Microbix Biosystems Inc.

5 November 2020

MBX-T: $0.36, MBXBF-OTC: $0.275

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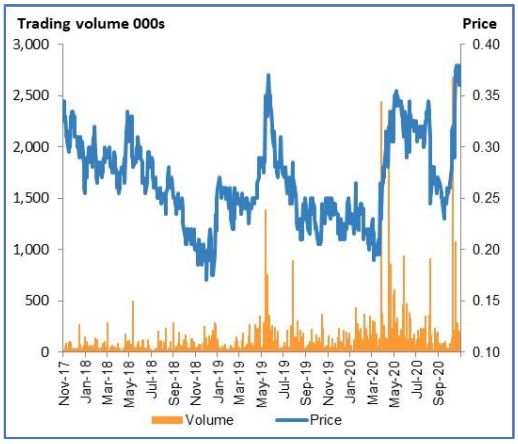
Price	$0.36	Market Cap		$39,158
Target Price	$1.40	Debt		$3,863
Projected Return	289%	Convert. Debt		$5,176
52 Week Range	0.39/0.17	Cash		$402
Basic Shares (000's)	108,773	EV ($m's)		$47,795
FD Shares (000's)*	159,115			
Insiders	12.0%			
Y/E September	**2019**	**2020E**	**2021E**	**2022E**
Revenues ($000s)	13,412	10,299	24,651	32,637
EBITDA ($000s)	1,679	169	6,406	9,232
EPS	0.00	-0.02	0.03	0.05
EV/EBITDA	28.5x	283.2x	7.5x	5.2x
*=FD # shares assumes conversion of CD				



Profile

Microbix Biosystems Inc. (MBX-T) is a Canada-based life science company and manufacturer of viral and bacterial antigens and cell, culture-based biological products and technologies. MBX's catalogue of antigens covers +30 bacterial and viral pathogens implicated in maternal, pediatric, childhood, respiratory, sexually transmitted and insect-borne diseases. MBX is now focusing on a higher growth opportunity: its QAPs™ product line, targeting quality controls within accreditation organizations, IVD equipment manufacturers and clinical laboratories. Partners are being sought for its development asset, Kinlytic Urokinase, a biologic thrombolytic drug used to treat blood clots. MBX recently entered the high-volume viral transport media (VTM) market through a strategic relationship with the Government of Ontario. VTM sales are expected to become MBX's largest revenue stream within months of launch due to the Province's local sourcing requirements.

Disclosure

ease refer to important disclosures on page 41.

TRANSFORMATIONAL PROVINCIAL DEAL ACCELERATES REVENUE GROWTH AND FACILITATES SCALING OF BASE INFECTIOUS DISEASE BUSINESS

- **VTM (51% of revenues in F2022E)**. On 13 October 2020, Government of Ontario announced a $1.45m grant to MBX for 50% of the capital required to volume produce VTM and QAPs™ products. Strategically, the objective of the grant is to facilitate local sourcing of COVID-19 products by the Province. VTM is a new product line for MBX we forecast $11.0m in VTM revenues in F2021E, a significant contributor to our 139.4% total revenue growth forecast in F2021E.
- **Antigens (29% of revenues in F2022E).** The immunoassay antigen market is mature and can be volatile (e.g. strength of the flu season, customer inventory levels). MBX revenues are a function of client end market penetration, which is driven by growth in infectious /chronic disease testing, increased use in point-of-care (POC) settings, technological advancements, and cost reductions. We forecast low single digit revenue growth.
- **QAPs™ (18% of revenues in F2022E).** Quality assessment products (QAPs™) targeting clinical laboratory accreditation organizations have plateaued. MBX is a) expanding into two additional markets: instrument qualification/training targeting medical device manufacturers; and quality controls (QC) for clinical laboratories; b) introducing new products in STIs (e.g. HPV) and respiratory infections (e.g. COVID-19). We forecast revenue growth of 167% in F2021E and 50% for F2022E.
- **Distribution/production expanded**. To penetrate these new QAPs™ markets, MBX signed 6 new distribution agreements since March 2020 covering Canada, US, European Union, UK, Scandinavia, Australia and New Zealand.
- **Improved cash flow.** The size of the Provincial VTM opportunity, expanding gross margins of the base business and a marginally increased costs base is forecast to drive substantial improvement in EBITDA, and hence free cash flow.
- **Development asset.** Management is actively seeking development partners for Kinlytic™ urokinase (KU) development asset. Several parties are under NDA and have accessed the data room. This has the potential to be a material event for MBX if/when signed.
- **Target price $1.40**. Our target price is derived using the average of EV/EBITDA and EV/Sales valuation approaches and a $5.0m notional value for the KU development asset.

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Executive Summary

Microbix Biosystems Inc.'s (MBX) base business has been as a leading supplier of antigens for over 30 years. Its focus is on supplying purified and inactivated viruses to immunoassay format medical tests to assess the exposure to, or immunity from those pathogens. It has acquired expertise in infectious diseases, particularly rubella, cytomegalovirus (CMV) mycoplasma pneumoniae, chlamydia pneumoniae and dengue.

This base revenue stream has grown by roughly 9% p.a. from F2016-F2019, has a client base of >100 multinational infectious disease diagnostics companies, with a majority of sales to a few clients. The end market is mature and sales can be lumpy as clients respond to seasonal demands such as the strength and length of the flu season and their own inventory levels.

MBX entered its second line of business, quality assessment products (QAPs™) in F2008. These products comprise samples of pathogens that are created to resemble patient samples in order to support the proficiency testing (PT) of clinical laboratories. PT is a tool for assessing laboratory performance and verifying the accuracy and reliability of test results, in other words to ensure confidence in the quality of a laboratory's performance. This has been a steady state revenue stream of roughly $1.0m p.a. for the past 3 years. But, strong growth is now emerging as a result of the creation of new QAPs™ products and entry into new markets as described below.

In addition, MBX currently has one development project: Kinlytic® Urokinase (KU), a formerly FDA registered drug used to treat blood clots. However, given that production ceased, it requires a partner to help fund the US$20m required to validate production to qualify for the supplemental Biologics Licensing Application (sBLA) to resume sales in the US. Management is actively seeking development partners for KU and several parties are under CDA/NDA and have accessed the data room. We believe that the economics of the project are compelling and that a partner will be found.

MBX has commenced with three strategies to improve financial performance of its base operations.

The first, is to improve returns of its base business, antigens, by transitioning production from the traditional roller bottle method of production to bioreactors. The benefit is a lower cost of production resulting in both higher gross margins and lower average selling prices (as clients also benefit from the lower cost of production). The strategy had the support of a major client and commenced in 2015.

In August 2019, the six bioreactors were fully commissioned, and the largest client transitioned to the new production methodology. The benefits of the transition are expected to be seen with effect from FQ1/21 as all clients move through the last of the roller bottle inventory and move their purchases to new bioreactor product.

The second operational strategy is the focus on the expected rapid growth of the QAPs™ product line due to:

- Expansion into two new product areas:
    - Medical device equipment manufacturers (PROCEEDx™ products). MBX received a request to develop custom QAPs™ for a specific customer, and

    - Clinical laboratory chains (REDx™ products), assisted by increased regulatory focus on quality controls in diagnostic testing for human infectious diseases
- Increased focus on infectious diseases generally after COVID-19
- New product introductions in the sexually transmitted and respiratory disease categories, particularly human papillomavirus (HPV) and COVID-19 REDx™ controls,
- Six new distributor agreements all signed since March 2020 targeting QAPs™ markets. The new distribution network is highly scalable with regards to new product introductions
- Ability to supply molecular testing (nucleotides) reagents (vs only protein reagents for antigens),
- Ability to simplify testing within laboratories as QAPs™ products are vendor equipment agnostic (i.e. consolidate multiple controls tests to a single vendor)

It's worth noting that QAPs™ products are MBX branded, and hence will assist MBX with brand awareness whereas antigen products are key components included in immunoassay tests, and hence are unbranded.

To cater for the expected growth, MBX has commenced on the initial stage of what will ultimately be a 10-fold increase in production. We expect to see an acceleration of QAPs™ sales commence in FQ1/21E and to fully impact F2021 and beyond. Commencing with FQ1/20, QAPs™ revenues are being disclosed.

With regards to the **third strategy**, On 13 October 2020, MBX and the Government of Ontario jointly announced that Ontario had approved a $1.45m grant to cover 50% of the costs of to automate production of MBX's QAP™ products and volume produce a new product line for MBX, viral transport media (VTM). VTM are used in patient sampling kits collecting throat and nasal swabs from human patients. Each COVID-19 test requires a VTM vial.

We view this announcement as transformational for MBX. If the Ontario Government were to take just 25% of the volume production it is helping fund by F2022E, **provincial orders alone are forecast to more than double MBX F2021E revenues over F2020E as this business line scales to $16.7m in F2022E.**

The combined impact of the two operational strategies applied to the base business and the addition of VTM revenues is forecast to result in a significant increase in EBITDA. Rapidly growing QAPs™ revenues are not expected to be as lumpy as antigen sales and a forecast stable gross margin of ~48% on a substantially higher revenue base due to the addition of the VTM product line, is forecast to result in EBITDA growing from $1.7m in F2019 to $9.2m in F2022E.

In our valuation, we have provided a notional $5.0m for the development asset, Kinlytic Urokinase (KU). We acknowledge that a final deal has the potential to be significantly larger, but the timing and structure of a partnership transaction to return KU to market is difficult to predict.

Our $1.40 target price is derived from the average of the EV/EBITDA and EV/Sales approaches and applying a $5.0m notional value for the KU development asset. The valuation multiples were derived from a group of seven comparable companies and applied to MBX's F2022E estimates. The different valuations derived using these two approaches, when applied to our MBX forecasts, reflects the different level of EBITDA margin between the group (31.0%) and MBX (28.3%). This approach gives MBX credit for a significantly higher revenue growth rate.

Recent Events

On 13 October 2020, MBX and the Government of Ontario jointly announced that Ontario had approved a $1.45m grant to cover 50% of the costs of to automate production of MBX's QAP™ products and volume produce a new product line for MBX, viral transport media (VTM). VTM are used in patient sampling kits collecting throat and nasal swabs from human patients.

We view this announcement as materially beneficial to MBX. If the Ontario Government were to purchase just 25% of volume production it has funded, **Provincial orders are forecast at $11.0m in F2021E ramping to $16.7m in F2022E (Figure 2), contributing significantly to our forecast of a 139.4% increase in F2021E revenues over F2020E**.

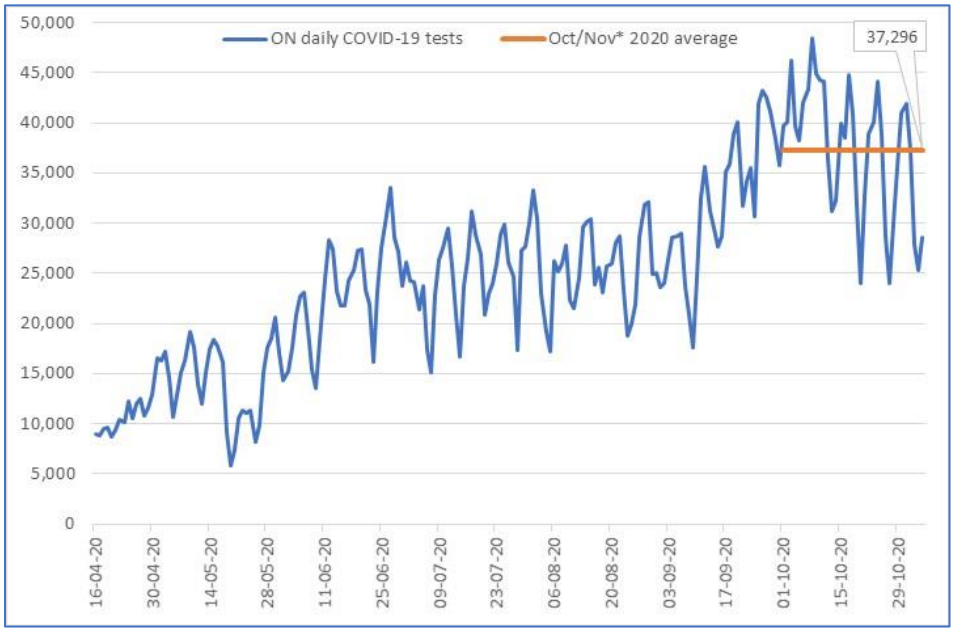
Per the Government of Ontario, the grant will enable MBX to achieve volume production of:

- VTM – 60,000 units/day
- QAPs™ - 10,000 units/day

The grant is being provided by the Ontario Together Fund (OTF), targeting investments that will increase the province's stockpile of Ontario-made products and personal protective equipment (PPE). The Fund is funding businesses to provide innovative solutions or retool their operations, within the context of COVID-19, in order to manufacture essential medical supplies and equipment, including gowns, coveralls, masks, face shields, testing supplies, equipment and ventilators.

