs recombinant antigens that are produced in a recombinant expression system, either as a protein or a virus like particle that usually has just a single targeted epitope).

According to management, Microbix has long standing relationships with its antigen customers, and in the last 15 years, has rarely had any of its samples sent to customers refused, which we believe demonstrates the robustness of this business segment.

However, in FY 2020 and 2021, Microbix' sale of antigens was negatively impacted by the fewer number of patients seeking diagnosis and care for diseases other than COVID-19, resulting in a decline in demand for non-COVID-19 IVD immunoassays (the company does not currently supply native or recombinant antigens of the SARS-CoV-2 virus, but does sell QAPs and DxTM geared towards COVID-19 testing).

Going forward, antigen sales are expected to rebound due to:

1) The resumption of testing for non-COVID-19 diseases, utilizing the increased testing capacity that was expanded during the pandemic;

2) Increased testing for respiratory pathogens overall, in order to distinguish between COVID-19, flu and other respiratory pathogens, as well as identify co-infections;

3) Growth in Asia Pacific, as certain health tests become more widely used in the region (Microbix largely works with distributors in the region), as well as from customers in North America and Europe seeing IVD test growth in Asia.

Microbix also plans to expand its antigen product offering following the completion of upgrades to its biologicals lab, converting it from a BSL2+ to BSL3 biosafety level (planning completion expected by the end of 2022 and for the lab to be in commission by the end of 2023), and enabling Microbix to work on pathogens which can cause serious and lethal disease through the inhalation route (e.g., yellow fever virus, *Mycobacterium tuberculosis*), including potential emerging threats. The company is not likely to pursue the production of native SARS-CoV-2 production due to the rapidly evolving variant landscape (would make native antigens quickly obsolete) and the generally low demand for serological immunoassays for COVID-19, although would have the capabilities to with the BSL3 facility. The company has instead focused on making synthetic RNA controls to support COVID-19 PCR testing as part of its QAPs program.

According to management, given the current antigen production lab space, the company could theoretically support $100M in annual antigen sales, although our and management's forecasts for this segment are much more modest (discussed later).

Quality Assessment Products (FY 2021 sales of $4.7M)

With its introduction of QAPs, Microbix moved away from simply making IVD reagents and into the commercialization of higher margin standalone products.

QAPs are made from either inactivated native pathogens or whole genome synthetic constructs which are designed to simulate patient samples and be used as controls for the assessment of the systemic accuracy of IVD tests. They are available in liquid (require refrigerated storage) and swab format (Copan FLOQSwabs; which can be stored at ambient temperatures) and are compatible with molecular tests (e.g., PCR) and immunoassays.

QAPs are considered premium controls since they emulate both the total workflow of the test and are an accurate representation of the organism (i.e., all surface proteins for an antigen test and whole genome for a molecular test). Top tier labs typically purchase high quality controls from third parties (required under ISO15189 standards), however, some labs may turn to cheaper alternatives, develop their own controls (e.g., plasmids that require refrigeration prior to use or retained patient samples), or forgo controls entirely.

For COVID-19, Microbix has developed QAPs to support the accuracy of PCR tests for the virus (development work began in February 2020, with first sales in Canada, the EU and the U.S. in June 2020) and later developed QAPs for various SARS-CoV-2 variants of concern, as well as QAPs for COVID-19 antigen and serological tests. However, COVID-19 QAPs are only a small portion of Microbix's entire QAPs portfolio, that includes more than 70 discrete products, which it sells either directly or through a network of 9 distributors covering over 30 countries.

Microbix has 3 main categories for its QAPs:

- **PTD** (priced at US$10-20/unit) – This is a line of control products that are sold directly to third party lab accreditation organizations and are usually white-labelled. Since they are used for research purposes internally within clinical labs, they are not directly regulated by the FDA. The lab accreditation market is the first market that Microbix pursued for its QAPs, and is therefore the most penetrated, although relatively small in comparison to other markets for QAPs, since there is a limited pool of these accreditation organizations. Management has indicated that in FY 2021, sales in this subsegment doubled to approximately $2M from its historical base of approximately $1M annually. Our forecasts for QAPs sales in the lab accreditation market assume sales will grow from $2.4M in 2022 to $3.0M in 2025 (discussed later).

- **PROCEEDx** (priced at US$15-30/unit) – This is a line of controls that are used by OEMs, research labs and teaching centers to perform routine device or equipment performance testing, validation and verification, as well as for the training of personnel. These products are usually branded as PROCEEDx or PROCEEDxFLOQSwab, irrespective of the application. When sold directly to diagnostic OEMs, which is the largest market for PROCEEDx, these QAPs are often included in POC IVD test consumables to serve as controls (QAPs are typically included in POC test cartridges at fixed ratios of 1/25, 1/40 or 1/50). As a result of their applications, these products are either designated as for research use only, and do not require FDA approval, or are approved as part of the combined POC sold by the partner OEM. The key differentiation for PROCEEDx QAPs compared to similar products on the market is their FLOQSwab format, which take up and elute back liquid more consistently and are shelf stable for 2 years (discussed later), and their compatibility across most currently used testing platforms, including many being suitable for immunological and molecular assays. While diagnostic OEMs is a relatively new market for Microbix, this segment accounted for the majority of the remaining $2.7M of total $4.7M QAPs sales in FY 2021 (excluding the approximately

$2M of sales to lab accreditation organizations). However, management is very bullish for this segment and is targeting annual sales in the tens of millions. Our forecasts for QAPs sales in the diagnostic OEM market assume sales will grow from $5.0M in 2022 to $20.0M in 2025 (discussed later).

ONBOARDx – This is not a new category of QAPs but test kits assembled of PROCEEDx products, which are used for instrument qualification (IQ), operator qualification (OQ) or process qualification (PQ). They are tools primarily used for verifying the performance of new test systems and training lab personnel.

- **REDx** (usually priced at over US$30/unit) – This is a line of QAPs used for evaluating lab testing performance, procedures and workflow that are sold to clinical labs, either directly or through distributors. REDxFLOQSwab products are used as controls in molecular or antigen based IVD assays and are designed to improve the outcomes of these tests through the early detection of any deviations from desired test performance (as mentioned previously, they catch systemic lab errors). All REDxFLOQSwab controls are classified as Class I medical devices (do not require FDA premarket approval) and are licensed for sale in the U.S., EU and Canada (are FDA/CE certified for IVD use and are manufactured under ISO 13485 and 21CFR Part 820). While Microbix still has limited penetration with clinical labs, the company is targeting to secure multiple lab and distributor accounts of over $100K annually and annual sales in the tens of millions in this market. Our forecasts for QAPs sales in the clinical lab market assume sales will grow from $0.8M in 2022 to $5.1M in 2025 (discussed later).

Microbix's QAPs can also be segmented by their disease application, which includes:

- **COVID-19** – The SARS COMPLETE line includes QAPs for SARS-CoV-2 molecular diagnostics (PCR tests) and QAPs for SARS-CoV-2 immunoassays (detection of SARS-CoV-2-specific antibodies in blood). The molecular diagnostic QAPs contain the SARS-CoV-2 whole genome (cDNA; including different versions for all variants of concern) and human cells, to mimic a patient sample, and are available in liquid formats and FLOQSwabs. The immunoassay QAPs contain the SARS-CoV-2 nucleocapsid protein on FLOQSwabs.

- **Other respiratory pathogens** – These lines of QAPs are for molecular and immunoassays used in the detection of other respiratory pathogens, including for adenovirus, parainfluenza-3, RSV, rotavirus, influenza-A and -B, as well as various combinations of these pathogens.

- **Sexual transmitted infections** - These lines of QAPs are for molecular and immunoassays used in the detection of herpes simplex virus-1 and -2, *Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis, Mycoplasma genitalium*, as well as various combinations.

- **Human papilloma virus (HPV)** – The HPV panel of QAPs is for molecular and immunoassays, and is prepared in HOLOGIC's (NASDAQ:HOLX; unrated) ThinPrep PreservCyt, a methanol-based reagent that serves as a transport, preservative, and antibacterial medium for gynecologic samples.

- **Gastrointestinal (GI) infections** – The GI panel of QAPs is for molecular and immunoassays used in the detection of *Cryptosporidium parvum, Giardia lamblia* and rotavirus, as well as various combinations.

- **Proficiency test products** – These are the products that are used by external lab accreditation organizations to ensure the accuracy of test results conducted by clinical labs.

As we discuss later, the COVID-19 pandemic impacted Microbix' QAPs business both positively and negatively. On the positive side, the company benefitted from the launch of COVID-19 specific QAPs, with sales growth being driven by the high volume of COVID-19 PCR testing that was conducted globally, and the need for controls for these tests. On the negative side, the pandemic disrupted the normal ordering patterns for some QAPs and the launch of new lines, such as the HPV panel.

Going forward, Microbix expects QAP sales growth to be driven by the creation of new proprietary products, including multiplex QAPs (enable the running of one single control for multiple viral pathogens) and QAPs for detecting antimicrobial resistance (Microbix's recently announced collaboration with SpeeDx (private) will develop QAPs to facilitate the registration and commercialization of SpeeDx diagnostic assays for antimicrobial resistant strains of *Mycoplasma genitalium*). Additionally, the progressively tighter surveillance of clinical labs in the U.S. and EU is expected to increase the utilization of existing and new lines of QAPs. We discuss our assumptions for the business in later sections.

COPAN Partnership

Microbix formulates some of its QAPs products with COPAN's FLOQSwab technology. COPAN is a private Italian company, with global sales, that specializes in the development of bacteriology transport swabs, transfer pipets, viral transport systems and flocked swabs.

COPAN's FLOQSwabs consist of a molded plastic applicator stick, with a variable sized and shaped tip. The tip of the applicator is coated with short nylon fibers that are arranged in a perpendicular fashion. FLOQSwabs have no internal core to trap the specimen.

