

**2020 2<sup>nd</sup> Investor Conference**

# **Corporate Presentation**

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**Science • Integrity • Transparency**

**2020.06.22**

# Forward-looking Statement

- This presentation contains forward looking statements. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.
- Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements.
- Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future.
- Further, certain forward looking statements are based upon assumptions of future events which may not prove to be accurate. The forward looking statements in this document speak only as at the date of this presentation. Oneness Biotech does not undertake any obligation to update or revise forward looking statements in this presentation nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

# Financial Report

**As of 2020.6.22**

# Market Value & Financials

## 2019-2020 Q1 Financials

Currency in thousand NTD	2020Q1	2019Q1	Different
Revenue	3,245	4,184	(939)
R&D Exp.	120,785	24,239	96,546
Net Loss	191,597	30,379	161,218
Total Assets	6,868,730	2,711,995	4,156,735
Total Liabilities	642,878	493,563	149,315
Owner's Equity	6,225,852	2,218,432	4,007,420

## 2014-2020 Chart (NTD)



Previous Close	Day's Range	Year's Range	Market Cap
251	228-251	19.4-251	88.6bn

(Currency in NTD)

# Consolidated Statement of comprehensive income

(Currency in thousand NTD)

Item	2020 Q1	2019 Q1
Operating revenue	3,245	4,184
Operating costs	3,660	4,376
Gross profit (loss) from operations	(415)	(192)
Selling expenses	115	114
Administrative expenses	23,706	13,151
Research and development expenses	120,785	24,239
Total operating expenses	144,606	37,504
Net operating loss	145,021	37,696
Non-operating income and expenses	(46,576)	7,317
Net loss	191,597	30,379
Earnings per shares	0.54 dollars	0.16 dollars

# Consolidated Balance Sheets **ONENESS**

(Currency in thousand NTD)

Item	2020/3/31	2019/12/31	2019/3/31
Cash, Securities and Cash in banks	1,543,769	1,588,133	664,278
Other current assets	125,434	100,370	98,944
Property, plant and equipment	630,907	640,443	572,583
Investments	1,359,026	1,425,932	715,836
Other Intangible assets	2,452,890	2,462,470	52,228
Other assets	756,704	762,306	608,126
<b>Total assets</b>	<b>6,868,730</b>	<b>6,979,654</b>	<b>2,711,995</b>
<b>Total liabilities</b>	<b>642,878</b>	<b>520,961</b>	<b>493,563</b>
<b>Total share capital</b>	<b>3,529,048</b>	<b>3,524,908</b>	<b>1,957,522</b>
<b>Capital surplus</b>	<b>3,761,393</b>	<b>3,745,588</b>	<b>802,329</b>
<b>Accumulated deficit</b>	<b>(611,394)</b>	<b>(422,196)</b>	<b>(284,936)</b>
<b>Other equity interest</b>	<b>(453,195)</b>	<b>(389,607)</b>	<b>(256,483)</b>
<b>Total equity</b>	<b>6,225,852</b>	<b>6,458,693</b>	<b>2,218,432</b>

# Summary of Consolidated Financial Statements for the Years Ended March 31, 2020

## 1. Summary of Net Loss NTD 191,597 thousand :

- Oneness Biotech invests NTD 120,785 thousand to develop innovative new drugs. The current pipeline covers drugs under phase I, phase II, and phase III development, Such R&D expenditure contributes to 63.04% of total net loss.
- For risk diversification purpose, Oneness reinvests in Diamond Biofund Co., Ltd(venture capital), Sineu Pharma Co., Ltd(venture capital) and Microbio (Shanghai) Co., Ltd. from which the recognize net loss and financial assets profit and loss were NTD 46,991 thousand, 24.53% of the total net loss. The selling & administrative expenses were NTD 23,821 thousand, which is 12.43% of the total net loss.