MBX approached the Government of Ontario to create and secure a locally-based supply of high quality VTM. The grant aligns with the Ontario Health and Public Health Ontario's strategy to secure multiple sources for swab kits and transport media thereby ensuring a reliable supply of high-quality kits, including domestically produced products.

Figure 1: Ontario daily COVID-19 tests



Source: https://covid-19.ontario.ca/data; KRC Insights *=average from 1/10/20-4/11/20

During the month of October 2020 (up to October 25), the Government of Ontario has averaged 39,412 daily tests for COVID-19 (Figure 1).

QAPs™ products use is not mandated in Ontario, however, use of VTM is essential, hence the Government of Ontario's strategic move to finance the ability to source product locally.

Below we produce a back-of-envelope estimate of the potential impact to MBX revenues of the grant and concomitant potential orders from the Government of Ontario (Figure 2).

The capacity expansion partially funded by the grant implies a revenue run rate of $198.0m at 100% capacity ("A" in Figure 2). However, given that Ontario labs are not obligated to purchase QAPs™ products, we assume that MBX sells only 10% of this additional capacity into the Ontario market, AND the Province sources only 25% of its VTM requirements from MBX, this implies additional revenue to MBX of ~$17.5m by F2022E ("B" in Figure 2).

Figure 2: VTM revenues at 100% volume production (A) and sold into Ontario (B) ($000s)

	Daily volume	ASP	Capacity	Annual revenues	Plant capacity
QAPs™	10,000	$25	100%	$90,000	
VTM	60,000	$5**	100%	$108,000	
Plant capacity (A)				$198,000	
	Daily volume	**ASP**	**ON Offtake**	**F22E Annual revenues**	
QAPs™	746	$25	10%	$671	0.7%
VTM	37,296*	$5**	25%	$16,783	15.5%
Ontario Offtake (B)				$17,454	

Source: Volumes: Ontario Government; Pricing and other: KRC Insights; *=COVID tests (Figure 1) , **=KRC estimate ASP=Average Selling Price

Provincial certification of the VTM products is the critical next step in MBX's ability to receive orders from the province, and hence start generating revenues. We expect certification prior to the end of December 2020 and management expects to deliver the first batch of 50,000 vials in December 2020/January 2021.

Further, the expansion leaves substantial excess production capacity for QAPs™ and VTM products. We are forecasting a 166.7% increase in QAPs™ revenues in F2021E driven by its new distribution agreements targeting the adoption of PROCEEDx (qualification of new instruments, training) and REDx (QC and QA in clinical laboratories) controls. QAPs™ revenues are anticipated to commence ramping in FQ1/21E as MBX began shipping against a $500k order which is expected to be fulfilled in FQ1/21E. Management anticipates follow on orders.[1] Additional VTM customers are being sought.

[1] MBX press release 29/10/20

Brief History and background

MBX started business as a virus antigen company in October 1990 through the amalgamation of Animal Health Laboratories Inc. (private) and Autocrown Corp. (public):

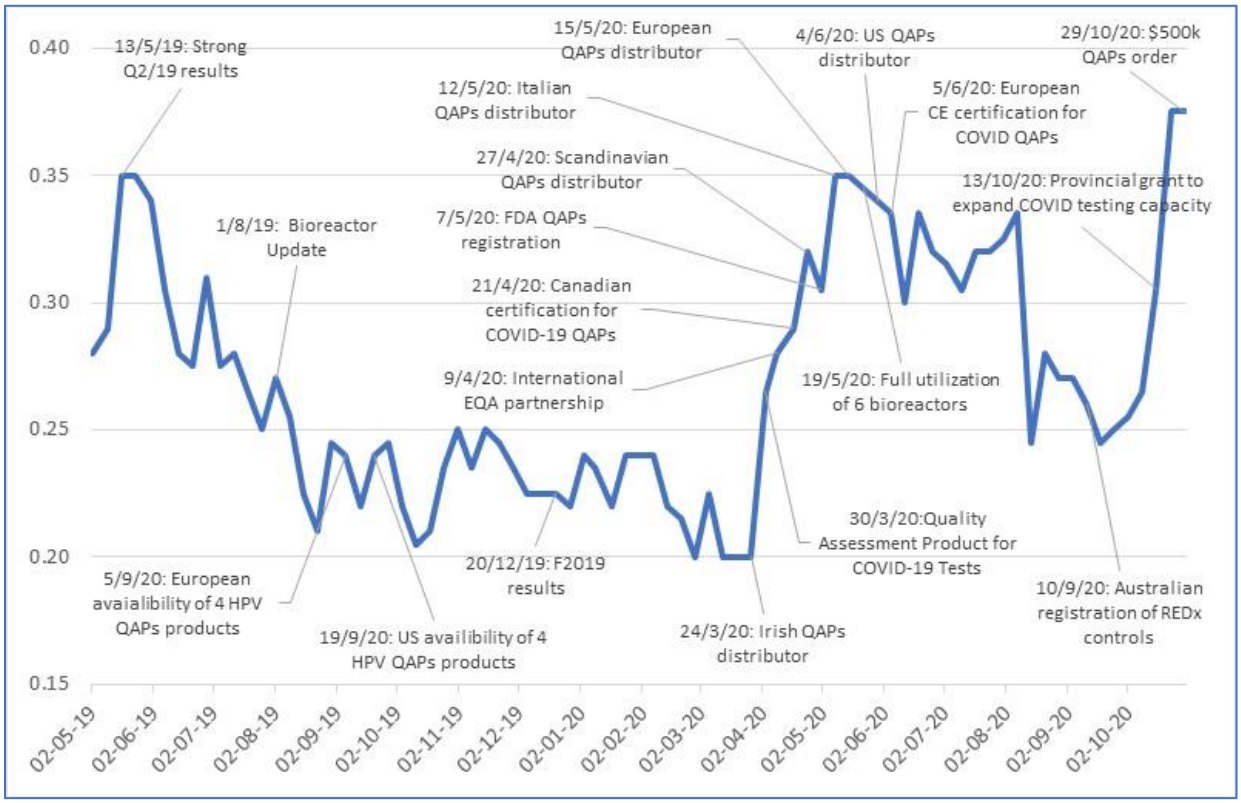
- 3 October 1978 – Animal Health Laboratories Inc. (private) was incorporated
- 27 April 1980 – Autocrown Corp (public) was amalgamated
- 4 May 1984 – Animal Health Laboratories Inc. changed its name to Microbix Biosystems Inc.
- 1 October 1990 – Microbix was amalgamated with Autocrown under the laws of the Province of Ontario

MBX undertakes business at 2 locations:

- 265 Watline Avenue, Mississauga, 14,000ft^2 (registered office, principal address). It is also the registered facility for the Public Health Agency of Canada (PHAC) license to handle human pathogens or toxins under the Human Pathogens and Toxins Act (HPTA)
- 235 Watline Avenue, Mississauga, 10,000ft^2 (offices, currently being modified to accommodate a 10-fold increase in QAPs™ production)

Figure 3 shows recent material press releases against a price graph. The share price responded favourably to the new QAP distribution agreements announced in 2020 (Figure 6), but not to the OTF grant.

Figure 3: MBX share price and selected news events past 18 months



Source: Refinitiv Eikon, KRC Insights

Refer to Appendix I for a listing of recent press releases.

Over the past three years (review period) revenues have grown 12.1% p.a. and EBITDA slightly lower at 10.2% as yield issues negatively impacted margins (Figure 4).

Figure 4: MBX financial summary 2016-2019 ($000s)

	2016	2019	3-year CAGR	Explanation
Sales ($)	9,517	13,016	12.1%	Growth a function of two primary drivers: Appointment of Meridian Life Science Inc. as distributor into China, Hong Kong and Macau, secondly, growth of QAPs™ product line ~7% of revenues.
Gross margin ($) (%)	4,980 (52.5%)	6,647 (48.8%)	9.6%	Antigen yield control issues and slow conversion to bioreactor products by the main bioreactor customer offset the benefit from higher margin QAP sales. Both issues now resolved.
EBITDA ($)	1,253	1,679	10.2%	Growth in line with gross margin as expenses controlled
Total debt ($)	9,725	9,893	0.6%	(Includes convertible debentures) Debt levels increased marginally despite debt restructuring in 2017 ($2.5m charge) which involved reduction of debenture holders' security position to subordinated debt to allow TD Bank and EDC to provide working capital credit facilities.
Total assets ($)	25,247	19,630	-8.0%	2018 LumiSort asset written down ($7.9m charge)

Source: Company reports, KRC Insights

Significant highlights/events during the review period and to current include debt restructuring, development asset write off, production yield issues and two financings (Figure 5):

Figure 5: MBX fiscal highlights 2016 to current

Fiscal year	Achievements
2017	Recorded $10m in revenues. QAPs™ generated 10% of revenues Completed validation of bioreactors (in strategy to migrate its largest client from roller bottles) Incurred $2.5m debt restructuring charge MBX signed an expanded customer supply agreement with an existing customer for antigens. Agreement called for $25m in revenues over 5 years, $10m being incremental (driver of the bioreactor strategy). Cameron Groome appointed President and CEO
2018	Experienced yield issues with a roller-bottle antigen which negatively impacted gross margins Wrote down LumiSort development asset ($7.9m charge) after re-evaluation of commercial viability. Sales to MBX's two largest customers helped drive 22.8% sales growth MBX raised $3.1m (net of costs) to reduce debt, fund repayment of payables, and facility expansion Completed upgrading production facilities at a cost of $1.2m which included upgrading to 6 bioreactors. Attained ISO 13485:2016 Medical Devices Certification
2019	Revenue growth (7.2%) limited by inventory reductions at Asia-Pacific distributor and delays by major customer in moving over to bioreactor product. Gross margins recovered to 48.8% from 42.9% in 2018 Received $2.75m contribution over four years from FedDev Ontario to expand QAP production at a total cost of $9.9m to outfit 10,000ft^2
2020	MBX completed a private placement raising $2.1m (net) Signed six distribution agreements (Figure 6) Creation, registration, and launch of COVID-19 control products into multiple geographies $1.45m grant from Government of Ontario's Ontario Together Fund to expand QAPs™ and launch new VTM product line

Source: Company reports, KRC Insights

The first half of 2020 was a productive period for MBX as the company positioned itself for growth in its QAPs™ product line by signing six distribution agreements covering 22 countries (including 6 of the G7), all of which include COVID-19 products. (Figure 6)

Figure 6: MBX distribution agreements

Date	Distributor	Products	Geography
12/1/17	Meridian Life Science, Inc.*	Antigens	China, Macau, Hong Kong, Taiwan, India, Singapore, Malaysia, Australia, New Zealand, Thailand, Vietnam, the Philippines and Pakistan
24/3/20	The Medical Supply Company of Ireland (MSC)		Republic of Ireland and Northern Ireland.
9/4/20	Oneworld Accuracy	QAPs™**	Canada initially, then world wide. Focus is COVID-19 Proficiency and Accreditation markets
27/4/20	Labquality Oy	QAPs™**	Denmark, Estonia, Finland, Latvia, Lithuania, Poland, and Sweden.
12/5/20	Diagnostic International Distribution S.p.A	QAPs™**	Italy
15/5/20	R-Biopharm AG	QAPs™**	Australia, Belgium, Canada, France, Germany, Luxembourg, Netherlands, New Zealand, Norway, Spain, and the United Kingdom.
4/6/20	Alpha-Tec Systems, Inc.	QAPs™**	US, with non-exclusive access to Central and South America

Source: Company reports, KRC Insights. *=subsidiary of Meridian Bioscience, Inc. (VIVO-Q) **=includes COVID-19 controls

We include Meridian Life Sciences as it is MBX's Far East distributor and a significant customer. It is a subsidiary of Meridian Bioscience Inc. (VIVO-Q, not rated).

Markets

MBX supplies biological ingredients, antigens and control products for infectious diseases (Figure 7) to over 100 multinational diagnostics companies globally. MBX's antigens are used in immunoassays and sold directly to end customers. Control products (QAPs™) are used in the quality control of tests and currently sold directly to laboratory accreditation organizations with expansion into test developers and clinical laboratories.

While the majority of sales are direct for both antigens and QAPs™ (control products), increased use is being made of distributors (Figure 6).

As at 30/9/20, five customers accounted for 74% of revenues and more than 95% of revenues are exported (US, European Union (EU) and Asia-Pacific). The Asian distributor is based in the US; as a result, Asian sales are included in US sales. This increased use of distributors is deemed necessary for timely access to QAPs™ end-users in the EU and US.

The MBX business is divided into three reporting segments:

1. **Antigen products and technologies**. Both antigen and QAPs™ sales are reported here, however, effective Q1/20 MBX is now disclosing QAPs™ sales as well. MBX's antigens are used in immunoassays and generate ~90% of revenues. QAPs™ are currently primarily sold to laboratory accreditation organizations and generate ~7% of revenues.