FLOQSwabs are considered to be the gold standard for sample collection and antigen and nucleic acid deposition, due to their consistent surface area on each swab, making antigen deposition predictable and liquid elution more consistent, as well as being stable for 2 years (particularly advantageous for POC tests). These are key attributes for a test swab since clinical labs track the performance data of controls over extended periods of time, necessitating consistency across runs. Given the strong reputation and brand recognition of COPAN's FLOQSwabs, we believe that by developing its QAPs using this technology, Microbix will further differentiate its products as being premium and higher quality than many others on the market.

Microbix and COPAN have a long-standing relationship, where Microbix has purchased COPAN's FLOQSwabs for many years. In 2020, the two companies formalized a partnership, whereby Microbix was given exclusive access to COPAN's intellectual property, enabling it to manufacture controls and other QAPs on COPAN's FLOQSwabs. The two companies agreed to co-brand the QAPs swab product lines as "REDxFLOQSwab" and "PROCEEDxFLOQSwab." Microbix has a transfer price agreement with Copan and pays undisclosed variable royalties on the products, depending on the category (in the single digit range).

Viral Transport Medium (FY 2021 sales of $4.5M)

Microbix's DxTM viral transport medium is designed for use in the collection and transport of specimens containing viruses, including SARS-CoV-2, for viral nucleic acid testing (PCR testing).

The DxTM packaging tubes contain 3 ml of the medium that is able to accommodate 80 mm and 100 mm breakpoint swabs for transportation. The formulation is designed to stabilize viral components and suppresses microbial contamination. As a result, DxTM enables the collection and transport of samples in areas where refrigeration is not readily available (can be used in temperatures of 2-25°C), until the samples can be transferred to the clinical lab for testing.

DxTM is Health Canada approved and was first commercially launched on January 28, 2021 for the transport of patient samples collected for SARS-CoV-2 PCR testing. For this application, DxTM was shown to be equivalent to the current gold standard viral transport medium (tested compared to COPAN's viral transport media by Public Health Ontario) in terms of handling and extraction. However, the key differentiating feature of DxTM vs most other viral transport media on the market is that it is made in Canada (produced at Microbix's facilities in Mississauga, with ingredients and materials from Canadian suppliers). This was particularly important during the initial phase of the COVID-19 pandemic when there were acute shortages in medical testing reagents and equipment.

Microbix began work on its DxTM in early 2020 and in October 2020 it was announced that the project was awarded an Ontario Together Fund grant of $1.45M (fund to help businesses pivot their typical manufacturing operations to focus on producing health solutions to combat COVID-19) to cover 50% of the cost to scale-up production of DxTM for Ontario's PCR testing of SARS-CoV-2, as well as certain QAPs also used for SARS-CoV-2 testing. Microbix began building the inventory at risk in anticipation of Ontario demand and in April 2021, the Ontario government placed a $4.3M order for DxTM, which was recognized in fiscal 3Q and 4Q-2021 (smaller scale private sector sales began in fiscal 2Q-2021). In December 2021, Ontario announced a $4.7M reorder of DxTM, with $1.8M delivered in fiscal 1Q-2022 and the remaining $2.9M to be delivered in fiscal 2Q and 3Q-2022.

Microbix's DxTM is one of three viral transport media that are qualified by the Ontario government for COVID-19 PCR testing, but the only domestic supplier. So far, the large purchase order from Ontario has been lumpy, causing some uncertainty and volatility in the stock, but Microbix is looking to secure a long-term supply agreement which would de-risk the business. Another risk is the high concentration with the province of Ontario, which currently accounts for 90-95% of all DxTM sales and which the company is looking to diversify by pursuing other Canadian provinces, but Ontario will remain its preferred customer. Microbix could potentially sell DxTM outside of Canada but would not be a domestic supplier in that case and thus would have limited differentiation in the market.

To pursue new customers, Microbix is currently in the process of scaling its DxTM manufacturing. Microbix began its DxTM production at 50K vials per week using semi-automated methods (certain weeks could produce up to 100K vials if doing double shifts) and is targeting more-automated production, eventually up to 500-600K vials per week, upon full automation, expected in July 2022 (details discussed later).

While the DxTM formulation was intended for COVID-19 PCR testing, it can be used for the transport of all any viral test sample and may also be used for isolating and growing viral pathogens from patient specimens due to its non-inactivating properties. The current formulation cannot be used for bacterial specimens, which would require another formulation for culture testing.

Differentiation

While still a niche player in the IVD market, we believe Microbix's reputation as a developer of high quality reagents and products can be credited to the company's long-standing focus on having best in class protocols, ensuring consistent and efficient product production, as well as its focus on internal R&D, resulting in the steady introduction of innovative products. Across all its product lines, Microbix is regularly optimizing its production protocols, whether it be using bioreactors for improving yields in antigen production or using automation to rapidly scale the production of QAPs and DxTM. Microbix has also built-in redundancy into its processes. As a result of all of the above, the company has a stellar track record of having not had a single product sent back by a customer in 15 years.

Microbix's R&D output can best be monitored through its presentation at scientific meetings, which the company uses to showcase new products to customers, that compete on test accuracy and technological differentiation, and have recently included:

- A poster presenting the performance results of its QAPs supporting molecular diagnostic tests for the Omicron variant of the SARS-CoV-2 virus (2022 Clinical Virology Symposium of the American Society of Microbiology);
- Two posters on the performance results of its QAPs that support multiplexed molecular screening tests for several respiratory viruses, including adenovirus, enterovirus, influenza-A and -B, metapneumovirus, parainfluenza-2 and -3, RSV, rhinovirus, SARS-CoV-2 and seasonal coronavirus OC43 (Labquality Days and European Society of Clinical Microbiology and Infectious Diseases meeting 2022);
- A poster on the performance results of its QAPs supporting HPV (8 high risk types) molecular diagnostic screening tests (European Research Organization on Genital Infection and Neoplasia meeting 2022);
- A poster demonstrating the performance of its SARS-CoV-2 QAPs, used as positive controls for PCR testing of various variants of concern across different testing platforms, in the context of external quality assessment by OEMs and clinical labs (American Association for Clinical Chemistry meeting 2021);
- A poster presenting a novel neutralizing anti-SARS CoV-2 human monoclonal antibody formulation (PROCEEDx SARS-CoV-2 Ab) for use as a cross-platform positive control for external quality assessment of various serological assays and systems (European Society of Clinical Microbiology and Infectious Diseases meeting 2021);
- A poster demonstrating a novel *Mycoplasma genitalium* (including an antimicrobial resistant strain) positive control for quality assessment of cross platform PCR testing (American Association for Clinical Chemistry meeting 2020);
- A poster demonstrating a novel HPV (high risk, but low occurrence strains) positive control for quality assessment of cross platform genotype PCR testing (American Association for Clinical Chemistry meeting 2020).

While some of these novel products result in patents being awarded that can directly block competitors from marketing similar products (listed below), the production side of the business is largely based on internal protocols and knowhow which is also strictly guarded although rarely patentable.

- Patent WO 2019/218093 A1 covers quality control compositions and whole organism control materials for use in nucleic acid testing;
- Patent US8631715 was licensed from Copan and covered the development of controls on FLOQSwabs.

Regulatory Hurdles Faced by Microbix

In the U.S., most testing components, kits and instruments are regulated by the FDA as medical devices, which ensures their safety and effectiveness, unless they are reagents used in the development of other IVD products.

Since Microbix's antigens are considered simply ingredients or reagents of IVD tests, they are not classified as medical devices and thus are not directly regulated by the FDA. Instead, the final IVD test, of which the antigens are a part of (typically represent approximately 5% of the value of the test), is required to be cleared, which is the responsibility of the customer. Each batch of antigens sent must be validated buy the customer, which is why there is an emphasis on product quality and reliability, and why customer relationships are often sticky.

Despite the antigens themselves not being regulated by the FDA, Microbix's manufacturing facilities are, and all of its products are manufactured under strict quality management and are certified under the requirements of ISO9001 and ISO13485 standards.

Microbix's other products are considered IVD medical devices. The level of scrutiny an IVD medical device faces by the FDA is based on its deemed risk to a patient: Class I products are the lowest tier since they are deemed to pose the lowest risk to patients and public health if they are inaccurate (e.g., cholesterol tests); Class II products pose moderate risk (e.g., pregnancy tests); and Class III are considered to pose the greatest risk if inaccurate (e.g., genetic test to guide cancer therapy). Most Class I and some Class II products are exempt from FDA premarket approval, while Class III all require FDA approval prior to being used in patients.

For FDA premarket approval, there are two regulatory pathways: the 510(k) pathway is for medical devices that are deemed to be "substantially equivalent" to a product already on the market and qualify as low-to-moderate risk; or the Premarket Approval (PMA) pathway, which is more stringent and requires a company to demonstrate the safety and efficacy of its product before it can be marketed. Through either pathway, an IVD test must have evidence of safety and effectiveness through analytical (is the test able to accurately measure a given analyte) and clinical validation (is the test able to accurately identify a particular condition).

Microbix's current product portfolio includes Class I and II medical devices (QAPs), in addition to the reagents not subject to FDA approval (antigens), as just discussed.

Similar principles apply in Europe, where most IVD products are regulated as medical devices and are classified into classes A, B, C and D based on their intended purpose and their inherent risks. Health Canada also regulates medical devices according to classes and Microbix's DxTM is regulated under a Medical Device Establishment License (MDEL), issued to Class I manufacturers.

Kinlytic

Overview

Kinlytic (urokinase for injection) is a thrombolytic agent ("clot-busting" drug) that was approved in the U.S. and Canada for treating pulmonary embolism, coronary artery thrombosis and intravenous catheter clearance.

Urokinase, the principal active ingredient of Kinlytic, is an enzyme produced in the kidneys and found in the urine, as well as the extracellular matrix of other tissues, where it acts on the fibrinolytic system to dissolve blood clots. Its primary substrate is plasminogen, the inactive form of the protease plasmin. When plasmin is activated, it triggers a proteolytic cascade that results in thrombolysis and extracellular matrix degradation.