# Summary of Consolidated Financial Statements for the Years Ended March 31, 2020

## 2. Financial situation stable , important financial ratio :

Current ratio	Quick ratio	Debts ratio
2,058.9%	1,972.7%	9.4%

## 3. Important assets explanation :

Items	Amounts	Account for total assets ratio	Explanations
Cash、 Securities and cash in bank	1,543,769	22.5%	The funds for new drug research and development are sufficient.
Property, plant and equipment	630,907	9.2%	Oneness Biotech Co., Ltd has already built large scale chromatographic extraction and pharmaceutical manufacturing site for supply of tON101 opical cream after NDA. Is granted.
Equity investment	1,359,026	19.8%	Reinvest in Microbio (Shanghai) Co., Ltd and other biotech venture capital companies for diversifying risk in research and development of new drugs .
Other Intangible assets	2,452,890	35.7%	This is obtained by acquiring FB825 and other new drug fair values from consolidated Fountain Biopharma Inc.
Other assets	882,138	12.8%	Including inventory、 right-of-use assets、 Goodwill、 other non-current assets



# R&D Progress

**As of 2020.6.22**

# Growth Foundation



# FB825 Global Licensing

530 million deal package with upfront payment of US\$40M+ milestone payments of US\$490M+ high single-digit to double digit royalties

- **1<sup>st</sup> milestone achieved under global profitability strategy**
- **Performing AD trial in US with high quality and standard**
- **Win-win partnership by performing tech transfer practicalities**
- **International visibility on R&D capability can be increased after global deal. This helps future licensing negotiation.**

# FB825 Progress

- **Upfront payment of US\$18.48M, the remaining \$15.12M will be made upon agreed timeline.**
- **1<sup>st</sup> patient has been dosed in AD trial in US. Aim to complete the trial in 2021.**
- **Subjects for P2a Asthma trial will be enrolled from Taiwan executed by MBS in collaboration with CRO. Aim to complete in 2022.**

# FB825 Key Elements

## Ph2a Trial Progress in US

- 1. Clinical endpoints**
- 2. Risk management for US pandemic**

# ON101 Successful Ph3 Results

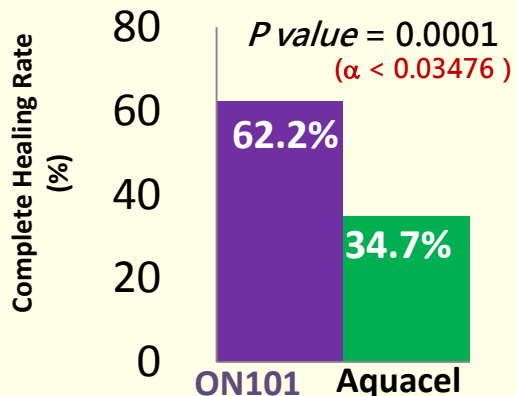
**1<sup>st</sup> DFU drug met primary endpoint among global trials in 23 years**

- **1<sup>st</sup> new drug with positive Ph3 results which achieved the 2<sup>nd</sup> milestone under global profitability strategy**
- **2 key efficacy endpoints indicate ON101's statistical superiority in healing. Safety profile also showed ON101 is well-tolerated.**
- **In hard-to-heal wounds, ON101 also showed superior efficacy to the comparator.**
- **The only drug in the world that achieve superior healing in wound >5cm<sup>2</sup>**

# ON101 Phase 3 Topline Data

## Primary Endpoint

Complete Healing Rate (FAS)



## Secondary Endpoint

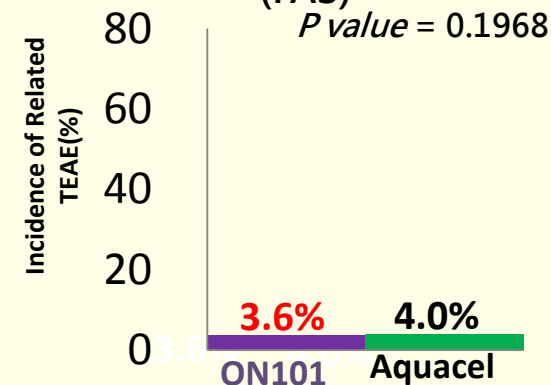
Time to Complete Healing (FAS)

*P value = 0.001*

	ON101	Aquacel
Time to complete healing in 50% subjects	14 weeks	NA

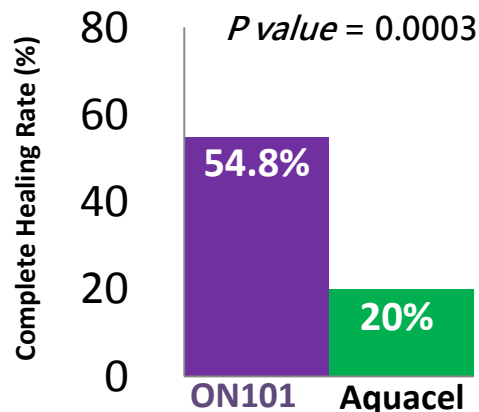
## Safety

Treatment Emergent Adverse Event (FAS)