2. **Royalties**. Comprise ~3% of revenues, and relate primarily to a rabies vaccine technology created by MBX and out-licensed.
3. **Development asset**. Kinlytic Urokinase (KU), is a development project. KU is an FDA-approved biologic drug for clearing blood clots in a variety of conditions. MBX is seeking partners to help fund the return of the drug to the US and other markets. KU is carried on the balance sheet at a cost of $3.1m.

MBX's antigen and controls products are listed in Figure 7.

Figure 7: MBX antigen and control products (QAPs™)

	Products				Products	
Pathogen	**Antigen**	**Controls**		**Pathogen**	**Antigen**	**Controls**
Respiratory Disease Testing				***ToRCH Pregnancy Immunity Testing***		
Adenovirus	√	√		Toxoplasma Gondii	√	
Chlamydophila pneumoniae	√	√		Rubella	√	
Influenza A H1N1	√	√		Cytomegalovirus	√	
Influenza A H3N2	√			Herpes Simplex type 1 (HSV1)	√	√
Influenza B	√	√		Herpes Simplex type 2 (HSV2)	√	√
Mycoplasma pneumoniae	√					
Parainfluenza type 3	√	√		***Tropical Disease and Other Testing***		
Respiratory Syncytial Virus	√	√		Dengue type 1,2,3,4, NS1	√	
SARS-COV-2 (molecular)		√		Epstein Barr Virus	√	
SARS-COV-2 (antigen)		√		Hepatitis A Virus	√	
				Rotavirus	√	√
Sexually Transmitted Disease Testing				Shigella (toxin)		√
Chlamydia trachomatis	√	√				
Mycoplasma genitalium (Mgen)		√		***Vaccine Immunity Testing***		
Neisseria gonorrhoea		√		Measles	√	√
Trichomonas vaginalis		√		Mumps	√	√
Human Papilloma Virus (various)		√		Rubella	√	
				Varicella zoster	√	

Source: MBX Annual Information Form, KRC Insights

Antigens (90% of revenues) [2]

MBX's major antigen products (Figure 7) comprise concentrated, purified, intact and inactivated bacteria, parasites or viruses that are used as a key ingredient in immunoassay tests that establish the presence (or lack) of human antibodies to that bacteria or virus.

Below we cover:

- What is an antibody?
- What is an antigen?
- Immunoassays

[2] Per 2019 annual report

What is an antibody?

Antibodies are substances produced by a person's immune system to help defend against infection. They are produced by certain types of white blood cells when these white blood cells encounter a foreign substance or cell. It typically takes several days to begin to produce antibodies.[3]

An antibody is a Y-shaped protein (Figure 8) secreted by certain types of white blood cells which have the ability to identify unique components of pathogens such as viruses and bacteria. The two tips of the Y latch onto the components of the pathogen at a unique target called the epitope.

The antigen binding site shows how a specific antibody will bind to a specific antigen target. So, if a person has antibodies to a particular microorganism, it means that the person has been exposed to that microorganism and has produced an immune response. However, because many antibodies can remain in the bloodstream long after an infection has resolved, finding antibodies to a microorganism does not necessarily mean the person is still infected. The antibodies may remain from a previous infection.[4]

What is an antigen?

MBX's antigens are purified and inactivated bacteria and viruses which are used in the immunoassay format of medical tests to assess exposure to, or immunity from, those pathogens.

Generally, antigens are foreign proteins or their fragments that enter the host body (e.g. human body) via an infection. However, in some cases, the body's own proteins may act as antigens and induce an autoimmune response. Bacteria and viruses contain antigens, either on their surface, or inside. These antigens can be isolated and used to develop vaccines.

When an antigen enters the body, the immune system produces antibodies against it. Antibodies are always Y-shaped . An antibody recognizes and targets the specific foreign substance (antigen) that triggered its production, so each antibody is unique, made for a specific type of microorganism (e.g. virus or bacteria). The region of an antigen that interacts with an antibody is called the epitope.

By virtue of the epitope, the antibody is able to recognize the antigen and marks the pathogen for neutralization by the immune system, either by killing it or preventing it from entering a healthy cell.

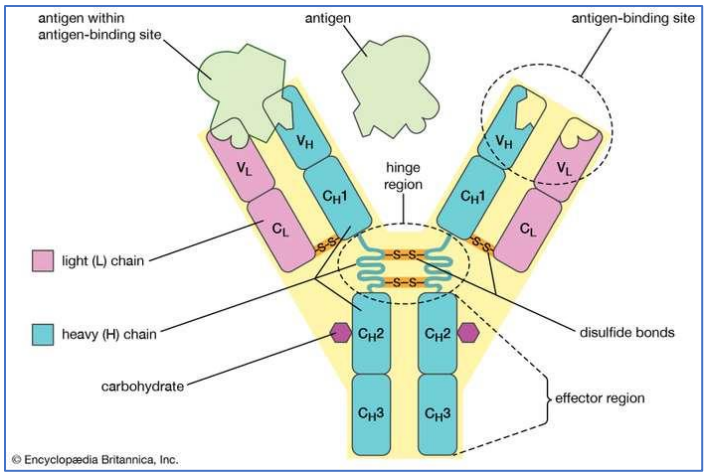
Human cells are capable of producing over 10 billion types of antibodies, each defending against a specific antigen. While an oversimplification, it reflects the wide variety of immunoassay test potential targets for diagnosing a specific disease.

In turn, antibodies are divided into five classes. They are distinguished by the type of heavy chain they contain. The variation in heavy chain polypeptides (Figure 8) allows each immunoglobulin class to function in a different type of immune response or during a different stage of the body's defense.

[3] https://www.merckmanuals.com/en-ca/home/infections/diagnosis-of-infectious-disease/diagnosis-of-infectious-disease

[4] https://www.merckmanuals.com/en-ca/home/infections/diagnosis-of-infectious-disease/diagnosis-of-infectious-disease

Figure 8: Antibody Structure



Source: https://www.britannica.com/science/antibody

Once infected, the antibodies can sometimes persist for life and provide the traditional target for immunoassay tests.

Immunoassays

The two most common methods for diagnosing a viral infection are the polymerase chain reaction (PCR) and immunoassays.[5] MBX's antigens are sold into the immunoassay test market. It has exposure to the PCR market through its QAPs™ product line.

Sensitive immunoassays have detection limits on the order of 1 picogram per millilitre (pg/mL), corresponding to approximately one million protein molecules per sample. In contrast, PCR can sometimes detect down to a single nucleic acid molecule. However, because PCR and related technologies are complex and expensive, immunoassays win in terms of cost and speed of results.

Immunoassays detect the presence of specific immune proteins (antibodies). While these assays can take on a wide range of different formats, they generally consist of an antigen which binds virus-specific antigens from the patient sample. By adding a further reporter protein, it is then possible to detect a virus-specific signal confirming (or not) the presence of an ongoing or past viral infection.

Diagnostic tests that measure an antigen antibody reaction, and for infectious diseases, can:

- suggest the presence of a pathogen,
- establish exposure to a pathogen, or
- assess the level of immunity to a pathogen.

It is important to note that PCR tests cannot test for the last two usages, which are important clinically, hence the requirement of immunoassays in these instances.

[5] https://thenativeantigencompany.com/why-we-need-antigen-and-antibody-tests-for-covid-19/

MBX is a leading supplier of natural pathogen-derived antigens to many multinational producers of immunoassays. It has traditionally used the roller-bottle method for cultivation of the antigen but is moving to bioreactors.

Appendix II lists three market research report summaries covering the Immunoassay market, MBX's, primary end market. The principal takeaways from the reports are summarized in Figure 9:

Figure 9: Immunoassay market (MBX's primary end market)

Current size of the market	Roughly US$18bn
Growth rate	~5% p.a.
Major drivers of growth	Growth in infectious and chronic diseases, rising drug/alcohol tests, increased use in point of care settings, technological advancements, cost reductions
Typical applications:	Therapeutic drug monitoring, oncology, cardiology, endocrinology, autoimmune diseases, infectious diseases testing*.
End markets	Hospitals, clinical laboratories, blood banks, academic research centres, pharmaceutical and biotech companies.
Major players**	Abbott Laboratories, Becton Dickinson and Co., bioMérieux SA, Danaher Corp., DiaSorin S.p.A., F. Hoffmann-La Roche Ltd, Merck, Ortho-Clinical Diagnostics/Carlyle Group, Quidel Corp. Siemens Healthineers, Sysmex Corp., Thermo Fisher Scientific Inc.
	*=MBX target market **=MBX customers/target customers

Source: Research reports per Appendix II, KRC Insights

Leading names in immunoassays are often leading names in the in-vitro device (IVD) market as well. Kalorama's latest reporting indicates that, together, Roche, Abbott, Siemens Healthineers, Beckman Coulter, and Alere (now acquired by Abbott) lead immunoassays, earning over 40% of the market.[6] There are more than 100 other companies competing for immunoassay market share.

Offsetting the growth potential of the market, the primary factor limiting growth is described as follows:

Inadequate reimbursement is a major factor restraining the growth of the immunoassay market. In the US, Medicare last revised its reimbursement mechanism for some IVD tests, including immunoassays and molecular tests, in 2012. Some of these molecular pathology tests do not have their own Healthcare Common Procedure Coding System (HCPCS) codes and are instead billed using unlisted codes. In such cases, Medicare Administrative Contractors (MACs) establish a payment amount for their local jurisdictions. According to the CMS, ~75% of tests showed reductions in reimbursement rates from January 2017. Some of these tests include molecular tests, targeted NGS analysis panels of five to 50 genes, and cancer tests. These developments have been adversely affecting the US molecular and genetic testing market, which, in turn, will restrain the growth of the immunoassay market.[7]

Kalorama segments the immunoassay into two immunoassay IVD test types: Sandwich assays (ELISA) and Radioimmunoassay. The market for immunoassay testing is defined as follows:

- Centralized testing (70.6% of the market in 2016) comprising reference laboratories, hospitals, HMOs and others
- Point of care (25.9% of the market), comprises self testing and professional testing
- Blood screening (3.5%)

[6] https://kaloramainformation.com/immunoassays/
[7] https://www.marketsandmarkets.com/Market-Reports/immunoassay-market-436.html

MBX customers sell into all of the above markets.

Below we provide a brief overview of the Enzyme-linked immunosorbent assay (ELISA) process and how MBX's antigens are incorporated into these assays.

Enzyme-linked immunosorbent assay (ELISA) is an assay that incorporates antibodies and color change to identify an analyte. ELISA is used in many applications, including screening serum antibody concentrations, drug screening and allergen testing. ELISA is considered a "wet lab" analytic biochemistry assay as the sample and reagents are in solution.

The ELISA protocol requires many different reagents in its five-step procedure: 1) antigens to coat the microtiter plate wells 2) blocking reagents for unbound sites to prevent false positive results; 3) antibodies 4) anti-(species) IgG conjugated to an enzyme; and 5) substrates that react with the enzyme to produce a coloured product (indicating a positive reaction). In addition to the procedure reagents, additional reagents such as wash buffers, stop solutions and stabilizers can enhance the quality of the ELISA assay.[8]

There are 4 types of ELISA assays (Figure 10).

Figure 10: Four types of ELISA

Source: https://www.bosterbio.com/protocol-and-troubleshooting/elisa-principle

One of the trends in the immunoassay market is the reduced cost driven by the migration to integrated analyzers that test for several pathogens in a single test. This contributes to pricing pressure across the industry.

[8] https://www.biocompare.com/Immunochemicals/6963-ELISA-Reagents/

MBX's focus is on the infectious diseases segment of the market, a high growth market as infectious diseases require fast and effective detection for proper outcomes. Common infectious diseases tests can be categorized as:

- Respiratory
- Hepatitis
- Childhood
- Gastrointestinal
- Vector borne
- Sexually transmitted
- TORCH
- Other

Comparable facility

To provide context for MBX's production facilities, we compared it to Meridian Bioscience Inc. (VIVO-Q, not rated), its close antigen competitor that is also MBX's Asia-Pac distributor. Its Median Life Science Biopharmaceutical facility is a direct competitor to MBX. In Figure 11 we highlight its capacity against MBX's.

Figure 11: MBX and Meridian antigen facilities

	MBX	VIVO facility
Size	24,000 ft^2	45,000 ft^2
Employees	80	70
Facility certification	ISO 13485:2016, ISO 9001:2015, MDEL (Canada), FDA registered, Pathogens and Toxins License (Canada)	ISO 9001, USDA, QSR, FDA-CDRH audited, customer audited
Bioreactors	7 perfusion tank bioreactors*	4 wave bioreactors
Bioreactor capacity	~70L (10.5L each)	100L (25L each)
Antigen capacity:	2,000 bottles/week (historically)	1,500 bottles/week for diagnostic antigen production, 30L spinner flasks, 40 10x10 cell factories, SPF egg incubator
Capacity	More than 60 products, including purified viral and other pathogenic antigens	75 products including purified viral antigens, monoclonal antibodies and recombinant proteins

Source: Company reports, KRC Insights, https://www.pharmaceutical-technology.com/projects/meridian-facility/

*= each reactor is the cell equivalent of 800 roller bottles, the standard size of a roller bottle batch.