There are two forms of urokinase which differ in their size and how they are isolated, but with equal plasminogen activating ability, with Kinlytic being the smaller version of urokinase (low molecular weight form). Kinlytic is isolated from human neonatal kidney cells grown in tissue culture, where the donor tissue is first screened for infectious diseases, including several hepatitis viruses and human immunodeficiency viruses. In contrast, high molecular weight urokinase is obtained through anonymous urine samples and due to the low concentration of the protein, donations from thousands of people are required, making screening more challenging and resulting in a greater safety risk.

Historical Background

The backstory for how Microbix came to develop Kinlytic spans several decades. Urokinase was originally launched by Abbott Laboratories (NYSE:ABT; unrated) in 1978 (also the low molecular form), initially marketed as Abbokinase, and was the leading thrombolytic drug in the market (peak sales of US$300M) until a manufacturing disruption in 1998 resulted in it getting pulled from the market (a routine inspection of the Abbott manufacturing facility producing Abbokinase discovered manufacturing deficiencies, raising concerns over possible contamination of the product by pathogens).

Abbott eventually corrected the manufacturing deficiencies and the product was returned to the market in 2002, however, while Abbokinase was off the market, new approaches to the treatment of thrombolysis were developed, most notably the use of recombinant tissue plasminogen activator (t-PA), branded as Cathflo Activase (alteplase; Genentech/Roche; SWX:ROG; unrated) which quickly replaced Abbokinase in clinical practice (2020E sales of US$2.5B globally; Coherent Market Insights, May 2021).

Abbott ended up selling Abbokinase to ImaRx (private) in 2006 for US$20M (included 4 years of inventory), which also coincided with Abbott splitting into two companies (spun off its hospital business as Hospira). ImaRx began selling old inventory of urokinase in October 2006 and by September 30, 2007, it had received aggregate net proceeds of approximately US$14.4M from wholesaler sales.

In 2008, Microbix acquired the rights to Abbokinase from ImaRx, which it renamed Kinlytic, with the goal of bringing the drug back to the market. As part of the deal, Microbix acquired the remaining urokinase inventory (expired now), regulatory filings and related assets for US$2M upfront, as well as the assumption of US$0.5M in chargeback liabilities for commercial product already in the channel at the time. An additional $2.5M was payable to ImaRx upon release by the FDA of the three lots of urokinase that were subject to a May 2008 Approvable Letter. Microbix assumed full responsibility for ongoing regulatory activities associated with the product.

Microbix already had expertise in manufacturing this protein at commercial scale and in performing the numerous biochemical and functional analyses required to reintroduce the drug to the marketplace. This is because in the mid-90s, it developed a biosimilar of urokinase (Abbott's patents expired in 1993), called ThromboClear, that was isolated using the same HNK cell culture techniques. According to Microbix, Abbott engaged in uncompetitive behaviour to block the commercial manufacturing of Microbix's urokinase, including entering into an exclusive supply agreement with the manufacturer of the HNK cells used by both companies. Ultimately the court ruled in Microbix's favour but no significant damages were awarded.

Development Plan

Microbix's initial plan was to return Kinlytic to the market for all approved indications, which would have required a significant investment (approximately US$100-120M) that was untenable for a company of its size, resulting in the asset languishing since it was acquired.

Current management has shifted its focus exclusively on the catheter clearance indication due to its large market (discussed below) and straightforward development path. Microbix believes Kinlytic would be able to split the catheter clearance market with tPA, which currently has a near monopoly, but we are not aware of any obvious advantages of Kinlytic in this indication, although the company may compete on cost and convenience (e.g., room temperature stable and would come in a kit).

Based on its discussions with the FDA, management believes that a supplemental Biologics License Application (sBLA) filing would require producing new batches of Kinlytic according to the original drug file (to demonstrate that the composition of the drug is similar to what was previously on the market), which Microbix owns, followed by completing comparability studies (run a clinical trial to compare Kinlytic to saline in its ability to restore flow with a catheter in 180 minutes). In total, Microbix estimates that to get Kinlytic back on the market for catheter clearance, it would require an investment of US$20M (catheter clearance requires a much lower dose of Kinlytic than for pulmonary embolism, necessitating a much smaller manufacturing footprint) and 2.5 years.

To obtain the required redevelopment funding, Microbix has been trying to secure a partner for Kinlytic for some time. However, management believes the COVID-19 pandemic has made this more challenging for two reasons:

1) The pandemic has disrupted the business of hospital-oriented product companies, the most obvious potential partners for Kinlytic, due to fewer hospital procedures being conducted the last two years, reducing new product budgets at these companies; and

2) The restrictions on physical travel, which made it more difficult to advance negotiations, conclude partnerships, and manage off-site manufacturing or clinical trial work.

As a result, management is not giving any guidance on the timing of securing a partner but remains optimistic that it will derive value from the asset, with the desire to secure a material upfront fee and retain a meaningful proportion of economics.

Microbix does not plan to develop the program independently but has indicated a willingness to potentially co-fund development of the drug.

Since the company has been trying to partner Kinlytic for some time, we view this as a low probability event and as a result, do not include Kinlytic in our valuation of the company. Microbix itself has written-off the carrying value of the asset to zero on its balance sheet.

Market

The catheter clearing market is dominated by a single product, Cathflo Activase, which has approximate sales of US$350M in the U.S. and $50M in Canada (the drug is only approved for catheter clearance).

Another drug approved for the indication is Streptase (streptokinase; CSL Behring; NYSE:CSL; unrated), although the drug is also approved for the management of acute myocardial infarction, pulmonary embolism, deep vein thrombosis arterial thrombosis or embolism and catheter clearance. However, Streptase is rarely used in the U.S. due to the risk of immunologic reactions in individuals who have previously had strep throat infections.

Facilities

Microbix currently operates 3 buildings in Mississauga, with a total 34,000 square feet on its campus: 265, 235 and 275 Watline Avenue. Each building houses a mixture of warehousing, office, and manufacturing space, with over 100 staff employed across the 3 facilities.

265 Watline Avenue (14,000 sq ft; primary antigen production)

This is Microbix's original building and is wholly owned (purchased in 2008) by the company. The 14,000 square foot facility includes a combination of office, manufacturing and testing space. The purpose-built manufacturing component is primarily used for Microbix's antigen production, with a lab that meets CL2+ standards (required for HIV, hepatitis C, West Nile virus, *Mycobacterium tuberculosis* and other pathogens) and a bioreactor production site. The facility is FDA and Health Canada approved and meets the international quality standards, ISO:9001 (for antigen production) and ISO:13485 (for QAPs and DxTM production). This enables the safe production and subsequent inactivation of viral and bacterial pathogens at industrial scale.

The facility is designed to have built-in redundancy to ensure continuity of product supply (e.g., seed and cell banks are kept at multiple sites) and the ability to maintain continuous operations during any power outage (e.g., through a custom generator system and uninterrupted power supply).

Management estimates that its current antigen production facilities could theoretically support $100M in annual antigen revenues.

Planning is currently underway to upgrade a portion of the lab to a BSL3 production site (e.g., adding new negative pressure area and wash stations), giving Microbix flexibility to work on a greater spectrum of pathogens (e.g., chikungunya virus), including emerging threats. Planning for the lab upgrades is expected to be completed by late 2022, with it being fully in commission in the back end of 2023.

Exhibit 6. Microbix's facilities at 265 Watline Avenue.

Source: Company documents

235 Watline Avenue (10,000 sq ft; primarily QAPs production)

Microbix's second facility is a leased 10,000 square foot space that is primarily focused on the production of noninfectious liquid and swab based QAPs. This facility contains 3 new, purpose-built labs in addition to semi-automated and automated QAPs production, fill, finish, and packaging space.

Microbix's new R&D/QC lab is designed to support the scaling of its QAPs production. The facility is now fully built out and the company is in the process of increasing the amount of automation equipment it will house (requires moving out some DxTM production to its third facility), which should be realized in the next month or two. Once completed, the QAPs manufacturing facility will be able to support $50M in annual QAPs sales before requiring further upgrades.

Exhibit 7. Microbix's facilities at 235 Watline Avenue.

Source: Company documents

275 Watline Avenue (10,000 sq ft; primarily DxTM production)

Microbix's third facility was recently leased (July 2021) and is 10,000 square feet. The primary focus of the facility will be the large-scale production of DxTM (including further scale-up and full automation of the production process), development of new product lines and substantial warehousing space.

The physical structure of the facility was completed in April (qualified for use by the end of June), with equipment expected to arrive in late summer. Initial semi-automated production capacity at the facility will 50K vials/week (100K vials/week when double shifting) and up to 500-600K vials/week upon full automation, expected by the end of the summer.

Control Support Systems

In addition to lab and production enhancements, Microbix is also making investments in its systems infrastructure, including:

- Electronic quality management system (eQMS) - Utilizes MasterControl for electronic QA documents, training, auditing, nonconformance, electronic batch production and testing records etc. (implementation 2022/2023);
- Enterprise resource planning system (ERP) – Utilizes NetSuite for managing financials, planning & budgeting, dashboards, reporting, inventory control, purchasing, payroll, vendor management, sales and complaints (implementation 2022/2023);
- Lab information management system (LIMS) - Software platform to manage samples, test results and data to improve laboratory productivity; Drives lab automation, integrates equipment with QC/R&D report generation; Supports e-lab notebooks and improves compliance (implementation in 2023).

Upgrade Costs

Total costs for Microbix's upgrades are expected to cost $5.5M, funded by cash on hand following a bought deal financing (raised $6.9M at $0.60/share on May 19, 2021; with a 1/2 warrant with each share exercisable at $0.80 for 24 months) and entails:

- $1.2M on automation and expanding QAPs and DxTM capacity;
- $2.6M on upgrades at all three of its facilities;
- $0.6M on the control support systems; and
- $1.1M for new product development and QC testing.

Once the manufacturing and IT system upgrades have been fully implemented, Microbix believes that it has the infrastructure to support $100M in annual product revenue.