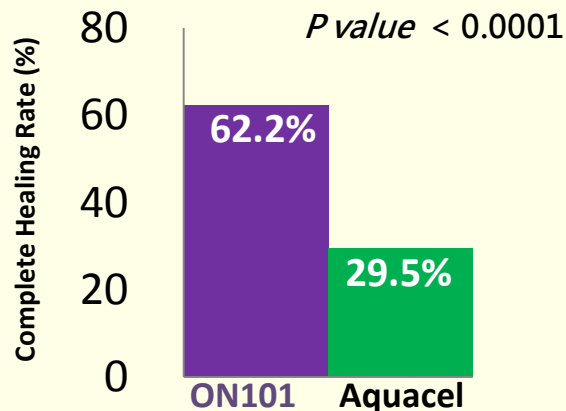
## Plantar Ulcers

Complete Healing Rate (FAS)



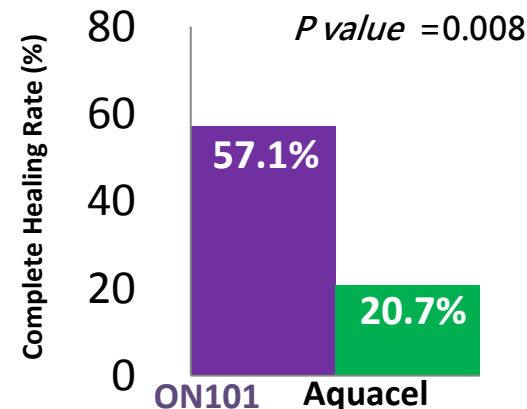
## Wagner Grade 2 Ulcers

Complete Healing Rate (FAS)



## >5cm<sup>2</sup> Ulcers

Complete Healing Rate (FAS)



# ON101 vs. Regranex

**Best Healing Efficacy in Ulcers >5cm<sup>2</sup>**

Ulcer area	Regranex Complete Healing Rate in 20 weeks	
1 cm <sup>2</sup>	53.1%	
1.25 cm <sup>2</sup>	51.2%	
2 cm <sup>2</sup>	45.7%	
3 cm <sup>2</sup>	38.8%	67%
4 cm <sup>2</sup>	31.9%	
5 cm <sup>2</sup>	25.8%	57%

**Regranex 20wks Complete Healing 50%    ON101 16wks Complete Healing 62%**



# ON101 Progress

- **2020.07 Pre-NDA meeting application with NMPA for NDA**
- **2020.07 Final CSR will be submitted to TFDA for NDA**
- **2020.07 Medical device registration application with US FDA**
- **2020.08 Publication drafting for clinical data and novel mechanism**
- **Aim to complete NDA in 2020 with TFDA**
- **To complete cultivation of drug material across 10 acres land in 2020**
- **Performing PICs/GMP certification on drug substance and drug product in 2020 Q3**

# ON101 Key Elements

- **NDA progress in Taiwan and China**
- **US, EU, India market access under medical device registration**
- **Pricing strategy for new drug/medical device**
- **Market channel and operation in global markets**
- **Global licensing negotiation**

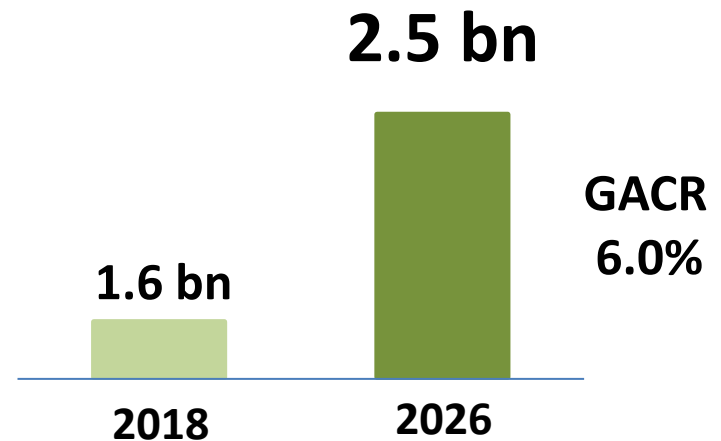
## 2 Cornerstones for Oneness

- Oneness R&D capability and credibility have been recognized by global pharma through licensing of FB825. This helps Oneness future licensing negotiation.
- Ph3 results of ON101 are important milestone for market launch. ON101 as a potential blockbuster new drug will be a cornerstone for Oneness profitability.
- By achieving 2 milestones in global licensing and launching blockbuster new drugs, it is believed to key cornerstones for Oneness future development.