Traditional fed-batch bioreactor systems consist of tanks that are usually between 10,000-25,000 liters and batch runs are 7-21 days. In contrast, perfusion bioreactors culture cells over much longer periods, even months, by continuously feeding the cells with fresh media and removing spent media while keeping cells in culture.[9] However, as MBX is producing viruses, the process of infecting the cells ultimately kills them, limiting its production runs to about four weeks in its bioreactors.

[9] https://cellculturedish.com/perfusion-bioreactors-with-so-much-to-offer-they-deserve-a-closer-look/

Impact on MBX

As mentioned earlier, the immunoassay market is a large, mature market (Figure 9). Primary drivers of growth include increased prevalence of chronic and infectious diseases, advancements in point of care (POC) testing products and growing patient awareness of POC testing. Emerging economies, specifically China and India, offer growth opportunities. The US is the largest immunoassay market geographically.

Given that MBX sells into large multinational diagnostics companies, its immunoassay revenue profile is expected to mirror that of its end clients. Hence MBX revenues will be a function of:

- Clients' market penetration and growth of existing products
- Clients' new product introductions
- Extent of clients' outsourcing of antigen production

Within this context, MBX is seeking additional paths to increase revenues. Specifically:

- **New geographies.** 12 Jan 2017 it signed a distribution agreement with Median Life Science, Inc., a subsidiary of Meridian Bioscience Inc. (VIVO-Q, not rated), for the Asia Pacific region.
- **Increased penetration of existing clients.** On 8 August 2017 MBX signed a 5-year expanded supply agreement with an existing global diagnostics customer. The agreement called for $25m in revenues with $10m of that incremental revenues. The agreement formed the basis for MBX's transitioning manufacturing from roller-bottle to bioreactors. The bioreactor transition was complicated by the slow transition by the customer to the new product. That is resolved and we expect bioreactor revenues to accelerate in Q1/21.
- **New products.** Other products are also expected to transition to bioreactors, or more efficient production methodologies.

With regards to COVID-19, there are 3 types of tests that are FDA approved for the detection of COVID-19:

- Nucleic acid amplification tests (molecular tests) - also known as genetic, RNA or PCR tests
- Antibody tests - also known as serology or immunoassay tests
- Antigen tests – that look for pathogen antigens directly

MBX does not supply antigens for immunoassay tests for the Coronavirus that causes COVID-19. However, we expect that MBX antigen sales will benefit from a related increase in testing for respiratory pathogens in general, such as influenza (flu).

However, MBX is targeting the QAPs™ market for COVID-19 testing, outlined below.

Quality Assessment Products (QAPs™) (7% of revenues[10])

MBX's laboratory quality assessment products (QAPs™) are a logical extension of its existing antigen production expertise. QAPs™ are targeted at different markets with different uses vs antigens.

Specifically, QAPs™ support clinical lab proficiency testing, enable assay development and validation, or help ensure quality control of clinical diagnostic tests. QAPs™ comprise three product lines (Figure 12) and are sold to clinical laboratory accreditation organizations, diagnostics companies, and clinical

[10] Per 2019 annual report

laboratories. QAPs™ are sold through distributors into 22 countries including US, Canada and 18 European Union countries.

Figure 12: MBX QAPs™ products, target markets, sales opportunities

	Target market	Sales opportunity
PTDx™ (usually unbranded)	External quality assessment (EQA) and proficiency test (PT) programs – accreditation organizations	Sales commenced 2008. Currently bulk of QAPs™ sales. See new agreement with Oneworld Accuracy (Figure 6)
PROCEEDx™ (usually branded)	Research Use Only (RUO) products for use in test system IQ/OQ/PQ, Verification / Validation and Training – diagnostics equipment manufacturers	Sales commenced 2019. Refer to QAPs™-specific contract work for POC instrument testing for viral respiratory pathogens (PR 1/6/20 and 29/10/20).
REDx™ (branded)	Designed to improve the diagnostic quality outcome by early detection of deviations from desired assay performance. Works with nucleic acid and/or antigen based assays – clinical laboratory chains.	Sales commenced 2020. Expected to show highest growth, refer new distribution agreements (Figure 6), specifically HPV and COVI-19 products

Source: Company reports, KRC Insights

QAPs™ sales commenced in 2008, contributed ~$1.0m to revenues in 2019 and are made primarily to proficiency testing organizations in North America. With the new distribution agreements, we expect penetration into the EU. New product introductions, such as HPV and COVID-19, should also help to grow this segment.

QAPs™ target the immunoassay, nucleic acid (PCR) and antigen test controls markets. PCR or antigen tests are used to directly detect the presence of genetic material or an antigen directly, rather than the presence of the body's immune response, or antibodies.

The primary driver for MBX's control products sales is increased scrutiny by regulatory bodies on diagnostics laboratories which will positively impact MBX's REDx™ controls (Figure 12). This increased scrutiny is being driven in part by the evolution of quality management globally, based on ISO standards.

Specifically, recent developments in increased regulation of laboratory developed tests (LDTs) can be summarized as follows:

Figure 13: Reforms to statutory regulations of LDTs

	US	EU	Australia	Canada
Effort to create statutory regulation for market access for LDTs	The US FDA has attempted to assert regulatory authority over this field since 1992. A current congressional bill attempts some regulation.	The EU recently introduced a new regulation for in vitro diagnostics in 2017, covering many LDTs. To take full effect by 2022.	Australia's Therapeutic Goods Administration (TGA) began developing a system to track and regulate these technologies in the 2000s, relying heavily on laboratory accreditation.	None
Effort to track LDTs	The FDA has written warning letters but there is no comprehensive effort to track tests and publicly identify them.	Currently unclear whether the EU will publish a registry of the LDT tests covered by the new regulation.	Track all LDTs in a non-public registry and track high-risk LDTs in a public registry.	None

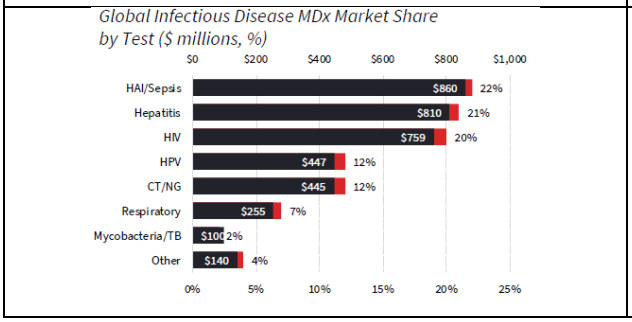
Source: https://www.cmaj.ca/content/suppl/2019/09/24/191.39.E1067.DC1, Appendix III

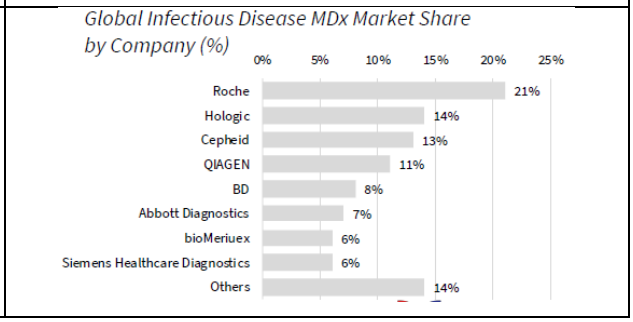
- **Canada**: LDTs are not subject to statutory regulation, but rather laboratory regulation and accreditation which involves oversight from provincial governments, nongovernmental organizations and professional societies.
- **Australia**. Starting in 2010, only the highest-risk laboratory-developed tests have been subject to external evaluation and tracking in a public registry. For lower risk tests, Australia relies on standards for accreditation in compliance with the National Association of Testing Authorities.
- **United States**. In 2010, the FDA considered a policy change such that all in vitro tests would be regulated in the same manner. In 2014, the FDA issued draft guidance to propose clear oversight of laboratory-developed tests, now withdrawn and replaced with a discussion paper in 2016. A bipartisan bill was drafted proposing a regulatory framework for all in vitro diagnostics, it remains a work in progress.
- **Europe**. A new EU regulation on in vitro diagnostics was passed in 2017 and is to be implemented in 2022- laboratory-developed tests manufactured on an "industrial scale" will be subject to review.

MBX has experienced success recently with its human papillomavirus (HPV) REDx controls. On the basis of MBX's control products portfolio (Figure 7) an analysis of this market shows the opportunity for MBX (Figure 14) which may be extended to other products bearing in mind the current emphasis on COVID-19.:

Figure 14: Global Infectious Disease Market

Global Infectious Disease MDx* Market	Global Infectious Disease MDx* Market Share



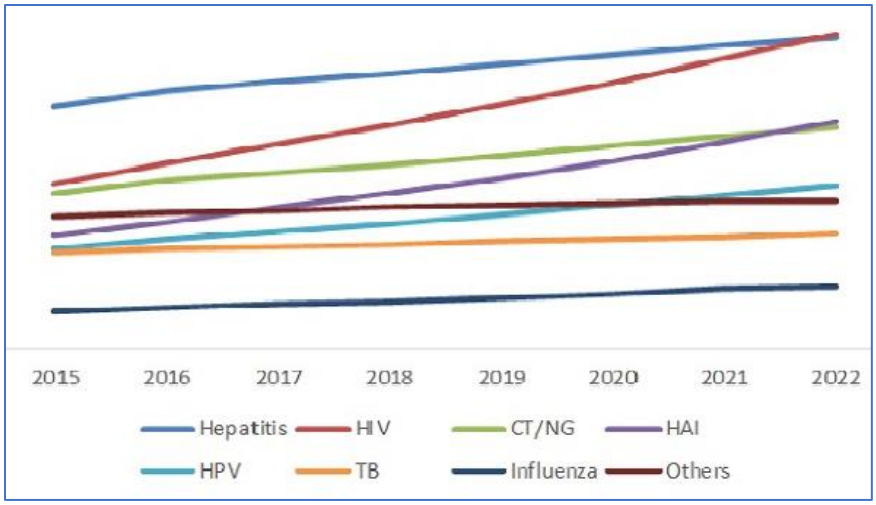


Source: MBX Corporate presentation Spring 2020, KRC Insights *=molecular diagnostics

The global HPV MDx testing market is roughly 12% of the global MDx testing market, it is growing at ~7%p.a.

Spending on control products is typically <=10% of the testing market. This reference can be extrapolated into growth opportunities by disease as reflected by Marketandmarkets Infectious Disease Diagnostics Market Global Forecast to 2022 (Figure 15).

Figure 15: Infectious Disease Diagnostics Market – By Disease Type



Source: https://www.marketsandmarkets.com/Market-Reports/infectious-disease-diagnostics-market-116764589.html

With regards to MBX's HPV REDx controls in the US, it is targeting the 34,000 clinical laboratories certified or accredited under the U.S. "CLIA" regulations (refer to Regulation section below). MBX expects it may sell directly to the largest chains of labs, with support from distributors for other lab customers.

With regards to MBX's HPV REDx controls in the European Union, initial European sales efforts will be first directed to clinical laboratories in France, Germany, Italy, and the United Kingdom. Microbix expects it may sell directly to the largest chains of labs, with support from national distributors reaching for other customers.

All REDx Controls are FDA (US)/ CE (EU) certified for IVD use and are manufactured under ISO 13485 and 21CFR Part 820 standards.[11]

MBX has lined up the same strategy for its newly introduced COVID-19 control tests.

In Appendix IV we summarize two research reports covering the Infectious Disease Diagnostics Market.

Impact on MBX

MBX has sold QAPs™ to customers since 2008 and has generated ~10% of total revenues in each year since at least 2017, averaging roughly $1.0m p.a. over this period. However, the company is gearing up for significant growth of this revenue stream, and commencing with the FQ1/20 results, QAPs™ revenues are now being disclosed separately.

Apart from regulations, primary drivers of this growth includes:

- The addition of five respiratory analytes (COVID molecular+antigen, Flu A, Flu B, RSV)
- Introduction of an HPV line (initially types 16, 18 and 45, with more to follow)

[11] https://microbix.com/collections/redx-controls

- Expansion into other sexually transmitted diseases (initially *Mycoplasma genitalium*).
- Geographic expansion into Europe targeting proficiency testing organizations
- New customers. Referring to the press releases of 1/6/20 and 29/10/20, MBX is working with a diagnostics equipment manufacturer to develop viral respiratory QAPs™ for its new point-of-care instrument. Once FDA clearance and CLIA waivers are secured, first-year revenues are expected to exceed $1.0m
- COVID-19 market penetration, driven by positive and negative controls in both liquid vial and dried swab formats
- Strategic relationship with the COPAN Group

MBX product lines, target markets and sales potential of its QAPs™ lines was presented in Figure 12.