Competitors

While Microbix operates in a niche segment of the IVD market (reagents and controls for IVD tests), there are several companies with comparable products, many of which are much larger, more established and with broader product offerings.

That said, Microbix has developed a reputation for having high quality and reliable products, which has enabled it to assemble a mix of high-profile customers and collaborators (Exhibit 4) in a market that is growing and generally quite sticky with respect to customer retention. Notably, some of these competitors are also Microbix's customers/collaborators for certain products (e.g., Microbiologics (private), Meridien Bioscience (NASDAQ:VIVO; unrated) and Bio-Rad (NYSE:BIO; unrated)). In the case of native antigen production, while many of the larger players in the market could theoretically develop their own versions, it is often more reliable and cost efficient to turn to Microbix for more niche reagents (e.g., those antigens that they would need maybe one run per year vs the multiple runs per month that Microbix does).

While not an exhaustive list, we highlight some of Microbix's key competitors below.

Meridien Bioscience

Meridien has been in the IVD business for more than 40 years and is based in Cincinnati, Ohio. The company has two subsidiaries: Meridien Life Sciences, which sells molecular reagents for IVD tests (e.g., enzymes and master mixes for PCR assays, antigens and antibodies); and Meridien Diagnostics, which sells IVD tests themselves (for gastrointestinal, pediatric, respiratory and other conditions).

While Meridien has a broad product portfolio, it primarily competes with Microbix in the production of native and recombinant antigens used as components of IVD tests. Meridien states that it offers more than 3,000 antigens and antibodies covering more than 325 infectious diseases, cancer biomarkers, cardiac and metabolic disorders, hormone imbalances and autoimmune diseases. Meridien is best known for its native antigens for ToRCH assays, which compete directly with Microbix's ToRCH offering.

Meridien also has positive controls for IVD tests are in a range of formats that can be used to assess different steps within a molecular diagnostic assay process (e.g., extraction, reagent performance, PCR cycling), which are similar to Microbix's QAPs.

While the products are similar, Meridien is much larger in scale than Microbix, with FY 2021 revenues of US$317.9M and US$190.1M in the Life Sciences segment alone. Meridien also has a larger independent commercial footprint, with its own sales infrastructure in Asia, while Microbix operates in this rapidly growing market exclusively through distributors.

The Native Antigen Company (private)

The Native Antigen Company is based in Oxford, UK, and was founded in 2010, but acquired by LGC Group (private) in 2020.

The company develops and manufactures antigens and antibodies, as well as offering a range of services to the diagnostic and biopharmaceutical industries. Its main focus is the production of recombinant antigens using its proprietary VirtuE expression system designed to produce "native-like" recombinant antigens that have correct folding and many of the glycosylation sites found in native antigens.

While annual sales for The Native Antigen Company are not known, in 2020, Mercia Asset Management sold a 49.4% stake in the business for £18.0M.

Fapon Biotech (private)

Fapon in a global IVD reagent company based in Shanghai, China. The company was founded in 2001 around its core technology platform to develop raw materials for infectious disease IVD testing, first in China, and then globally.

One of its offerings its portfolio of infectious disease recombinant antigens, which compete with Microbix's native antigens, although are of lower cost and lower quality, in our opinion.

The company has a much larger footprint than Microbix, with 1300+ products, 1000+ global partners and 520+ patents.

Werfen (private)

Werfen is a family-owned company based in Barcelona, Spain, that was founded over 50 years ago. It is a developer, manufacturer and distributor of specialized diagnostic instruments, related reagents, automation workcells and data management solutions, for use primarily in hospitals and clinical laboratories.

Werfen's OEM business line is involved in researching, developing and manufacturing customized assays and biomaterials. The company states that it has over 80 long term customers in the IVD industry that utilize its immunoassays and biomaterials in their test development, including 6 out of the top 10 IVD manufacturers.

The OEM line directly competes with Microbix's antigen business, however, unlike Microbix that offers native and recombinant pathogenic antigens, Werfen only offers recombinant antigens, generated using its BES in vivo expression system (uses insect larvae as living bioreactors). While both approaches can be desirable, depending on the context, native antigens are generally preferred since they more closely mimic the native pathogens found in patient samples.

Werfen has a workforce of 5,500 and operates directly in nearly 30 countries (in more than 100 countries when including distributors), with R&D and production centers in the U.S. and Europe. Its last annual report indicated that its 2020 revenues were €1.7B.

Vircell (private)

Vircell is a Spanish company that was founded in 1991 and specializes in the development and production of ready to use reagents for the diagnosis of infectious diseases. The company specializes in the in-house production of antigens and the development of diagnostic test kits.

The company's products are currently distributed in over 90 countries, across 5 continents.

Randox Laboratories (private)

Randox was established 40 years ago and is based in Northern Ireland, with distribution in over 145 countries.

The company's product offering includes diagnostic reagents, quality control products and clinical chemistry analyzers, as well as its Randox biochip technology that has applications in immunoassays and toxicology testing.

Randox is a leading provider of QC products for molecular infectious disease testing, including viral, bacterial and fungal targets. Its Qnostics Control range is a line of whole pathogen controls designed to mimic the performance of patient samples, which can be used to monitor the performance of the entire testing process including extraction, amplification and detection. Randox' products are analogous to several of Microbix's QAPs products, although Microbix's products are differentiated by their broad IVD test equipment compatibility and elegance of the FLOQSwab format, considered to be the gold standard for sample collection and which Microbix has an exclusive license on.

However, Randox is much larger than Microbix, with 3,300 employees, including 650 research scientists and engineers, with manufacturing and R&D capabilities in 4 jurisdictions across 3 continents. Randox last publicly available earnings disclosure indicates revenues of £181M for the 18 months ended June 2020.

Thermo Fisher Scientific (NYSE:TMO; unrated)

Thermo Fisher is one of the largest global suppliers of scientific instrumentation, reagents, consumables and software services. The company was founded over 60 years ago and is based in Waltham, Massachusetts, with several well-known brands under its umbrella: Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, Patheon and PPD.

Thermo Fisher's microbiology QC products are designed to ensure their reproducibility of clinical test results for over 600 microorganisms, with similarity to several of Microbix's QAPs, although Thermo Fisher has a more expansive product offering.

As one the biggest players in the scientific instrumentation and tools space, Thermo Fisher's revenue totaled US$39.2B in 2021, with 30% of the revenue in the diagnostics and healthcare division. The company has over 125,000 employees and operates in over 600 locations globally.

Microbiologics

Microbiologics is a provider of biological control materials, assay services and consulting for microbiology, molecular diagnostics and virology applications. The company was founded over 50 years ago and is based in Saint Cloud, Minnesota.

When Microbiologics was first founded, its business was the provision of testing services for the detection of microbial contamination in environmental sources. The company subsequently moved into the manufacturing and selling of lab supplies, such as lyophilized microorganisms, and now also specializes in the development and sale of controls to biopharmaceutical companies developing anti-infective drugs, vaccines and therapeutics. Across its entire portfolio, its products are sold in over 150 countries.

Among those products is a line of QC sets and panels for monitoring testing processes and equipment that compete with Microbix's QAPs.

Microbiologics employs more than 200 people across 4 locations (in Minnesota, California, Kentucky and Michigan).

LGC Standards (private)

LGC Standards is a division of LGC Group, an international player in laboratory services, measurement standards, reference materials, genomics and proficiency testing.

LGC's portfolio includes over 300,000 reference materials and analytical standards, with a customer network that covers over 13,000 labs in more than 160 countries, conducting over 2,000 proficiency tests each year. Some of LGS Standards' product compete with Microbix's QAPs, including its AXIO Proficiency Testing line, which offers products for proficiency testing of clinical labs for QA/QC testing and accreditation.

LGC has 27 offices and 2,300 employees, with manufacturing facilities in the UK, U.S., Germany and China.

Bio-Rad Laboratories

Bio-Rad was founded 70 years ago and is another large American developer and manufacturer of specialized technological products for life science research and clinical diagnostics markets.

A key offering for the company is its QC products for key diagnostic areas that are similar to Microbix's QAPs.

Bio-Rad is based in Hercules, California, but has offices in 35 countries globally, with approximately 7,900 employees and 2021 revenues of US$2.9B.

Antylia Scientific (private)

Antylia Scientific is a life science tools company based in Vernon Hills, Illinois, that develops and markets a portfolio of products for the healthcare and environmental markets. The company was founded more than 65 years ago and today has more than 200,000 SKUs across its different business lines.

Its ZeproMetrix line consists of quality solutions for the infectious disease diagnostics market, including external quality controls, verification panels, proficiency panels, customized OEM products/services. ZeptoMetrix's patented NATtrolTM process renders highly purified microorganisms noninfectious while allowing internal nucleic acids to remain intact, designed to be used as reference material for molecular diagnostic testing applications. Antylia's ZeproMetrix line competes directly with Microbix's QAPs in the third-party quality controls market.

Qnostics (private)

Qnostics is based in Glasgow, Scotland, and has been providing molecular controls to IVD manufacturers, clinical research organizations and end-user clinical molecular diagnostic labs for 15 years.

Its specialty is the development, manufacture and distribution of infectious diseases molecular controls for use within molecular labs and nucleic acid testing (NAT) assays. The primary focus for the company is on infectious diseases, including the availability of hundreds of molecular characterized viral, bacterial and fungal targets. These products are directly competitive with Microbix's QAPs.

Forecasts

Antigens

Antigen sales totaled $9.1M in FY 2021, up from the $8.8M in FY 2020, but still below the $13.1M recorded in FY2019. Management has guided to relatively flat antigen sales in FY 2022 or modestly below FY 2021 levels (BB estimate: $8.2M).

While this product segment has been negatively impacted by the COVID-19 pandemic (was growing 7% Y/Y pre-pandemic), as lockdowns and hospital restrictions hampered the overall volume of IVD testing for non-COVID-19 diseases, the recovery is expected to occur gradually due to limited backlog - many of the tests for which Microbix produces antigens are time sensitive (e.g., ToRCH testing is conducted only during pregnancy) and regional differences in re-open rates.