# FB704A Progress

## New Indications

- The results of *in-vivo* study combining FB704A with 1<sup>st</sup> line drug in liver cancer didn't reflect statistical significance
- Systemic inflammatory diseases
- Systemic sclerosis is systemic inflammatory disease addressed by no biologics
- P2 study planned in 2020



Market forecast for SSc

Source: Grand View Research

# Progress of R&D Drugs

## ■ OB318 (HCC new drug)

- Optimize the fermentation process and safety study
- 2020.06.29 kickoff phase 1 clinical study enrolled 30 late stage HCC patients. Estimated time to finish study in 2021.

## ■ FB918 (mAb for allergic asthma)

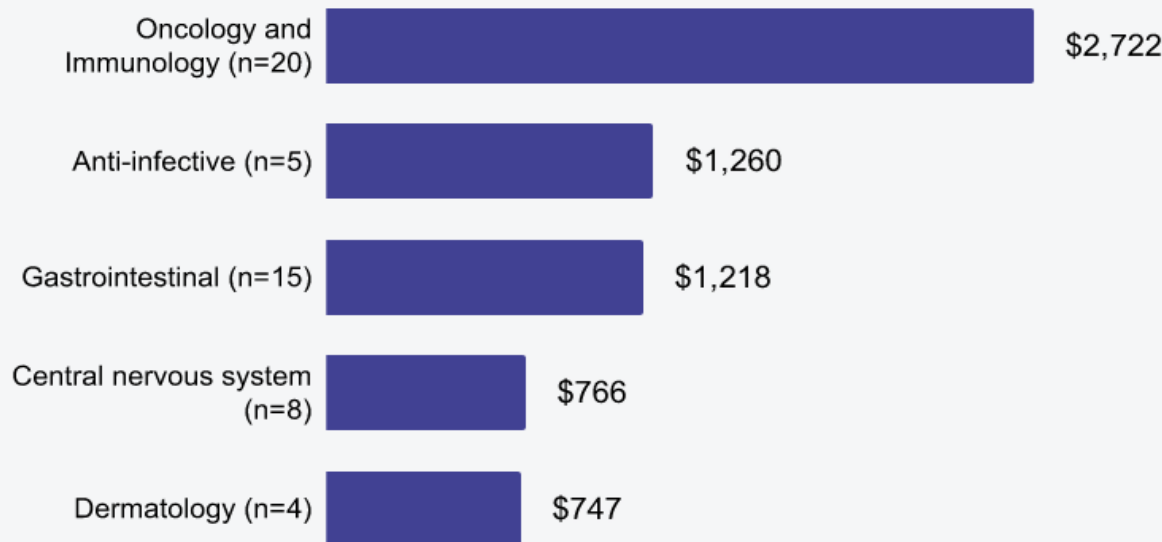
- Regulate Th1/Th2 cytokines to inhibit inflammatory reaction.
- High affinity screening completed and under evaluated and reviewed internally.
- Progress of clinical trial will be decided by the end of 2021 based on the future study results.

# Issue of Depository Receipts

# Estimate the cost to develop a new drug at US\$1.3Bn

## R&D costs highest for cancer, immunology medicines

Estimated median expense on new drugs approved by U.S. FDA between 2009-2018, in millions of dollars



Sanofi cost **6 Billion USD** in developing Dupixent (AD new drug)