MBX has commenced selling REDx COVID-19 controls to clinical laboratories in Canada. In its press release of 6/5/20, MBX highlighted initial production volumes:

- 4,000 units (swab and vial) were produced
- Capacity is 5,000 units/week of swabs, 10,000 units/week liquid vials
- Provided to public health and privately-operated clinical laboratories in Canada
- Scheduled to ship to proficiency accreditation agencies in Canada and internationally
- Work with multiple nucleic-acid based test (NAT) methods (i.e. across a wide variety of diverse manufacturers' diagnostics equipment)

With regards to regulatory clearance for COVID-19 control products to support molecular tests, US FDA clearance was announced on 7/5/20 and European CE registration was announced on 5/6/20.

When granted its FedDev loan, MBX announced that the loan was, in part, to facilitate a 10-fold increase in QAPs™ production. To place this production expansion in context, the following events occurred:

- **FedDev loan (30/7/20)**. With an interest-free $2.75mm Federal Economic Development Agency for Southern Ontario (FedDev Ontario) loan, MBX is in the process of upgrading its 10,000ft^2 facility to facilitate a 10-fold increase in capacity. The loan is to be disbursed over 4 years and leverage $7.15m in expected capex and other costs, implying $9.9m to be spent on QAPs™ portfolio and production expansion.
- **New distribution agreements.** MBX signed six new distribution agreements
- **Expansion of QAPs™ production capacity (27/5/20)**. Additional space is to provide for a 10-fold increase in capacity. Initial cost is ~$825k, was completed in October 2020 and facility validation is expected in December 2020. Weekly capacity of 5,000 swabs/10,000 vials is to be increased to 20,000 swabs/50,000 vials before full automation of processes that will further increase capacity to 20,000 swabs/150,000 vials.
- **Development of custom QAPs™ (1/6/20).** A new customer is looking to support registration and drive sales of its new point-of-care instrument and is paying for development of custom QAPs™ for its instrument. Sales to MBX in the first year are expected to be 100,000 units, or $1.0m in revenues.

With regards to COVID-19, MBX has had its nucleic acid products approved by the FDA and European Union for sale into control environments undertaking large scale testing for the virus. These

environments seek third party confirmation that staff are correctly trained and tests are being effectively undertaken, QAPs™ fulfills this role.

MBX followed an aggressive timeline with regards to its development of its COVID-19 QAPs™ products (Figure 16).

Figure 16: MBX COVID-19 QAPs™ development timeline

`	Event
Feb 20	Internal discussions around product development commenced
30/3/20	Imminent availability of QAPs™ products (COPAN FLOQSwabs) as prototype neared regulatory approvals
9/4/20	Announced a partnership with Oneworld Accuracy to provide an international testing proficiency/accreditation program
21/4/20	Health Canada licensing of commercial products
6/5/20	Commenced shipment of COVID-19 QAPs™ to clinical laboratories in Canada
7/5/20	Announced FDA registration and immediate availability to clinical laboratories in the US
5/6/20	Announced CE mark registration and immediate availability to clinical laboratories in 18 countries in Europe

Source: Company reports, KRC Insights

On 20/10/20, MBX announced a new QAPs™ product line supporting the accuracy of COVID-19 antigen-test workflows. This is an expansion of its existing lab-based nucleic-acid ("NAAT" or "RT-PCR") testing product. The antigen based products are initially targeted to support the six antigen-based tests that have thus far been authorized for emergency use by the FDA.

External validation of these products was completed with multiple test makers facilitating the assembly of the detailed technical file necessary to register/license its COVID-19 antigen-test QAPs for clinical lab use. Once this regulatory work is completed, they will become widely available for lab testing workflow support.

We expect COVID-19 QAPs™ sales to commence impacting meaningfully from FQ1/21 and beyond as the seeded distributors reorder.

Viral Transport Media (VTM)

VTM is a vial of liquid into which swabs of patient samples are placed. VTM preserves the stability of any virus that is present until it can be tested by the clinical lab.

Any shortage of VTM means that lab-based nucleic-acid (PCR) testing for COVID-19 disease cannot be conducted.

Ontario currently has no domestic manufacturer(s) of VTM, and the Government of Ontario has worked with MBX to obviate this limitation.

Generally, through the Ontario Together Fund (OTF), MBX was provided with a $1.45m grant to increase production of COVID-19 testing supplies. The objective of the new $50m OTF is to help businesses provide innovative solutions or retool their operations in order to manufacture essential medical

supplies and equipment, including gowns, coveralls, masks, face shields, testing equipment, testing reagents and ventilators. In other words, to facilitate the local manufacture of COVID-19 products to help meet Ontario's needs.

Specifically, the Government of Ontario currently sources its VTM requirements out of province and is now setting up the infrastructure, through MBX, to source its requirements locally. This move addresses the issues of security of supply and facilitates with improved COVID test planning.

Impact on MBX

We view this transaction as a transformational event for MBX. Through the sponsorship of the Government of Ontario, MBX is entering a new market. Given the Province's level of testing (Figure 1) and its implied orders, this product line has the potential to become MBX's primary revenue stream within the next year.

Potential F2021E revenues are forecast at $11.0m growing to $16.7m in F2022E assuming that the Ontario Government orders only 25% of its VTM requirements from MBX (Figure 2). The Province has funded 50% of the cost of volume production capacity expansion at MBX through a $1.45m OTF grant.

Royalties (3% of revenues)

Relates primarily to a rabies vaccine delivery technology licensed to the Ministry of Natural Resources for usage in wildlife vaccination baits.

Kinlytic® urokinase (KU) (0% of revenues)

KU is a development asset reflected on the balance sheet at a cost of $3.1m.

KU is an injectable thrombolytic or "clot-buster", is approved in the U.S. and Canada. Its target applications are catheter clearing and pulmonary embolisms. However, the lead opportunity is for its FDA-approved catheter clearance in the US.

The US catheter clearance market is a monopoly with no new entrants for over 15 years. Genentech's Cathflo Activase® (tPA) is the market leader. Clearing blood clots from intravenous catheters is now a >US$330m monopoly in the USA, held by tPA and growing by about 10% annually. Once production is restarted, management is targeting sales of KU of ~US$200m p.a. based on 40% market penetration.

KU was originally launched by Abbott (as Abbokinase®) and was the leading anti-thrombolytic drug in the market, generating peak annual sales of more than US$300m, before Abbott discontinued sales due to manufacturing issues. MBX has manufactured KU at commercial scale and has performed numerous biochemical and functional analyses on the product that demonstrate its ability to undertake its reintroduction into the marketplace. Figure 17 outlines the KU timeline.

Figure 17: Kinlytic® Urokinase (KU) timeline

April 2006	ImaRx Therapeutics (IMRX-Q) acquired Abbokinase® (then) from Abbott Laboratories for US$15m satisfied by way of a promissory note.
January 2008	IMRX signed a letter of intent (LOI) with MBX to manufacture and continue selling urokinase beyond the existing inventory.
7/5/08	MBX signs LOI with IMRX for $17m to acquire urokinase inventory and related assets.
11/6/08	LOI terminated due to MBX's inability to raise the cash, compounded by the FDA's requirement that additional testing was needed to approve the urokinase stability testing program.
24/9/08	IMRX divested its urokinase business to MBX for an upfront payment of US$2m, the assumption of US$500k in chargeback liabilities for commercial product currently in the distribution channel and an additional US$2.5m payment to be made to ImaRx upon release by the FDA of the three lots of urokinase that were subject to a May 2008 Approvable Letter. MBX assumed full responsibility for ongoing commercial and regulatory activities associated with the product.
26/4/18	MBX announced the engagement of Torreya Partners LLC of New York to assist it in finding a partner to enable the re-launch of KU into the United States market.

Source: Company reports, KRC Insights, various

MBX is required to restart validated production and the new production must show to be equivalent to past batches. As a consequence, it requires new investment in order to return it to market under the U.S. supplemental Biologics Licensing Application (sBLA) process. Refiling with the FDA should take ~2.5 years at a cost of approximately US$20m, which includes accessing an approved manufacturing plant.

MBX continues to work actively with Torreya Partners to find a partner to assist with the relaunch KU. Interested partners are under non-disclosure agreements (CDA/NDA) as they conduct due diligence including access to the "data room". Management remains optimistic that a development alliance will be struck.

Impact on MBX

The closing of a transaction with regards to out-licensing or appointing a development partner for its KU asset has the potential to be a material event for MBX.

While the timing of such a transaction and the structure of such a deal are difficult to anticipate, we believe that the economics are compelling such that a development partner will be found.

Regulation

Discussion of the products MBX offers is not complete without the regulatory context under which its products are sold. These regulations not only provide the framework for antigen and QAPs™ sales, but also are becoming a driver of potential future QAPs™ sales.

MBX sells into the US, Canada, Australia, European Union, UK, New Zealand and Scandinavia, however, we will focus on US regulatory framework as that is its largest market. A summary of US regulations is covered below and are summarized in Appendix III.

Food and Drug Administration

MBX's antigens are classified intermediate ingredients revalidated for use by the test makers to be used in *in vitro* diagnostics (IVDs) tests developed by its customers that analyze samples from the human body. These tests are regulated by the Food and Drug Administration (FDA) and its authority covers the diagnostic test and components, including reagents (such as antigens). This means that device manufacturers must submit studies confirming the tests' accuracy and usefulness in diagnosing a particular condition before bringing it to market. Once MBX's antigens form a part of those studies, manufacturers are very reluctant to change suppliers as so doing requires considerable time and expense.

ISO 13485

ISO 13485:2016 is the main global standard for a Quality Management System ("QMS") for the design and manufacture of Medical Devices, such as the REDx category of QAPs™. It is the medical device industry's most widely used international standard for quality management.

Compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements.[12]

This global standard is mandatory in some countries, and in the U.S. the FDA has proposed a rule which would harmonize U.S. FDA 21 CFR 820 with ISO 13485:2016, making ISO 13485 the FDA's mandatory QMS for Medical Devices (the rule is expected to be released in 2019). In the meantime, the medical device industry can rely on AAMI TIR102:2019, which is a bi-directional mapping tool that was released on August 30, 2019. [13]

Health Canada requires medical device manufacturers to comply with ISO 13485. The Medical Devices Regulations require Class II, III and IV medical devices to be manufactured (Class II) or designed and manufactured (Class III & IV) under CAN/CSA ISO 13485:2003.

Impact on MBX

Currently, 10 REDx™ SKUs are registered in both the EU and the US: HPV 16, 18, 45, positive/negative COVID vials/swabs and positive/negative *Mycoplasma genitalium*. These are the products directly benefitting quality of patient diagnosis by laboratories.

PTDx™ and PROCEEDx™ products are not regulated as medical devices as they are not used for actual patient diagnosis, but are still made under the ISO 9001 and 13485 standards.

MBX is ISO 13485:2016 compliant.

[12] https://en.wikipedia.org/wiki/ISO_13485
[13] https://13485store.com/medical-device-standards/what-is-iso-13485/

Capital structure

MBX's capital structure is shown in Figure 18:

Figure 18: MBX total capital employed at 30/6/20 ($000s)

	30/6/20
Share capital	35,357.1
Equity component of CDs	2,903.8
Contributed surplus	10,204.2
Accumulated deficit	-36,911.0
Total equity	11,554.1
Total debt	6,134.9
Total capital employed	17,689.0

Source: Company reports, KRC Insights

The convertible debentures are convertible at the option of the holder at any time and bear interest at 9.0% p.a. Of these, $500k mature in February 2022 (others 2028 and 2029). All convertible debentures (face value of $4.5m) are in the money based on the conversion price of $0.23.

The composition of MBX debt is provided in Figure 19:

Figure 19: MBX total debt at 30/6/20 ($000's)

	Current	Non-current	Total
Long term debt	267.9	2,156.9	2,424.8
Convertible Debentures	367.8	1,401.5	1,769.3
Lease liability	161.1	420.9	582.0
Non-convertible debentures	491.8	723.6	1,215.4
Other			143.3
Total	1,288.6	4,702.9	6,134.9

Source: Company reports, KRC Insights

Of the non-convertible debentures (face value $2.5m), $500k mature in April 2022, the balance in January 2029.

Given the recent share price appreciation, MBX could raise as much as $8.9m from the exercise of warrants and options (Figure 20).

Figure 20: MBX Common Share Purchase Warrants and Options at 30/6/20

	Number (000s)	Weighted average exercise price	Potential proceeds $000s
Warrants	1,500	0.55	
	21,785	0.35	$7,625
	23,285		
Options exercisable at 30/6/020	3,173*	0.39	$1,237
Total potential proceeds			$8,862

Source: Company reports, KRC Insights *=Of the 5.5m options exercisable at 30/6/20, 2.4m expired in October '20

Based on the current share price and the potential for further share price appreciation as the VTM opportunity becomes apparent to shareholders, we believe that a substantial portion of the $8.8m will be realised. However, only half of this amount is required by MBX to fund its 50% portion of the capacity expansion funded by the OTF grant and to fund the working capital required to scale its business to meet our revenue forecasts.

Forecasts

Revenues

With regards to Antigen, QAPs™ and VTM revenue forecasts, the variables taken into account with regards are forecasts are included in Figure 21. Viral Transport Media (VTM) sales is a new product line for MBX and we have forecast conservatively that MBX will sell only 20% of its capacity to the Government of Ontario per its grant of 13/10/20.