For example, patient sample collection for IVD testing typically occurs at in-person physician visits and despite COVID-19 restrictions easing in many regions, there has not been a complete resumption of in-person visits, dampening overall demand in some segments of the IVD market (data from Ontario shows that 33% of all primary care visits were virtual from January 21-March 2022; Canada Health Infowav).

Despite these challenges, we believe that most/all of Microbix's antigen business will eventually return and resume a growth trajectory. This is supported by the sticky customer relationships in the IVD reagent market, where customer relationships often span many years or decades, and increasing regulatory scrutiny of the IVD industry overall (discussed in more detail below).

Longer term, as COVID-19 moves toward an endemic disease and other respiratory pathogens reemerge, we believe growth in the IVD market will come from an overall increase in respiratory pathogen testing, boosting Microbix's antigen business. Management has indicated that it has already seen its flow of orders for some of its respiratory antigens increase. With the completion of its BSL3 facility, the company should also have the flexibility to offer additional antigens to IVD test developers in response to emerging threats and public health needs.

Another growth driver for the antigen business, particularly for ToRCH and respiratory diseases, is the Asia Pacific region, as the adoption of certain IVD tests increases (the COVID-19 resurgence in the region will have a negative impact on antigen sales in the near term).

Our forecasts for Microbix's antigen business conservatively estimate $8.2M in sales in FY 2022 (down 10% from FY 2021), followed by 7% growth in each subsequent year (growing to $10.0M by FY 2025), which is consistent with the pre-pandemic growth rate and the IVD industry growth rate of 6.9% from 2020-2024 (IVD Market Trends, 2021), with potential upside from Microbix's growth opportunities (e.g., increased respiratory pathogen testing and growth in Asia).

Exhibit 8. Forecast antigen sales from 2022-2025.

	2022E	2023E	2024E	2025E
Antigen sales	$ 8,173,819	$ 8,745,986	$ 9,358,205	$ 10,013,280
Y/Y growth	*-10.0%*	*7.0%*	*7.0%*	*7.0%*

Source: Bloom Burton estimates

QAPs

Microbix's product segment with the greatest growth potential is its QAPs business and the success of this segment is critical for the company achieving its $100M revenue target.

FY 2021 sales of QAPs totaled $4.7M, up from $1.5M in FY 2020 (+208% Y/Y; Microbix started commercializing the first QAP products in early 2020; FLOQSwab-based QAPs sales began in June 2020). Management has guided to QAPs sales doubling, or possibly tripling, for FY 2022 (inferring $9-14M; BB estimate: $8.3M).

When QAPs were first launched in 2020, lab accreditation organizations conducting proficiency testing (using PDx, usually white label) were Microbix's biggest customers and management estimates it has roughly double-digit percent market share in this more niche subsegment of infectious disease controls for accreditation proficiency testing market. However, while still growing, as a proportion of total QAPs sales, the lab accreditation market has shrunk as other segments have begun to take off (contributed nearly all the $1.5M in QAPs sales in FY 2020 and $2M of total $4.7M QAPs sales in FY 2021). The real value

drivers for the QAPs business are sales to diagnostic OEMs (which include QAPs in their kits of test cartridges at fixed ratios; using PROCEEDx and ONBOARDx) and sales to clinical labs (using REDx). While these new segments currently have lower market share, low-to-mid single digit percentages for each, Microbix's share is quickly growing in these larger markets (contribution went from minimal to $2.7M from FY 2020 to FY 2021), we believe due to the superior qualities of the QAPs (only controls formulated as FLOQSwabs, as well as having broad functionality across different testing platforms).

Management expects the current level of growth (doubling of the business each year) to be sustained in the medium term and to be driven by the introduction of new branded and proprietary products (e.g., HPV panel, multiplex respiratory panel, microbial resistance testing etc.) and the capitalizing on existing customer demand through the expansion of its manufacturing capacity. Based on its current expansion plans, Microbix could support $50M of QAPs sales before requiring further expansion. Management has indicated that it has firm interest from existing customers to justify the manufacturing investments, although we have limited visibility into the specifics of these discussions (discussed later).

While Microbix's QAPs business is still in the early stages of commercialization and therefore growing very rapidly as new products are introduced, new markets are pursued and capacity expands, future growth is also supported by wider industry trends, that we believe will be tailwinds for the business. Firstly, during the pandemic, a significant amount of lab capacity was built out to support the demand for COVID-19 PCR testing and we do not anticipate that this excess capacity will go to waste as the pandemic wanes. Instead, we believe public health agencies will be incentivized to increase the adoption of molecular testing for other diseases, increasing the overall demand for controls like QAPs.

Secondly, there has been a shifting sentiment among U.S. and European regulators towards stricter regulations on IVD tests, including for both POC IVD tests (many of these tests are currently on the market without compliant controls) and those conducted in clinical labs, and the use of controls like QAPs can help avoid systemic errors associated with these tests.

While Microbix's QAPs business does have some COVID-19 exposure, if the COVID-19 pandemic switches to more of an endemic disease, we believe the opportunities for Microbix would likely outweigh the risks. Microbix's current COVID-19-specific products account for approximately 1/3 of QAPs revenues and are geared towards PCR molecular tests and antibody immunoassays. Even if governments shifted away from large scale publicly funded PCR testing specifically for COVID-19 (as has already happened in the UK), we believe this would be replaced by more complex respiratory testing during what is traditionally cold and flu season, in order to tailor treatments and guide broader public health practices (e.g., utilizing Microbix's multiplex COVID-19, flu A & B and RSV QAPs).

Microbix's aggressive forecasts for its QAPs business rely significantly on the demand it believes it has from its relationships with prospective and current customers. However, due to our limited visibility into these discussions and negotiations, we have relied on the recent growth rates of the QAPs business and overall industry trends in our forecasts.

To more accurately model the QAPs business, we separated out each of the major customer subsegments: lab accreditation organizations, diagnostic OEMs and clinical labs (Exhibit 9).

- For the lab accreditation subsegment, we have growth slowing from the roughly 30% seen in FY 2021 to 20% in 2022 (to $2.4M) and 10% in 2023 (to $2.6M), before reaching the 6.4% growth rate that is estimated for the global lab proficiency market from 2021-2026 (to $2.8M in 2024 and $3.0M in 2025; ReportLinker 2022).

- Our forecasts for the diagnostic OEMs subsegment are driven by industry estimates of the global volumes of infectious disease POC tests (excluding at home self-tests, which QAPs are not relevant for; Kalorama Information 2021-2026), assuming that QAPs are only applicable for 70% of these POC tests. We assume that QAPs are included in the POC tests kits at a ratio of 1/40 (QAPs are typically included in POC test cartridges at fixed ratios of 1/25, 1/40 or 1/50). We also estimate that Microbix's current market share is 1.5% and that this will grow to 6.0% by 2025, with pricing of $25.20/unit (US$20/unit; assuming primarily the FLOQSwab format). Based on these assumptions, we estimate that sales to diagnostic OEMs will be $5.0M in FY 2022 and grow to $20.0M by FY 2025.

- For the clinical labs subsegment, our forecasts are driven by industry estimates of the global volumes of infectious disease immunoassays and molecular tests, the two testing modalities that QAPs are used for (Kalorama Information 2021-2026), assuming that QAPs are only applicable for 20% of these tests. We assume that QAPs are used at a ratio of 1/50 tests (slightly lower than for POC tests). We also estimate that Microbix's current market share is 0.2% and that this will grow to 0.8% by 2025, with pricing of $37.8/unit (US$30/unit). Based on these assumptions, we estimate that sales to clinical labs will be $0.8M in FY 2022 and grow to $5.1M by FY 2025.

Our combined QAPs sales across the three subsegments totals $8.3M in 2022 and growing to $28.0M by 2025 (assumptions described in Exhibit 9).

Exhibit 9. Forecast QAPs sales from 2022-2025.

	2022E	2023E	2024E	2025E
Proficiency testing sales	$ 2,400,000	$ 2,640,000	$ 2,808,960	$ 2,988,733
Y/Y growth		*10.0%*	*6.4%*	*6.4%*
Diagnostic OEMs				
POC infectious disease test volumes	760,000,000	750,000,000	755,000,000	754,000,000
Proportion applicable to QAPs	70.0%	70.0%	70.0%	70.0%
Control ratio (1/40)	0.025	0.025	0.025	0.025
Control volumes	13,300,000	13,125,000	13,212,500	13,195,000
MBX market share	1.5%	3.0%	4.5%	6.0%
MBX unit volumes	199,500	393,750	594,563	791,700
Unit price (US$20/unit)	$ 25.20	$ 25.20	$ 25.20	$ 25.20
MBX sales	$ 5,027,400	$ 9,922,500	$ 14,982,975	$ 19,950,840
Y/Y growth	*91.0%*	*97.4%*	*51.0%*	*33.2%*
Clinical Labs				
Infectious disease immuassay volumes	2,223,000,000	2,303,000,000	2,382,000,000	2,496,000,000
Infectious disease molecular test volumes	1,508,000,000	1,571,000,000	1,630,000,000	1,698,000,000
Total test volumes	3,731,000,000	3,874,000,000	4,012,000,000	4,194,000,000
Proportion applicable to QAPs	20.0%	20.0%	20.0%	20.0%
Controls ratio (1/50)	0.02	0.02	0.02	0.02
Control volumes	14,924,000	15,496,000	16,048,000	16,776,000
MBX market share	0.2%	0.4%	0.6%	0.8%
MBX unit volumes	22,386	61,984	96,288	134,208
Unit price (US$30/unit)	$ 37.80	$ 37.80	$ 37.80	$ 37.80
MBX sales	$ 846,191	$ 2,342,995	$ 3,639,686	$ 5,073,062
Y/Y growth		*176.9%*	*55.3%*	*39.4%*
Total QAPs sales	$ 8,273,591	$ 14,905,495	$ 21,431,621	$ 28,012,636

Source: Bloom Burton estimates

DxTM

While a new product category for the company, Microbix's viral transport media, DxTM, has become a significant source of revenue, with FY 2021 sales of $4.5M, stemming from its two large orders from procurement representatives for the Ontario government. Management expects DxTM sales to increase approximately 30-40% in FY 2022 to $5.9-$6.3M, predominantly driven by growth in Ontario.