Estimated more than \$6B sales in 2021

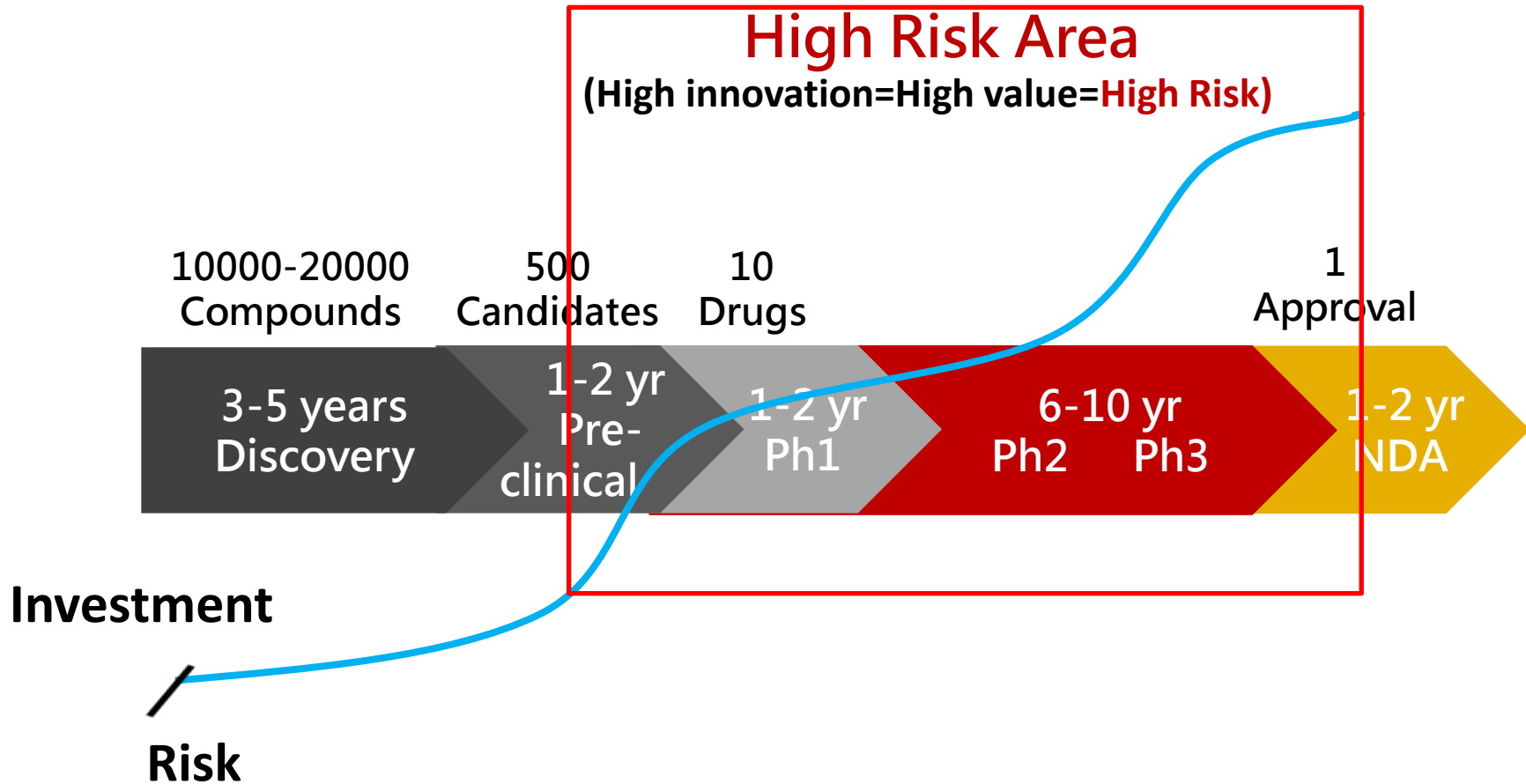
# DR Issuance

- **2020.06 Issue of DR has been approved in shareholders' meeting**
- **Purpose of DR : Keep sufficient funding for future R&D. This is to expand future R&D pipeline based on Oneness' strong R&D capability.**
- **Purpose and use of the fund by issuing DR will be applied with financial authority**
- **DR Issuance helps Oneness connect with international market**
- **Number of issuance of DR is expected to be less than approved number considering the stock price.**



Innovation =  
Value + Risk

# New Drug R&D: Investment and Risk



# Final Note on Investment Risk

**Investment in R&D biotech companies is with huge risk and can't guarantee returns or dividends within a short period of time.**

**Investors shall understand the nature and operation of the companies before making investment.**

# Thank you

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**3<sup>rd</sup> Investor Conference will be held in Sept 2020**

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