Figure 21: MBX revenue forecast considerations

Antigens	QAPs™	VTM
• Mature industry growing at ~ 5% p.a. • Sales can be lumpy due to end market dynamics such as timing and/or strength of a flu season • Distributor inventory management • Ability to penetrate IVD customers as immunoassays become more prevalent • New products • New geographic markets • Timing of bulk orders from diagnostic manufacturer customers, especially those managing their year end inventories • Bioreactor sales command lower ASPs but higher margins • COVID-19 increasing government recognition of the importance of infectious disease testing generally	• New products • New distributors (new geographies) • Custom manufacturing requests • Increased penetration of existing accounts • Greater cognizance of the importance of test accuracy • Pending new IVD regulations in the EU is driving greater professionalism for both tests and test controls • Initial seeding of new distributors expected to result in re-orders	• New product line based on existing technical capabilities • Subject to qualification, Province of Ontario expected to order a substantial portion of its VTM requirements from MBX.

Source: KRC Insights

For F2020 YTD, revenues growth was -20.4% due to (i) general disruptions to the normal testing flow due to COVID-19, (ii) extensive lockdowns in China, and (iii) an exceptionally strong flu season last year which saw lower antigen orders from customers this year.

Figure 22: MBX revenues by segment $000s

Sept. year-end	2018	2019	Q1/20	Q2/20	Q3/20	Q4/20E	2020E	2021E	2022E
Antigen products	12,191	12,068	1,946	2,358	2,246	1,897	8,447	9,292	9,571
% growth	23.2%	-1.0%	-17.5%	-36.9%	-19.6%	-40.3%	-30.0%	10.0%	3.0%
QAPs™		1,000	26	426	570	478	1,500	4,000	6,000
% growth			332.1%	-1.7%	141.0%	47.5%	50.0%	166.7%	50.0%
VTM								11,000	16,700
% growth									51.8%
Royalties	319	345	74	91	82	105	351	359	366
% growth	8.6%	8.0%	-21.5%	7.5%	0.1%	24.7%	2.0%	2.0%	2.0%
Total Sales	**12,511**	**13,412**	**2,046**	**2,875**	**2,898**	**2,480**	**10,299**	**24,651**	**32,637**
Total revenue growth	22.8%	7.2%	-16.8%	-32.4%	-6.8%	-30.9%	-23.2%	139.4%	32.4%

Source: Company reports, KRC Insights *company began segmenting QAP revs commencing F2020

For F2020E, with FQ4E/20 remaining, we forecast total growth of -23.2%. This implies continued softness in the antigen sales in FQ4/20E due to the COVID-19 distractions, and QAPs™ sales moving from initial seeding seen in FQ3/20 to initial reorders in FQ4/20E, to a more consistent growth pattern from FQ1/21E and beyond.

For F2021E we forecast 139.4% total revenue growth based on a return to stability of antigen sales, increased QAPs™ penetration with evidence commencing in FQ1/21E driven by a ramp in distributor orders and anticipated new QAPs™ product introductions through F2021 and beyond. The most significant event in F2021E is the initial sales of VTM products to the Government of Ontario. With the Provincial OTF grant facilitating production levels of 60,000 VTM vials per day, we have made the conservative assumption that the Province will order only 25% of its current daily requirements from MBX resulting in $16.7m in revenues (37,296/day x 25% x $5[14]) to MBX in F2022E. Our 25% takes into account the initial ramping and offtake by the Province of VTM product at the commencement of production in F2021E.

For F2022E, we forecast 32.4% total revenue growth based on stable antigen sales, continued success with QAPs™ products as respiratory products ramp and the continued pull-through of COVID-19 related products. As for VTM, we anticipate any tail off in COVID-19 infections, and hence testing, will be more than compensated for by the Province sourcing more of its VTM requirements from MBX and MBX finding additional customers for this new capacity.

Gross margins

Gross margins have varied from highs of 52.3.% in 2016 to lows of 42.9% in 2018 (Figure 23). We expect margins to settle ~48% in F2021E and F2022E due to the significant contribution from VTM sales.

[14] KRC Insights estimate

Figure 23: MBX Historical and forecast gross margins

Year	Gross margin	Explanation
2016	52.3%	Lower than 65.8% in 2015 as no license fees in 2016 and higher material costs
2017	47.2%	Decrease due to changes in product mix and production processing issues in the second half of the year
2018	42.9%	Decreased due to higher sales and change in product mix, full benefits offset by roller bottle antigen production yield control issues
2019	48.8%	Increased as antigen production yield issues resolved, positive changes in sales mix, some bioreactor antigen sales
2020E	49.1%	The marginal improvement in margins attributable to the move to bioreactor and increased higher margin QAPs™ sales. Margins would have been higher bar for a bioreactor problem experience in Q3, now resolved.
2021E	48.5%	The benefit of higher margin bioreactor-manufactured antigen sales and increased QAPs™ contribution offset by significant contribution from lower margin VTM sales.
2022E	48.3%	Consistent margins expected as sales mix similar to F2021E.

Source: Company reports, KRC Insights

Expenses

Expenses include Selling & business development, General & administrative, and R&D. Total costs are outlined in Figure 24.

Figure 24: MBX total costs ($000s)

Sept. year-end	2018	2019	Q1/20	Q2/20	Q3/20	Q4/20E	2020E	2021E	2022E
Total costs	5,260	5,438	1,352	1,271	1,539	1,399	5,561	6,286	7,343

Source: Company reports, KRC Insights

Total expenses are expected to remain stable in F2020E, but increase going forward as MBX continues to introduce new products and deal with increased sales levels. We expect higher sales cost as MBX focuses on selling the substantial manufacturing capacity generated by the OTF grant expansion.

Valuation

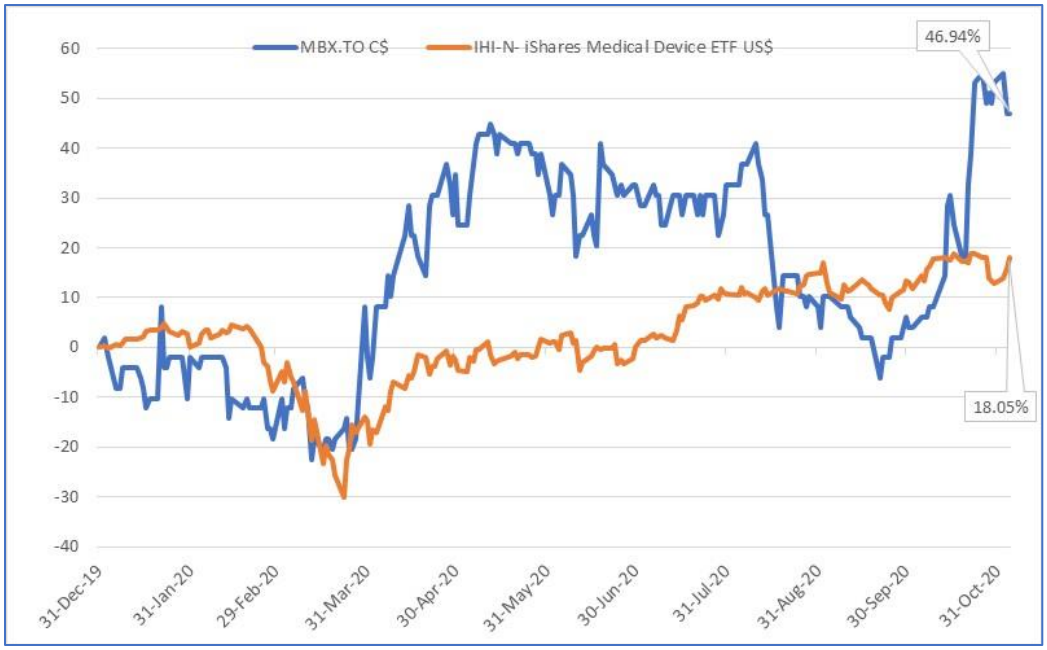
As an overview, on a year-to-date basis, the MBX share price has outperformed the iShares U.S. Medical Devices ETF (IHI-N), generating a +46.94% return vs +18.05% of the ETF[15] (Figure 25).

The recent MBX share price appreciation commenced towards the end of March 2020 when the company started announcing new QAPs™ distributors and COVID-19 QAPs™ availability.

IHI is a ~US$8.4bn ETF and its holdings comprise, amongst others, several MBX customers and/or companies listed in Appendix II. It offers exposure to U.S. companies that manufacture and distribute medical devices and is used to express a sector view.

[15] at 24/10/20

Figure 25: MBX share price vs iShares U.S. Medical Devices ETF (pricing at 4/11/20)



Source: Refinitiv Eikon, KRC Insights

On a more targeted basis, MBX's listed comparable companies are shown in Figure 26 and comprise the companies used to derive the valuation multiples used in the MBX valuation. The list includes competitor/distributor Meridian Bioscience Inc. (VIVO-Q) and immunoassay customers.

Figure 26: MBX comparable company valuations (currency per exchange, pricing at 4/11/20)

					EBITDA		Revenues		Rev	EV/EBITDA		EV/Revenues	
	Symbol	Price	Mkt Cap	EV	2020E	2022E	2020E	2022E	Growth	2020E	2022E	2020E	2022E
Microbix Biosystems Inc	**MBX.TO**	**0.36**	**39.2**	**47.8**	**0.2**	**9.2**	**10.3**	**32.6**	**216.9%**	**283.20x**	**5.18x**	**4.64x**	**1.46x**
Bio Rad Laboratories Inc	BIO.N	624.79	18,511.6	17,796.1	503.2	535.9	2,410.3	2,587.6	7.4%	35.37x	33.21x	7.38x	6.88x
Bio-Techne Corp	TECH.O	267.16	10,300.7	10,386.6	322.1	368.0	824.2	936.7	13.6%	32.24x	28.22x	12.60x	11.09x
Danaher Corp	DHR.N	240.52	170,860.0	190,277.3	6,289.4	8,082.7	21,912.9	26,703.0	21.9%	30.25x	23.54x	8.68x	7.13x
DiaSorin SpA	DIAS.MI	194.2	10,855.0	10,664.6	356.3	391.5	871.0	974.1	11.8%	29.93x	27.24x	12.24x	10.95x
Meridian Bioscience Inc	VIVO.O	18.07	774.5	809.9	75.6	67.8	249.2	274.3	10.1%	10.71x	11.94x	3.25x	2.95x
Quidel Corp	QDEL.O	266.43	11,208.1	11,137.2	510.8	958.8	1,596.2	2,996.1	87.7%	21.80x	11.62x	6.98x	3.72x
Thermo Fisher Scientific Inc	TMO.N	510.97	202,515.4	216,068.4	9,554.8	10,009.5	30,615.0	33,285.1	8.7%	22.61x	21.59x	7.06x	6.49x
Totals/**Average**							58,478.7	67,756.8	**15.9%**	**26.13x**	**22.48x**	**8.31x**	**7.03x**
QDEL-no meaningful F2022E esitimates, used F2021E and 32% EBITDA margin													

Source: Refinitiv Eikon, KRC Insights

The differences in valuation multiples between MBX and its group of comparables (Figure 26) can be attributed to:

- Size (revenues, number of employees, asset base, etc.)
- Stock liquidity
- Levels of profitability (EBITDA margin) and cash flow generation
- Focus on different businesses

However, in further analysis of the companies, we focused on five ratios that highlight the operational differences between MBX and its comparable companies which also reflects the opportunity to investors as MBX narrows these differences (Figure 27).

In the report we have detailed how MBX is ramping revenues and profitability. Here we show the potential impact to investors of the consequences of these actions with the implication that narrowing of these differences will contribute to MBX expanding its valuation multiple towards that of the group of comparable companies:

Figure 27: MBX vs comparable companies - selected ratio analysis (per last reported fiscal year end)

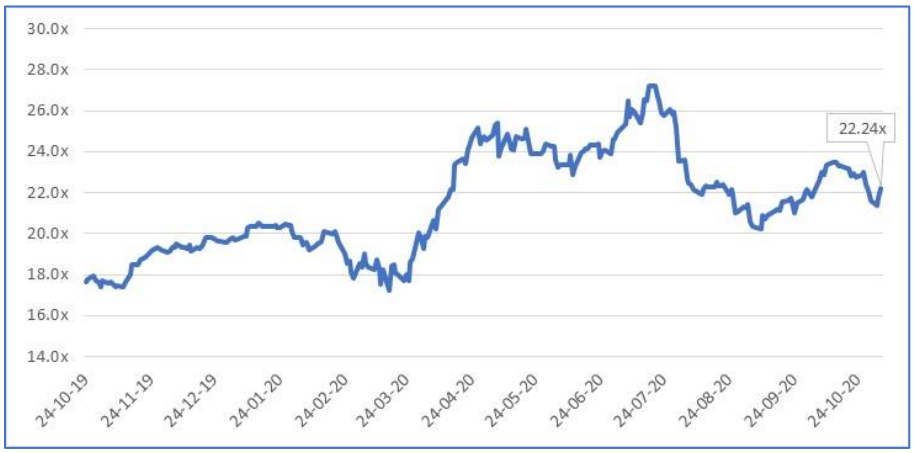
	MBX	Comps*	Explanation
Gross margins	48.8%	58.4%	We have forecast MBX's GMs will settle at ~48% due to the significant revenue contribution from VTM.
Revenues/employee	$168k	US$334k	We expect significant improvement to around $350k/employee as VTM and QAP™ sales ramp.
Inventory as % of total assets/inventory days	22.8%/ 238	7.8%/ 151	This ratio will decline as the business transitions to VTM and QAP™ sales. Antigen inventory should decline due to lower cost of production while both VTM and QAPs™ have significant shorter sales cycle (1 month vs 4-6 month and significantly lower cost of production vs antigens.
Fixed Asset turnover	2.02	5.38	This ratio is expected to improve to >3.0x after VTM and QAPs™ expansion.
Debt as % total assets	35.6%	18.0%	Expected to decline as higher sales volumes drive higher EBITDA contribution thereby facilitating free cash flow generation to fund both further growth and reduce debt.