Past FY 2022, management expects future growth of DxTM to be driven by new customers, primarily other Canadian provinces, enabled by Microbix's enhancements in production automation (Microbix is scaling DxTM production to 500-600K vials per week, which could support annual sales >$100M), however, we expect this increase to be offset by lower COVID-19 testing in all provinces. Outside of Ontario, management has indicated that it has ongoing dialogue with other provinces but has not been able to execute on additional supply agreements until it scales its supply (should begin scaling in July 2022).

Despite the unpredictability of future COVID-19 outbreaks and testing volumes, we believe Microbix will be able to maintain a consistent order flow from the Ontario government, albeit at lower levels than at the pandemic peaks, due to the obvious benefits for the province of having a domestic supplier of such a vital product for public health, given the current geopolitical climate and supply chain challenges. Microbix's DxTM is not used for travel testing purposes so was shielded from the ending of COVID-19 travel restrictions.

We believe DxTM's applicability for all viral samples means that the product will have utility even if COVID-19 transitions to an endemic disease and as other viral illnesses come and go (as we have discussed previously, we believe there will an uptick in viral testing for other diseases as public health systems seek to utilize excess testing capacity).

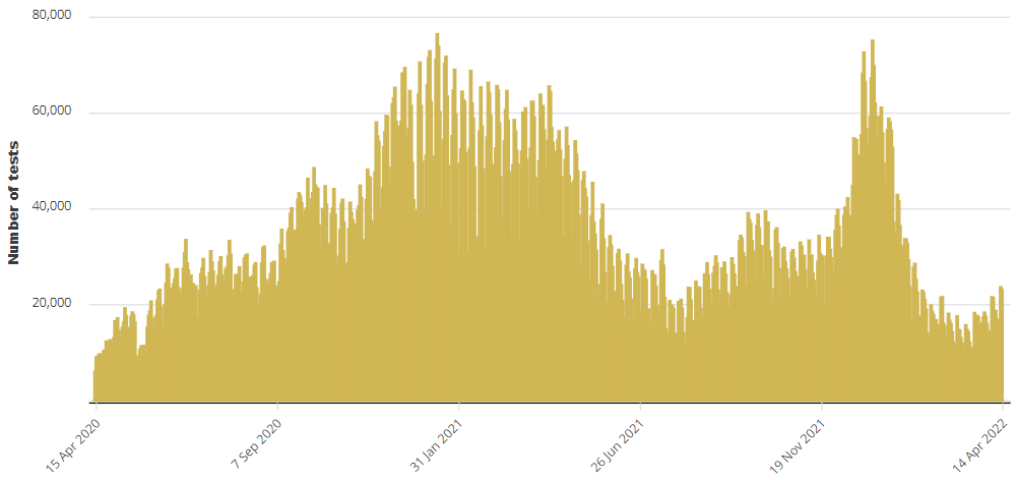
Microbix's reliance on large purchase orders from its largest customer, Ontario, is a risk for the DxTM business and has been a source of volatility for the stock. To overcome this, the company is looking to move towards standing orders with Ontario so that both parties can plan better, as well as diversifying the segment by pursuing sales in other provinces.

Our FY 2022 forecasts for DxTM assume that the remaining $2.9M of the December 2021 $4.7M purchase order from Ontario will be delivered in 2Q and 3Q-2022, with another $1.2M delivered in 4Q-2022 (forecast FY 2022 total sales of $6.1M; we do not forecast any sales to provinces outside of Ontario in FY 2022).

Past FY 2022, we forecast DxTM sales to include other Canadian provinces, including Quebec, Alberta and British Columbia, and to be driven by estimated PCR testing procedure volumes for COVID-19 and other respiratory diseases. To estimate future viral testing volumes, we used the current 7-day run rates for COVID-19 PCR testing and assume 70% of the levels in 2023, 65% in 2024 and 60% in 2025, accounting for a more endemic COVID-19 situation, partially offset by high testing for other viral diseases. We assume that Microbix currently has a 30% market share for viral transport media in Ontario (one of 3 suppliers and we do not believe the government will qualify more), and that this share will stay steady. In Quebec, B.C. and Alberta, we estimate that Microbix's market share will grow from 2% in 2023 to 6% in 2025 (lower penetration than in Ontario). Pricing of DxTM is estimated at $4/vial in all markets.

Based on these assumptions (summarized in Exhibit 11), we forecast DxTM sales of $6.1M in FY2022 and this level staying relatively stable, with $6.0M in 2025.

Exhibit 10. Number of COVID-19 PCR tests that were processed by Ontario labs each day from the start of the pandemic.



Source: COVID-19 Provincial Diagnostic Network Operations Centre (PNOOC)

Exhibit 11. Forecast DxTM sales from 2023-2025.

2023E	7-day Moving Average of Daily Tests	Moving Average Adjustment	Calculated Annual Tests	MBX Market Share	Vials Sold	Price/Vial	Projected Sales
Ontario	17,470	70%	4,463,585	30.0%	1,339,076	$4.00	$5,356,302
B.C.	4,162	70%	1,063,391	2.0%	21,268	$4.00	$85,071
Alberta	3,343	70%	854,137	2.0%	17,083	$4.00	$68,331
Quebec	18,612	70%	4,755,366	2.0%	95,107	$4.00	$380,429
							$5,890,133
2024E	**7-day Moving Average of Daily Tests**	**Moving Average Adjustment**	**Calculated Annual Tests**	**MBX Market Share**	**Vials Sold**	**Price/Vial**	**Projected Sales**
Ontario	17,470	65%	4,144,758	30.0%	1,243,427	$4.00	$4,973,709
B.C.	4,162	65%	987,435	4.0%	39,497	$4.00	$157,990
Alberta	3,343	65%	793,127	4.0%	31,725	$4.00	$126,900
Quebec	18,612	65%	4,415,697	4.0%	176,628	$4.00	$706,512
							$5,965,110
2025E	**7-day Moving Average of Daily Tests**	**Moving Average Adjustment**	**Calculated Annual Tests**	**MBX Market Share**	**Vials Sold**	**Price/Vial**	**Projected Sales**
Ontario	17,470	60%	3,825,930	30.0%	1,147,779	$4.00	$4,591,116
B.C.	4,162	60%	911,478	6.0%	54,689	$4.00	$218,755
Alberta	3,343	60%	732,117	6.0%	43,927	$4.00	$175,708
Quebec	18,612	60%	4,076,028	6.0%	244,562	$4.00	$978,247
Canada	51,540						
							$5,963,826

Source: Bloom Burton estimates; Government of Canada

Gross Margins

Microbix's gross margin equaled 59% in FY 2021 (vs 44% in FY 2020), 66% in 1Q-2022 and 64% in 2Q-2022. Gross margin can fluctuate Q/Q due to product mix, but was higher in 1H-2022 due to some higher margin antigen products sold in the first half of the year, which is expected to moderate back down to more historic levels (we forecast 58% gross margin in 3Q and 4Q-2022). Longer term, margins are expected to improve due to enhancements in antigen manufacturing efficiency (e.g., rubella bioreactor program and optimizing EBV production to improve yields), as the company moves away from selling simply IVD reagents (e.g., antigens) and towards higher margin products and medical devices (e.g., FLOQSwab QAPs and DxTM), as well as due to automation. Certain products, like the REDx line, have especially higher margins, above 70%, and Microbix aims to introduce new products with margins in those higher ranges.

Our forecasts assume gross margins of 61% in FY 2022, growing to 62% in 2023 and 63% in 2024 and 2025.

Operating Expenses

Microbix's operating expenses totaled $7.3M in FY 2021 (vs $6.2M in FY 2020), $2.3M in 1Q-2022 and $2.4M in 2Q-2022. Operating expenses are expected to increase in all areas (R&D, G&A and S&BD) as the company invests in its IT infrastructure, business development, R&D and manufacturing capacity, to drive its strategic growth.

Our forecasts assume that operating expenses will grow at a comparable rate to revenues in the medium term (growing an average of 22% annually from 2023 to 2025).

Valuation

We value Microbix based on an average of 3 different valuation methodologies:

DCF analysis of 2022 to 2035E free cash flow which comes out to $1.20/share. Our DCF uses a discount rate of 8% (Microbix's WACC of 6%, adjusted up for inflation) and a terminal growth rate of 4% (to account for long term inflation and population growth);

EBITDA multiple method which comes out to $0.87/share. We multiply 2023E adjusted EBITDA of $6.9M by 20.2 (multiple based on comps; Exhibit 12);

Revenue multiple method which comes out to $0.88/share. We multiply 2023E revenues of $29.8M by 4.7 (multiple based on comps; Exhibit 12);

Using an average of the 3 different valuation methodologies we arrive at our 12-month target price of $0.99/share, which we round up to $1.00/share. representing an 81.8% return to the current share price.

We assume a fully diluted share count of $182.0M in our valuation.

Exhibit 12. Comparable company analysis for Microbix.

Company	Est. Source	Ticker	Currency	Price	Market Cap (M)	EV (M)	EV/Revenue			EV/EBITDA		
							2021A	2022E	2023E	2021A	2022E	2023E
Meridian Bioscience Inc.	Con	NASDAQ: VIVO	USD	$27.05	$1,178.7	$1,134.9	3.6	3.3	3.5	na	na	na
Thermo Fisher Scientific Inc.	Con	NYSE: TMO	USD	$558.10	$218,474.9	$248,951.9	6.3	5.9	5.6	19.2	21.0	19.9
Bio-Rad Laboratories Inc.	Con	NYSE: BIO	USD	$535.58	$16,031.2	$15,366.8	5.3	5.3	5.0	22.7	22.9	20.4
Average							*5.1*	*4.8*	*4.7*	*20.9*	*22.0*	*20.2*
Microbix Biosystems Inc.	BB	TSX: MBX	CAD	$0.52	$69.7	$63.8	3.4	2.8	2.1	13.2	14.0	9.3

Source: FactSet

Investment Risks

Forecasting Visibility

A key risk to our valuation of Microbix is our limited visibility into the company's discussions with customers, which largely underlie management's aggressive growth forecasts for its business, particularly for QAPs, that exceed the overall industry trends, and management believes justify its investments in scaling production.

We have taken management's commentary into account, along with our competitive assessment of Microbix's products and the company's recent history of growth, but have more heavily relied on industry growth trends. As a result, we believe that our forecasts may be more conservatively biased, which we think is appropriate given our limited visibility in specific customer relationships and discussions.

Customer Concentration

While Microbix has over 100 customers across its various product segments, its largest 5 customers account for 63% of revenues, although 2 of the top 5 were brand new customers in FY 2021. The most concentrated business segment is DxTM, where the Ontario government accounts for 90-95% of sales.

The company is looking to diversify its business but pursuing new customers for all of its product segments, including adding new Canadian provinces as customers for DxTM.

COVID-19 Uncertainty

While COVID-19 has led to both gives and takes for Microbix, resulting in the growth of new product lines geared towards the disease (COVID-19 specific QAPs and DxTM), but reducing the overall demand for IVD testing outside of COVID-19 (management believes the pandemic has taken more than it has given), we believe that if COVID-19 testing went away completely, this would be a negative, but a low likelihood scenario for the company, primarily due to the decline in DxTM revenues (we do not believe all of the current DxTM demand would be met by Ontario and other provinces testing for other viral diseases).

Instead, we believe the most likely scenario and more favourable outcome for Microbix is if COVID-19 testing continued, albeit at lower levels, but was supplemented by increased demand for non-COVID-19 IVD tests, including other respiratory infections.

That said, the waxing and waning of COVID-19 waves has, and will continue to, added uncertainty to revenues and cause stock volatility for all companies with COVID-19 exposure, including Microbix, due to the difficulty in predicting future demand for testing volumes.

Exhibit 13. Microbix's forecast income statement.

Income Statements (C$)	2020A	2021A	1QA	2QA	3QE	4QE	2022E	2023E	2024E	2025E
Antigens	$ 8,702,109	$ 9,082,021	$ 1,766,416	$ 1,607,970	$ 2,039,759	$ 2,759,674	$ 8,173,819	$ 8,745,986	$ 9,358,205	$ 10,013,280
Y/Y Growth	*-33%*	*4%*					*-10%*	*7%*	*7%*	*7%*
QAPS	$ 1,527,998	$ 4,704,671	$ 1,149,151	$ 1,318,382	$ 2,032,120	$ 3,773,938	$ 8,273,591	$ 14,905,495	$ 21,431,621	$ 28,012,636
Y/Y Growth	*na*	*208%*					*76%*	*80%*	*44%*	*31%*
VTM	$ -	$ 4,506,900	$ 1,817,245	$ 1,860,704	$ 1,360,704	$ 1,020,528	$ 6,059,181	$ 5,890,133	$ 5,965,110	$ 5,963,826
Y/Y Growth	na	na					*34%*	*-3%*	*1%*	*0%*
Sales										
Product sales	$ 10,230,107	$ 18,293,592	$ 4,732,812	$ 4,787,056	$ 5,432,583	$ 7,554,139	$ 22,506,591	$ 29,541,615	$ 36,754,937	$ 43,989,741
Royalties	$ 294,797	$ 299,368	$ 122,787	$ 93,508	$ 41,537	$ 41,537	$ 299,368	$ 299,368	$ 299,368	$ 299,368
Total sales	$ 10,524,904	$ 18,592,960	$ 4,855,599	$ 4,880,564	$ 5,474,120	$ 7,595,676	$ 22,805,959	$ 29,840,983	$37,054,305	$ 44,289,109
Y/Y Growth		*77%*					*23%*	*31%*	*24%*	*20%*
Cost of goods sold										
Product costs	$ 5,808,978	$ 7,500,042	$ 1,616,136	$ 1,745,142	$ 2,281,685	$ 3,172,739	$ 8,815,702	$ 11,225,814	$ 13,599,327	$ 16,276,204
Royalties	$ 55,029	$ 48,978	$ 17,606	$ 19,123	$ 8,494	$ 8,494	$ 53,718	$ 53,718	$ 53,718	$ 53,718
Total costs of goods sold	$ 5,864,007	$ 7,549,020	$ 1,633,742	$ 1,764,265	$ 2,290,179	$ 3,181,233	$ 8,869,420	$ 11,279,532	$ 13,653,045	$ 16,329,922
Gross margin	$ 4,660,897	$ 11,043,940	$ 3,221,857	$ 3,116,299	$ 3,183,940	$ 4,414,443	$ 13,936,539	$ 18,561,451	$ 23,401,260	$ 27,959,187
		59%	*66%*	*64%*	*58%*	*58%*	*61%*	*62%*	*63%*	*63%*
Operating expense										
Research and development	$ 1,013,126	$ 1,033,254	$ 464,461	$ 502,897	$ 550,000	$ 550,000	$ 2,067,358	$ 2,584,198	$ 3,230,247	$ 3,876,296
General and administrative	$ 3,539,818	$ 4,316,032	$ 1,298,088	$ 1,295,522	$ 1,600,000	$ 1,650,000	$ 5,843,610	$ 7,304,513	$ 9,130,641	$ 10,956,769
Selling and business development	$ 632,554	$ 858,059	$ 337,781	$ 381,266	$ 406,809	$ 332,844	$ 1,458,700	$ 1,823,375	$ 2,279,219	$ 2,735,063
Financial expenses	$ 1,056,102	$ 1,085,554	$ 240,750	$ 203,125	$ 170,000	$ 170,000	$ 783,875	$ 680,000	$ 680,000	$ 680,000
Total operating expenses	$ 6,241,600	$ 7,292,899	$ 2,341,080	$ 2,382,810	$ 2,726,809	$ 2,702,844	$ 10,153,543	$ 12,392,085	$ 15,320,107	$ 18,248,128
Operating income before impairment	$ (1,580,703)	$ 3,751,041	$ 880,777	$ 733,489	$ 457,131	$ 1,711,599	$ 3,782,996	$ 6,169,366	$ 8,081,154	$ 9,711,059
Impairment of long lived assets	$ 3,078,585	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Interest accretion	$ -	$ 517,651	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Operating income before taxes	$ (4,659,288)	$ 3,233,390	$ 880,777	$ 733,489	$ 457,131	$ 1,711,599	$ 3,782,996	$ 6,169,366	$ 8,081,154	$ 9,711,059
Deferred income taxes	$ 1,568,237	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Net income and comprehensive income	$ (6,227,525)	$ 3,233,390	$ 880,777	$ 733,489	$ 457,131	$ 1,711,599	$ 3,782,996	$ 6,169,366	$ 8,081,154	$ 9,711,059
Net income per share										
EPS (basic)	$ (0.059)	$ 0.028	$ 0.007	$ 0.005	$ 0.003	$ 0.012	$ 0.028	$ 0.043	$ 0.055	$ 0.062
EPS (fully diluted)	$ (0.059)	$ 0.026	$ 0.006	$ 0.005	$ 0.003	$ 0.012	$ 0.026	$ 0.043	$ 0.055	$ 0.062
Weighted number of shares outstanding										
Basic	104,839,372	114,845,425	130,401,577	135,436,730	135,811,730	137,761,730	134,852,942	144,431,730	146,361,730	157,764,730
Diluted	104,839,372	141,683,209	146,770,808	143,650,122	143,275,122	141,325,122	143,755,294	144,431,730	146,361,730	157,764,730
EBITDA	**$ (524,601)**	**$ 4,836,595**	$ 1,121,527	$ 936,614	$ 627,131	$ 1,881,599	**$ 4,566,871**	**$ 6,849,366**	**$ 8,761,154**	**$ 10,391,059**
EBITDA margin	***-5%***	***26%***	*23%*	*19%*	*11%*	*25%*	***20%***	***23%***	***24%***	***23%***

Source: Bloom Burton

Exhibit 14. Microbix's forecast balance sheet.