Source: Refinitiv Eikon, KRC Insights *=average of 7 co.s in Figure 26 as per most recent annual report

Within the context of determining the context of the current comparables' valuation multiples as per Figure 26, we show the trend in EV (enterprise value)/NTM (next 12 months) EBITDA of this group in Figure 28 over the past year. The group has undergone multiple expansion as investors price in immunoassay companies as defensive plays and also the COVID-19 opportunity.

The current comparable company average EV/NTM EBITDA of 22.24x (Figure 28) is not extended and implies that our use of 22.5x EV/F2022E EBITDA multiple for MBX is reasonable.

Figure 28: MBX comparable companies' average EV/NTM EBITDA multiples LTM (pricing at 4/11/20)



Source: Refinitiv Eikon, KRC Insights

Using the average of both a EV/EBITDA and EV/Sales multiples as derived in Figure 26 reflects the appropriate valuation of the MBX shares. The difference between the derived valuations in Figure 29

based on MBX forecasts, with one based on sales and the other EBITDA, reflects the EBITDA margin differential between the comparable companies (31.0%) and MBX (28.3%). So, while we expect that because of product mix, MBX will not achieve the same level of EBITDA margin as its peers, its significantly higher revenue growth rate implies a higher valuation based purely on profitability metrics.

Figure 29: MBX valuation ($000s)

		EBITDA	Sales
EBITDA/Sales (2022E)	$000s	9,232	32,637
Multiple	x	22.5x	7.0x
Enterprise Value	$000s	207,731	228,456
Add: Cash 2022E	$000s	6,175	6,175
Less: Debt 2022E*	$000s	3,802	3,802
Implied market cap	$000s	210,103	230,829
Kinlytic urokinase	$000s	5,000	5,000
MBX valuation	$	215,103	235,829
FD # shares*	000s	159,115	159,115
Share price	$	1.35	1.48
Average (rounded)	**$**	**1.40**	
*=assumes conversion of the CDs.			

Source: KRC Insights

With regards to the number of shares, we have assumed conversion of the convertible debentures (Figure 30):

Figure 30: MBX fully diluted number of shares (000s)

	Shares	Options	Warrants	Convert. Deb	Total
As at Q2/20 (30/6/20)	108,773	7,493*	23,285	19,565	159,115
Average exercise price		0.32	0.36	0.23	

Source: Company reports, KRC Insights *=while 9,893k existed at 30/6/20, 2,400 expired 10/20

We provide $5.0m value for the Kinlytic Urokinase asset. Management is actively seeking partners to assist in the commercialization of this development asset. While the timing of closing and financial details of such a transaction are difficult to predict, we are confident that a development partner will be found, and hence we apply a notional value for KU. Given the size of the addressable market, such a transaction will be material to MBX.

We derive a $1.40 target price for MBX using an average of EV/EBITDA and EV/Sales approach and add $5.0m for the KU development asset.

Figure 31: MBX historical and forecast income statement ($000s)

Sept. year-end	2018	2019	Q1/20	Q2/20	Q3/20	Q4/20E	2020E	2021E	2022E
Antigen products	12,191	12,068	1,946	2,358	2,246	1,897	8,447	9,292	9,571
% growth	23.2%	-1.0%	-17.5%	-36.9%	-19.6%	-40.3%	-30.0%	10.0%	3.0%
QAPs		1,000	26	426	570	478	1,500	4,000	6,000
% growth			332.1%	-1.7%	141.0%	47.5%	50.0%	166.7%	50.0%
VTM								11,000	16,700
% growth									51.8%
Royalties	319	345	74	91	82	105	351	359	366
% growth	8.6%	8.0%	-21.5%	7.5%	0.1%	24.7%	2.0%	2.0%	2.0%
Total Sales	**12,511**	**13,412**	**2,046**	**2,875**	**2,898**	**2,480**	**10,299**	**24,651**	**32,637**
Total revenue growth	22.8%	7.2%	-16.8%	-32.4%	-6.8%	-30.9%	-23.2%	139.4%	32.4%
Cost of goods sold	**(7,141)**	**(6,865)**	**(1,003)**	**(1,554)**	**(1,543)**	**(1,342)**	**(5,442)**	**(12,696)**	**(16,879)**
Gross Margin	5,370	6,547	1,044	1,321	1,356	1,137	5,058	11,955	15,757
Selling and business dev.	(556)	(652)	(204)	(161)	(154)	(102)	(621)	(863)	(979)
General and admin.	(3,614)	(3,744)	(883)	(832)	(1,090)	(802)	(3,608)	(3,944)	(4,732)
Research and devel.	(1,090)	(1,042)	(265)	(278)	(295)	(295)	(1,133)	(1,479)	(1,632)
Total costs	(5,260)	(5,438)	(1,352)	(1,271)	(1,539)	(1,199)	(5,361)	(6,286)	(7,343)
Operating (Loss)/income	109	1,110	(308)	50	(184)	(62)	(504)	5,669	8,414
Interest paid	(852)	(1,066)	(277)	(268)	(257)	(278)	(1,080)	(1,080)	(540)
Other	(7,879)								
Net income before tax	(8,622)	44	(585)	(219)	(440)	(340)	(1,584)	4,589	7,874
Taxation		(12)				8	8	(23)	(39)
Net income	**(8,622)**	**32**	**(585)**	**(219)**	**(440)**	**(332)**	**(1,576)**	**4,566**	**7,835**
EPS - Basic	**($ 0.09)**	**$ 0.00**	**($ 0.01)**	**($ 0.00)**	**($ 0.00)**	**($ 0.00)**	**($ 0.02)**	**$ 0.04**	**$ 0.07**
EPS - FD	**($ 0.09)**	**$ 0.00**	**($ 0.01)**	**($ 0.00)**	**($ 0.00)**	**($ 0.00)**	**($ 0.02)**	**$ 0.03**	**$ 0.05**
Weighted avr. no. shares - FD	136,523	135,995	135,239	154,697	161,516	161,516	153,242	159,115	159,115
	2018	**2019**	**Q1/20**	**Q2/20**	**Q3/20**	**Q4/20E**	**2020E**	**2021E**	**2022E**
Gross profit %	42.9	48.8	51.0	45.9	46.8	53.9	49.1	48.5	48.3
Operating margin %	0.9	8.3	(15.1)	1.7	(6.3)	(2.5)	(4.9)	23.0	25.8
EBITDA $000's	799	1,679	(144)	221	(5)	97	169	6,406	9,232
EBITDA margin %	6.4	12.5	(7.0)	7.7	(0.2)	3.9	1.6	26.0	28.3
Effective tax rate %	--	26.8	--	--	--	2.3	0.5	0.5	0.5
Net margin %	(68.9)	0.2	(28.6)	(7.6)	(15.2)	(13.4)	(15.3)	18.5	24.0

Source: Company reports, KRC Insights

Appendix I: Recent press releases

Below is a summary of material press releases over the past 30 months. The list underscores the level of progress MBX is making with regards to gross margin improvement, QAPs™ product development and distribution:

- 18/1/18: Microbix Expands Quality Assessment Product Family - 48 new products being made available for sale under its PTDx™ and PROCEEDx™ brands. Press release also announced the new MBX website with ordering capability.
- 26/4/18: Microbix Engages Drug Licensing Advisor - engaged of Torreya Partners LLC of New York to assist in the re-launch of its clot-buster drug, Kinlytic® urokinase, into the United States market.
- 8/5/18: Microbix Completes Multiple Facility Upgrades – to support the expected growth of antigen demand, MBX undertook and completed 2x increase in power supply, expanded bioreactor capacity by 500% (adding 5 bioreactors to existing 1), added 2 processing ultrafuges amongst others.
- 24/12/18: Attained ISO 13485:2016 Medical Devices Certification – to help increase growth of its QAPs™ lines of quality assessment products by enabling it to target all three segments of the QAPs™ market.
- 5/2/19: Microbix Provides Quality Assessment Products Update – provided an update on the expansion of its quality assessment product lines (, announcing the addition of new customers, more products, and steps to expand its producti on capacity (leased an additional 10.3k ft^2 production space adjacent to existing 14k ft^2 facility).
- 18/4/19: Management changes: Dr. Kenneth (Ken) Hughes was appointed Chief Operating Officer (COO) and that Mrs. Kathryn Froh, its Vice President, Diagnostics retired.
- 30/7/19: Contribution of $2.75 Million to Scale-up, Meet Demand, and Create Highly-Skilled Jobs – FedDev Ontario contributed $2,752,500 (over 4 years) for Microbix to scale-up production at its antigen manufacturing facilities. Including: expansion of QAPs™ production and creation of new jobs. Forms base of $7.15m in expenditures over next 4 years.
- 1/8/19: Microbix Provides Bioreactor Update – MBX's largest customer completed tests and confirmed antigen order activity through 2020. First sales in FQ1/20.
- 5/9/19: European registration was obtained for four in-vitro diagnostic (IVD) control products for evaluating performance, procedures, and workflow of laboratory tests that detect and type HPV nucleic acids (DNA or RNA) in various human tissue samples.
- 19/9/19: U.S. availability of four in-vitro diagnostic (IVD) control products for evaluating performance, procedures, and workflow of laboratory tests that detect and type HPV nucleic acids (DNA or RNA) in various human tissue samples.
- 31/1/20: MBX completed a non-brokered private placement financing with gross proceeds of $2,355,000, by issuing an aggregate of 11,775,000 units ("Units") at a price of $0.20 per Unit.
- 24/3/20: Medical Supply Company of Ireland (MSC) was appointed as a distributor of quality assessment products (QAPs™) for the Republic of Ireland and Northern Ireland. This includes marketing, distribution, and logistical support for Microbix's QAPs™.
- 30/3/20: MBX creates QAPs™ product for COVID-19 tests - Imminent availability of QAPs™ products on COPAN FLOQSwabs, work with nucleic-acid based test (NAT) methods used to

detect the SARS-CoV-2 virus. Microbix to file for emergency-use authorizations from Health Canada, the U.S. Food and Drug Administration (FDA), and other regulatory authorities.

- 9/4/20: MBX and Oneworld Accuracy (1WA) announce a strategic collaboration (distributor) to provide a global external quality assessment (EQA) program.
- 21/4/20: MBX attained medical devices establishment licensing from Health Canada, enabling the immediate usage of its quality assessment products (QAPs™) by clinical laboratories, the Microbix COVID-19 QAPs™ have been shown to work with multiple nucleic-acid based test (NAT) methods.
- 27/4/20: MBX announced the appointment of Labquality Oy (Labquality) as a distributor of its Quality Assessment Products (QAPs™) in seven (7) countries.
- 6/5/20: Microbix began providing COVID-19 Test Quality Products as controls to clinical laboratories in Canada.
- 7/5/20: MBX announced U.S. availability of its SARS-CoV-2 quality assessment products (QAPs™) – FDA registration enabling immediate usage by U.S. clinical laboratories.
- 12/5/20: MBX announced the appointment of Diagnostic International Distribution S.p.A. of Milan (D.I.D.) as distributor of its Quality Assessment Products (QAPs™) for Italy.
- 15/5/20: MBX appointed R-Biopharm AG (R-Biopharm) as distributor of its Quality Assessment Products (QAPs™™) in eleven (11) countries (Australia, Belgium, Canada, France, Germany, Luxembourg, Netherlands, New Zealand, Norway, Spain, and the United Kingdom). Covers SARS-CoV-2 (COVID-19), Flu A, Flu B, RSV, high-risk types of HPV and other sexually transmitted infections.
- 19/5/20: MBX announced that it has achieved full utilization of the six bioreactor units it installed for manufacturing the “antigens” which are at the core of immunoassays that establish exposure or immunity to the Rubella virus, the cause of German Measles. Will benefit GM in Q1/21.
- 27/5/20: MBX commenced the build-out of its second facility that is initially intended to support a tenfold increase of production capacity for its QAPs™ quality assessment products.
- 1/6/20: MBX announced that it has been engaged to develop and supply custom quality assessment products (QAPs™) to support the registration and sales of a new point-of-care instrument and its tests for viral respiratory pathogens. First-year revenues from the agreement are expected to exceed C$ 1.0m.
- 4/6/20: MBX appointed Alpha-Tec Systems, Inc. (Alpha-Tec), a Calibre Scientific Inc. firm, as distributor of its Quality Assessment Products (QAPs™) for the United States.
- 5/6/20: MBX attained European Union “CE mark” (Conformité Européene) registration for its SARS-CoV-2 quality assessment products (QAPs™). The CE mark registration enables Microbix’s network of distributors covering 18 EU countries to immediately begin providing these products to clinical laboratories across the EU.
- 10/9/20: REDx™ Controls Attain Australian TGA Registration
- 13/10/20: Ontario Helps Microbix Ensure Provincial COVID Testing Capacity
- 15/10/20: New STI-Related QAPs™ Products (*Mycoplasma genitalium* (Mgen) infections)
- 20/10/20: QAPs™ to support accuracy of COVID-19 antigen-test workflows
- 29/10/20: New kit format QAPs™ and $500k OEM initial sale

Appendix II: Immunoassay Market Research

Summary of market research reports covering the immunoassay market, MBX's primary end market (Pre COVID-19):

Grandview Research Inc			Market Research Future			Acumen Research and Consulting		
Size of the market (US$bn)								
2018	**2025**	**CAGR**	**2018**	**2025**	**CAGR**	**2018**	**2026**	**CAGR**
18.02	25.4	5.0%	18.626	27.8	5.9%	18.7	26.1	4.9%
Major drivers:								
Infectious disease			Infectious disease			Infectious disease		
Chronic disease			Chronic disease			Chronic disease		
Rising geratric population			Incr. use of IA in POC			Incr. use in oncology		
Oncology is fastest growing			Technological advancement			Rising alcohol and drug testing		
Technological advancement						Technological advancement		
By technology:								
Radioimmunoassay (RIA)			Radioimmunoassay (RIA)			Enzyme Immunoassay (EIA)		
Enzyme Immunoassays (EIA)			Enzyme-linked Immunosorbent Assay (ELISA)			-Fluorescence IAs (FIA)		
Chemiluminescence Immunoassays (CLIA)			Enzyme-linked Fluorescent Assay (ELFA)			-Chemiluminescence IAs (CLIA)		
Fluorescence Immunoassays (FIA)			Chemiluminescence Immunoassay (CLIA)			Radioimmunoassay (RIA)		
Rapid Test			Rapid Test			Rapid test		
Others			Others			Others		
Applications:								
Therapeutic drug monitoring			Therapeutic Drug Monitoring			Endocrinology		
Oncology			Oncology			Therapeutic drug monitoring		
Cardiology			Cardiology			Autoimmune diseases		
Endocrinology			Endocrinology			Infectious disease testing		
Infectious disease testing			Infectious Diseases			Cardiology		
Autoimmune diseases			Autoimmune Diseases			Others		
Others			Others					
End markets:								
Hospitals (30.2% market, highest growth)			Hospitals			Hospitals		
Blood banks second highest growth			Clinical Laboratories			Pharmaceutical and biotech co.s		
Clinical laboratories			Blood Banks			Clinical laboratories		
Pharmaceutical and biotech co.s			Pharmaceutical and biotech co.s			Academic research centers		
Academic research centres			Academic and Research Institutes			Blood banks		
Other			Others			Others		
Major players*:								
Abbott laboratories			Abbott Laboratories			Abbott laboratories		
Becton, Dickinson & Company			Becton			Becton		
BioMérieux			bioMérieux SA			BioMérieux		
Danaher Corporation			Danaher Corporation			Danaher Corporation		
Ortho Clinical Diagnostics			DiaSorin S.p.A.			Dickinson & Company		
Quidel Corporation			Dickinson and Company			Ortho Clinical Diagnostics		
Roche Diagnostics			F. Hoffmann-La Roche Ltd			Quidel Corporation.		
Siemens Healthineers			Merck KGaA			Roche Diagnostics		
Sysmex Corporation			Ortho-Clinical Diagnostics/Carlyle Group			Siemens Healthineers		
Thermo Fisher Scientific, Inc.			Quidel Corporation			Sysmex Corporation		
			Siemens Healthineers			Thermo Fisher Scientific Inc		
			Sysmex Corporation					
			Thermo Fisher Scientific Inc.					
*=sorted alphabetically to facilitate comparison vs order listed in report summary.								

Appendix III: Regulation of *In Vitro* Diagnostic (IVD) Tests[16]

	FDA	Centres for Medicare and Medicaid Services
Primary statutory authority	Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976 (MDA)	Public Health Services Act, as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Oversees	All IVDs (including LDTs and reagents) are categorized as medical devices, but FDA has historically not exercised its regulatory authority with respect to LDTs.	Labs conducting tests on human samples. Inspectors evaluate the qualifications of lab personnel and testing processes, and validate tests, whether LDT or IVD.
Validation standard(s)	Analytical validity, Clinical validity	Analytical validity
How are tests validated?	Through premarket review, manufacturers of moderate- and high-risk IVDs must establish that a test detects or measures the intended analyte with appropriate precision and accuracy. Human studies are typically required to demonstrate the test's ability to predict a disease or condition as intended.	Labs performing tests that are not subject to FDA clearance or approval must establish performance characteristics of that test ("an analysis of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference interval").
When are tests validated?	At various points prior to the legal marketing of that test.	During inspections every two years (may be up to two years after an LDT is first performed).
Adverse event reporting	Mandatory reporting of adverse events by manufacturers, device user facilities (e.g., hospitals, nursing homes, etc.), and importers. Providers and patients may also voluntarily report serious adverse events.*	Not required. No mechanism exists to collect such information.
Recall authority	Yes	No

* U.S. Food and Drug Administration, "Medical Device Reporting (MDR)," https://www.fda.gov/medicaldevices/safety/reportaproblem/default.htm.

[16] https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/05/what-are-in-vitro-diagnostic-tests-and-how-are-they-regulated

Appendix IV: Infectious Disease Diagnostics Market

Summary of market research reports covering the Infectious Disease Diagnostics Market (Pre COVID-19):

	Meticullous Research			MarketandMarkets™		
	2018	2025	CAGR	2017	2022	CAGR
Size of the market:	8.6	12.88	5.9%	14.73	19.35	5.6%
Major drivers:	- Increasing global prevalence of infectious diseases			- Increasing prevalence of infectious diseases		
	- Growing awareness for early detection using specific diagnostic tests			- Shift in focus from centralized laboratories to decentralized point-of-care testing		
	- Growth in funding for research on infectious disease diagnostics			- Increased funding for research on infectious disease diagnostics		
	- Shift in focus from centralized laboratories to decentralized point-of-care testing			- Increased variety of reagents available and analytical techniques employed		
				- Launch of newer, faster, and more reliable products		
Fastest grower:	Immunodiagnostics because of IA			Asia Pacific fastest grower @ 8.3% p.a.		
				Hospital acquired infections segment (highest growth)		
By technology:	Immunodiagnostics			Immunodiagnostics		
	Clinical microbiology			Clinical Microbiology		
	Polymerase Chain Reaction (PCR)			PCR		
	Isothermal nucleic acid amplification technology (INAAT)			INAAT		
	DNA sequencing & Next-Generation Sequencing (NGS)			DNA Sequencing & NGS		
	DNA microarray			DNA Microarrays		
				Other Technologies		
Applications:	Hepatitis (largest application)			Hepatitis		
	HIV			HIV		
	Hospital-acquired infections			CT/NG		
	HPV			HAIs		
	Tuberculosis			HPV		
	Influenza			TB		
	Other			Influenza		
				Other Diseases		
End markets:	Hospital/clinical laboratories			Hospitals/Clinical Laboratories		
	Reference laboratories			Reference Laboratories		
	Academics/research institutes			Physician Offices		
	Other			Academic/Research Institutes		
				Other End Users		
Major players*:	Abbott Laboratories			Abbott Laboratories		
	BD			Becton, Dickinson and Company		
	bioMérieux SA			Biomérieux SA		
	Bio-Rad Laboratories			Bio-Rad Laboratories		
	Danaher			Danaher Corporation		
	DiaSorin S.p.A.			Diasorin		
	F. Hoffmann-La Roche Ltd			Luminex		
	Meridian Bioscience Inc.			Meridian Bioscience		
	Quidel Corporation			Quidel		
	Thermo Fisher Scientific Inc. among others.			Roche Diagnostics		
				Siemens AG		
				Thermo Fisher Scientific		
*=sorted alphabetically to facilitate comparison vs order listed in report summary.						

Appendix V: Directors of MBX

Martin Marino Ontario, Canada Pharmaceutical Executive (Chairman)	Mr. Marino has more than 30 years' experience in corporate legal roles and executive management functions, with emphasis on transaction-based corporate development. He also has considerable experience in conflict resolution and litigation management.
Mark A. Cochran, Ph.D. Virginia, USA Managing Director Johns Hopkins Medicine	Dr. Cochran was Executive Director of Johns Hopkins Medicine. His experience spans all levels of the drug discovery and development value chain, including operational and executive roles in the healthcare, venture capital, pharmaceutical, and biotech industries.
Joe Renner New Jersey, USA Pharmaceutical Executive	Mr. Renner, Chairman of Zydus Pharmaceuticals, Pennington, New Jersey, has more than 25 years' experience in the pharmaceutical industry. He has enjoyed a successful career leading businesses with many drug approvals in the United States.
Vaughn C. Embro-Pantalony Ontario, Canada Pharmaceutical Executive	Mr. Embro-Pantalony has held multiple executive roles in life sciences, with responsibility for licensing, business development, and strategic planning. His experience includes executive roles with Bayer, Novopharm and Terra International. He is a Chartered Director and Audit Committee Certified through McMaster University.
Dr. Peter M. Blecher Ontario, Canada Medical Director Centres for Pain Management	Dr. Blecher is the founder of several biotech ventures, including one purchased by MBX. He has practiced emergency medicine at Lakeridge Health, pain medicine at CPM Centers for Pain Management, and is Medical Director of Starseed Medicinal, Inc.
Cameron Groome Ontario, Canada Chief Executive Officer and President Microbix Biosystems Inc.	Mr. Groome is President and CEO of Microbix. Before joining Microbix, he was CEO of a company listed on the TSX Venture Exchange and EVP of a TSX-listed company – both in life sciences. Prior to his operational roles, he headed the healthcare activities of two national investment dealers.

Appendix VI: Terminology

Analyte: a substance whose chemical constituents are being identified and measured.

Antigen: An antigen is any substance that causes your immune system to produce antibodies against it. This means your immune system does not recognize the substance, and is trying to fight it off.

Bioreactor: A bioreactor is an apparatus for growing organisms (yeast, bacteria, or animal cells) under controlled conditions. Used in industrial processes to produce pharmaceuticals, vaccines, antigens or antibodies.

CE: Conformité Européene, a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

Clinical laboratory: is a healthcare facility providing a wide range of laboratory procedures which aid physicians in carrying out the diagnosis, treatment, and management of patients.

Epitope: specific area where a specific antibody binds with an antigen.

Immunoassays: quick and accurate tests that can be used on-site and in the laboratory to detect specific molecules.

Immunoglobulin: is the most common type of antibody in blood and other body fluids. Produced by plasma cells (white blood cells).

IVD: In vitro device (IVD) diagnostics are tests done on samples such as blood or tissue that have been taken from the human body. These are typically regulated.

Laboratory accreditation: A means of determining the technical competence of laboratories to perform specific types of testing, measurement and calibration.

LDT: A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

Microtiter plate: is a flat plate with multiple "wells" used as small test tubes. The microplate has become a standard tool in analytical research and clinical diagnostic testing laboratories

Proficiency testing: (PT) the performance evaluations for regulatory purposes, typically applies to laboratories and their specific tests or measurements.

Quality controls: also referred to quality assessment products (QAPs^{TM}), are inactivated and stabilized samples of pathogen are created to resemble patient samples in order to support one or more of (i) the proficiency testing (PT) of labs, (ii) test development, instrument validation and technical training, or (iii) quality management of patient testing by clinical laboratories.

Roller bottle: Cylindrical in shape, a roller bottle is used to grow and store cell cultures. Placed on a roller, roller bottles are slowly rotated and bathe cells that are attached to the inner surface of the bottle. Roller bottles are typically made of plastic or autoclavable glass.

ToRCH: An acronym for a group of infections that can cause significant birth defects and even fetal death. The ToRCH test measures the levels of an expecting mother's antibodies against five groups of chronic infections: toxoplasmosis, rubella, cytomegalovirus (CMV), herpes simplex virus (HSV) and other infections.

VTM: Viral Transport Media are vials of liquids into which swabs of patient test samples are placed. VTM preserves the stability of any virus that is present until it can be tested by the clinical lab.

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