Balance Sheets (C$)	2020A	2021A	1QA	2QA	3QE	4QE	2022E	2023E	2024E	2025E
Assets										
Current										
Cash and equivalents	$ 92,661	$ 9,986,312	$ 10,495,425	$ 12,201,008	$ 11,949,559	$ 13,421,704	$ 13,421,704	$ 24,550,698	$ 32,296,406	$ 44,925,885
Accounts receivable	$ 1,877,009	$ 4,175,116	$ 5,560,421	$ 4,547,783	$ 4,775,172	$ 5,013,931	$ 5,013,931	$ 6,016,717	$ 7,220,060	$ 8,664,072
Inventories	$ 4,292,664	$ 4,407,509	$ 4,850,297	$ 5,342,420	$ 5,475,981	$ 5,612,880	$ 5,612,880	$ 6,174,168	$ 6,791,585	$ 7,470,743
Prepaid expenses and other	$ 220,065	$ 495,045	$ 611,661	$ 1,005,113	$ 855,113	$ 705,113	$ 705,113	$ 105,113	$ 105,113	$ 105,113
Investment tax credit receivable	$ 10,433	$ 30,500	$ 30,500	$ 30,500	$ 30,500	$ 30,500	$ 30,500	$ 30,500	$ 30,500	$ 30,500
Total Current Assets	$ 6,492,832	$ 19,094,482	$ 21,548,304	$ 23,126,824	$ 23,086,325	$ 24,784,127	$ 24,784,127	$ 36,877,196	$ 46,443,665	$ 61,196,314
Deferred tax asset	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Property and equipment	$ 7,363,155	$ 8,082,749	$ 8,064,354	$ 8,244,805	$ 8,601,513	$ 9,373,221	$ 9,373,221	$ 9,530,261	$ 9,547,301	$ 9,424,341
Intangible assets	$ 1,742,024	$ 1,651,803	$ 1,613,432	$ 1,575,061	$ 1,575,061	$ 1,575,061	$ 1,575,061	$ 1,575,061	$ 1,575,061	$ 1,575,061
Total assets	$ 15,598,011	$ 28,829,034	$ 31,226,090	$ 32,946,690	$ 33,262,899	$ 35,732,409	$ 35,732,409	$ 47,982,518	$ 57,566,027	$ 72,195,716
Liabilities										
Current										
Accounts payable and accrued liabilities	$ 1,488,312	$ 1,794,923	$ 1,811,607	$ 1,494,619	$ 1,569,350	$ 1,647,817	$ 1,647,817	$ 1,977,381	$ 2,372,857	$ 2,847,429
Bank indebtedness	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Current portion of long term debt	$ 235,230	$ 212,760	$ 111,120	$ 111,120	$ 111,120	$ 111,120	$ 111,120	$ 111,120	$ 111,120	$ 111,120
Current portion of debentures	$ 892,125	$ 2,233,758	$ 959,917	$ 491,097	$ -	$ -	$ -	$ -	$ -	$ -
Current portion of lease liability	$ 158,633	$ 209,821	$ 199,726	$ 183,983	$ 183,983	$ 183,983	$ 183,983	$ 183,983	$ 183,983	$ 183,983
Deferred revenue	$ 1,315,738	$ 742,932	$ 1,063,857	$ 1,284,995	$ 1,284,995	$ 1,284,995	$ 1,284,995	$ 1,284,995	$ 1,284,995	$ 1,284,995
Total current liabilities	$ 4,090,038	$ 5,194,194	$ 4,146,227	$ 3,565,814	$ 3,149,448	$ 3,227,915	$ 3,227,915	$ 3,557,479	$ 3,952,955	$ 4,427,527
Non-convertible debentures	$ 713,853	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Convertible debentures	$ 1,419,834	$ 1,508,640	$ 1,535,292	$ 1,564,006	$ 1,624,006	$ 1,684,006	$ 1,684,006	$ 1,924,006	$ 2,164,006	$ 2,404,006
Lease liability	$ 383,306	$ 988,291	$ 958,618	$ 920,505	$ 855,505	$ 790,505	$ 790,505	$ 530,505	$ 270,505	$ 10,505
Long term debt	$ 2,371,503	$ 2,581,765	$ 2,388,189	$ 3,082,733	$ 3,107,733	$ 3,132,733	$ 3,132,733	$ 3,232,733	$ 3,332,733	$ 3,432,733
Total liabilities	$ 8,978,534	$ 10,272,890	$ 9,028,326	$ 9,133,058	$ 8,736,692	$ 8,835,159	$ 8,835,159	$ 9,244,723	$ 9,720,199	$ 10,274,771
Shareholders' Equity										
Share capital	$ 35,357,144	$ 43,609,601	$ 47,464,801	$ 48,947,691	$ 49,052,691	$ 49,561,691	$ 49,561,691	$ 54,653,891	$ 55,101,791	$ 58,886,871
Equity component of convertible debentures	$ 2,903,789	$ 2,903,789	$ 2,903,789	$ 2,272,567	$ 2,272,567	$ 2,272,567	$ 2,272,567	$ 2,272,567	$ 2,272,567	$ 2,272,567
Contributed surplus	$ 10,252,554	$ 10,703,374	$ 9,609,016	$ 9,639,727	$ 9,790,171	$ 9,940,615	$ 9,940,615	$ 10,519,594	$ 11,098,573	$ 11,677,552
Accumulated deficit	$ (41,894,010)	$ (38,660,620)	$ (37,779,842)	$ (37,046,353)	$ (36,589,222)	$ (34,877,623)	$ (34,877,623)	$ (28,708,257)	$ (20,627,104)	$ (10,916,045)
Total Equity	$ 6,619,477	$ 18,556,144	$ 22,197,764	$ 23,813,632	$ 24,526,207	$ 26,897,250	$ 26,897,250	$ 38,737,795	$ 47,845,827	$ 61,920,945
Total Liabilities and Equity	$ 15,598,011	$ 28,829,034	$ 31,226,090	$ 32,946,690	$ 33,262,899	$ 35,732,409	$ 35,732,409	$ 47,982,518	$ 57,566,027	$ 72,195,716

Source: Bloom Burton

Exhibit 15. Microbix's forecast cash flow statement.

Cash Flow Statement (C$)	2020A	2021A	1QA	2QA	3QE	4QE	2022E	2023E	2024E	2025E
Cash Flows from Operating Activities										
Net income	$ (6,227,525)	$ 3,233,390	$ 880,777	$ 733,489	$ 457,131	$ 1,711,599	$ 3,782,996	$ 6,169,366	$ 8,081,154	$ 9,711,059
Items not affecting cash										
Depreciation and amortization	$ 690,087	$ 822,040	$ 223,084	$ 258,292	$ 293,292	$ 328,292	$ 1,102,960	$ 1,242,960	$ 1,382,960	$ 1,522,960
Accretion of debentures	$ 255,883	$ 835,567	$ 69,632	$ 59,894	$ 60,000	$ 60,000	$ 249,526	$ 240,000	$ 240,000	$ 240,000
Stock-based compensation	$ 158,836	$ 377,828	$ 127,647	$ 150,444	$ 150,444	$ 150,444	$ 578,979	$ 578,979	$ 578,979	$ 578,979
Accretion interest expense	$ 23,027	$ 56,386	$ 24,132	$ 25,691	$ 25,000	$ 25,000	$ 99,823	$ 100,000	$ 100,000	$ 100,000
Deferred tax asset	$ 1,568,237	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Impairment of long term assets	$ 3,078,585	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Changes in non-cash working capital balances	$ 461,436	$ (3,218,475)	$ (1,609,287)	$ (334,578)	$ (286,219)	$ (297,191)	$ (2,527,274)	$ (1,234,511)	$ (1,425,284)	$ (1,648,599)
Net cash provided (used in) by operating activities	$ 8,566	$ 2,106,736	$ (284,015)	$ 893,232	$ 699,648	$ 1,978,144	$ 3,287,010	$ 7,096,794	$ 8,957,809	$ 10,504,399
Cash Flows from Investing Activities										
Purchase of property and equipment	$ (812,708)	$ (1,242,837)	$ (153,283)	$ (400,372)	$ (650,000)	$ (1,100,000)	$ (2,303,655)	$ (1,400,000)	$ (1,400,000)	$ (1,400,000)
Proceeds from government grant	$ -	$ 680,202	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Additions from internal development of intangible assets	$ (1,200)	$ (59,702)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Net cash provided (used in) investing activities	$ (813,908)	$ (622,337)	$ (153,283)	$ (400,372)	$ (650,000)	$ (1,100,000)	$ (2,303,655)	$ (1,400,000)	$ (1,400,000)	$ (1,400,000)
Cash Flows from Financing Activities										
Repayment of long term debt	$ (408,260)	$ (235,230)	$ (307,290)	$ (27,780)	$ -	$ -	$ (335,070)	$ -	$ -	$ -
Proceeds from government loan and grant	$ 742,085	$ 630,510	$ -	$ 1,072,102	$ 150,000	$ 150,000	$ 1,372,102	$ 600,000	$ -	$ -
Repayment of convertible and non-convertible debentures	$ (108,504)	$ (118,981)	$ (1,316,821)	$ -	$ (491,097)	$ -	$ (1,807,918)	$ -	$ -	$ -
Payment of lease liabilities	$ (173,648)	$ (192,495)	$ (62,674)	$ (63,534)	$ (65,000)	$ (65,000)	$ (256,208)	$ (260,000)	$ (260,000)	$ (260,000)
Issue of common share units, net of issue costs	$ 2,150,759	$ 6,131,567	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Proceeds from exercise of warrants and options	$ -	$ 2,193,881	$ 2,633,196	$ 231,935	$ 105,000	$ 509,000	$ 3,479,131	$ 5,092,200	$ 447,900	$ 3,785,080
Proceeds (repayments) of credit facility	$ (1,400,000)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Net cash (used in) provided by financing activities	$ 802,432	$ 8,409,252	$ 946,411	$ 1,212,723	$ (301,097)	$ 594,000	$ 2,452,037	$ 5,432,200	$ 187,900	$ 3,525,080
Net (decrease) increase in cash	$ (2,910)	$ 9,893,651	$ 509,113	$ 1,705,583	$ (251,449)	$ 1,472,144	$ 3,435,392	$ 11,128,994	$ 7,745,709	$ 12,629,479
Cash at beginning of period	$ 95,571	$ 92,661	$ 9,986,312	$ 10,495,425	$ 12,201,008	$ 11,949,559	$ 9,986,312	$ 13,421,704	$ 24,550,698	$ 32,296,406
Cash at end of period	$ 92,661	$ 9,986,312	$ 10,495,425	$ 12,201,008	$ 11,949,559	$ 13,421,704	$ 13,421,704	$ 24,550,698	$ 32,296,406	$ 44,925,885

Source: Bloom Burton

Important Disclosures

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Recommendation Categories	
Buy	Expected to materially outperform the sector average over the next 12 months.
Accumulate	Expected to outperform the sector average over the next 12 months or longer.
Hold	Expected to perform similar to the sector average over the next 12 months.
Sell	Expected to materially underperform the sector average over the next 12 months

Risk Rankings

Average – Volatility and risk expected to be comparable to the broader market; revenue and earnings have predictability; no significant cash flow and/or financing concerns over next 12 months Expected to outperform the sector average over the next 12 months or longer.

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Speculative – High volatility and risk expected; potential for balance sheet concerns, low public float. Stock may be suitable for only a small subset of equity investors willing to take on the risks of a high risk investment of equity investors.

Distribution of Ratings as of June 2022

Rating	Number	Percentage
Buy	18	72%
Accumulate	4	16%
Hold	2	8%
Sell	1	4%
Total	**25**	**100%**