



2022 3Q

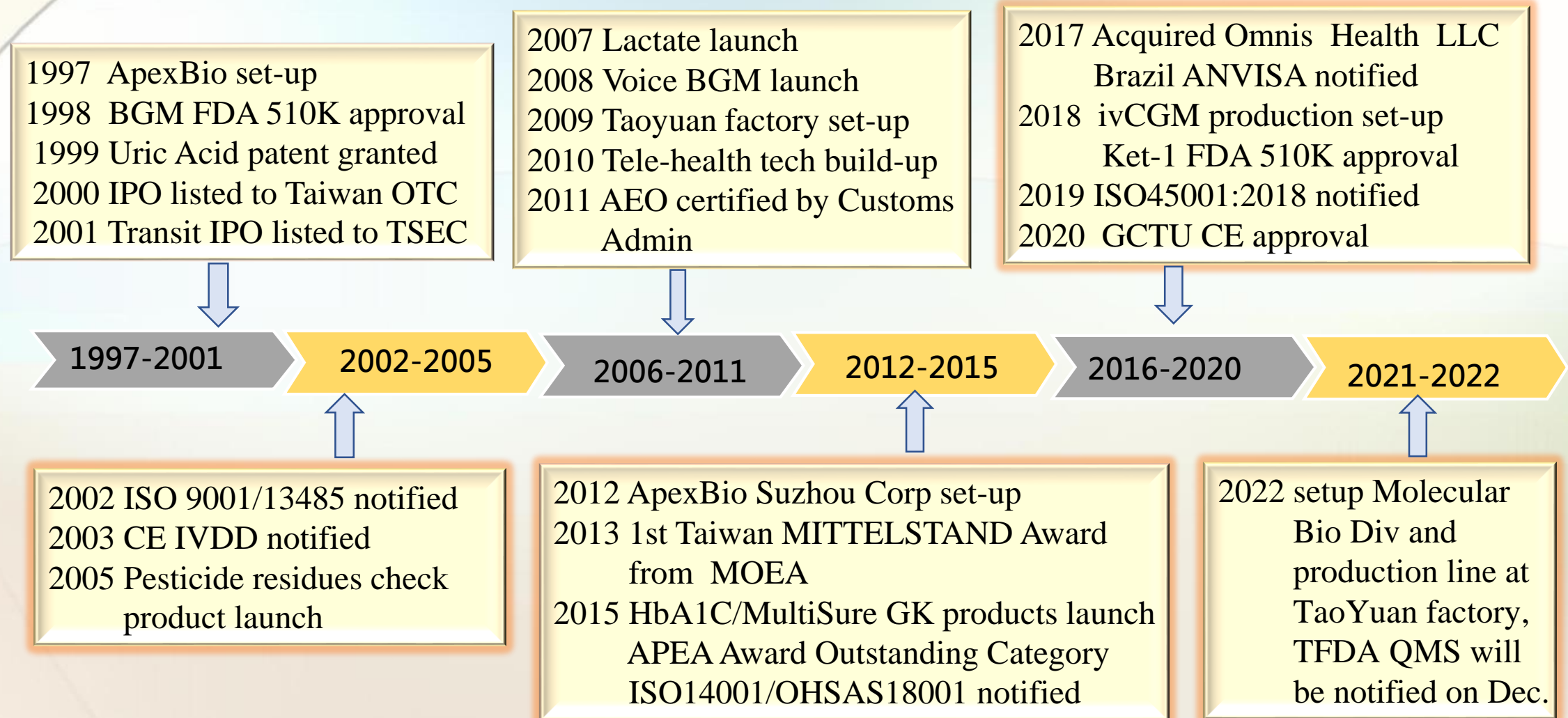
2022 Nov

APEXBIO

Company profile

Stock #	TSEC 1733
Industry	IVD Medical Device
Operation Locations	<ul style="list-style-type: none">• Head quarter: No. 7, Li-Hsin 5th Rd., Hsinchu Science Park, Hsinchu, Taiwan• Tao Yuan Factory: No. 180, Lane 70, Wuqing Rd., Dayuan Dist., Taoyuan City 337, Taiwan• Suzhou Corp.: Room 106, No.2, Kecheng Road, SIP, Suzhou, China• Omnis Health LLC : 1736 River Hills Dr Suite 6, Nashville, TN 37210,USA
Started	12/02/1997
IPO	06/13/2000(4101 OTC) 09/17/2001(1733 TSEC)
Capital	NTD 1 Billion
Chairman/CEO	Thomas Shen PhD
Employees	737 people (upto 9/30/2022)

Milestone



Quality system

Region	The Authority	Regulatory compliance
Taiwan	TFDA	GMP
EU	CE	ISO 13485:2016 CE mark number:CE0197 EN ISO 15197:2015
USA	FDA	510K's FDA on-site audit w/o 483 citations 2001/2006/2011/2016
China	CFDA	Medical Device Class II
Japan	PMDA	
Brazil	ANVISA	2017 passed on-site audit

ESH policy

In response to environmental protection and occupational safety and health policies, management procedures have been established year by year to consistently comply with the GRI guidelines in order to achieve the goal of sustainable of enterprises.

Certificate TW15/11085

The management system of

Apex Biotechnology Corp.

No.7, Li-Hsin 5th Rd., Hsinchu Science Park,
Hsinchu 30078, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

ISO 14001:2015

For the following activities

For the design and development, Manufacture and Distribution of In-vitro Diagnostic Devices used in the Monitoring of Blood Glucose and Uric Acid/Lactate/Hemoglobin/Cholesterol/Ketone/HbA1c etc, and Pesticide Residual system including Meters, Test Strips and control Solution including the Point of Care and Home use.

This certificate is valid from 25 October 2021 until 23 October 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 4. Certified since 23 October 2015

The audit leading to this certificate commenced on 22 September 2021
Previous issue certificate validity date was until 23 October 2021

Authorised by



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Certificate TW16/00926

The management system of

Apex Biotechnology Corp.

No.7, Li-Hsin 5th Rd., Hsinchu Science Park,
Hsinchu 30078, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

ISO 45001:2018

For the following activities

For the design and development, Manufacture and Distribution of In-vitro Diagnostic Devices used in the Monitoring of Blood Glucose and Uric Acid/Lactate/Hemoglobin/Cholesterol/Ketone/HbA1c etc, and Pesticide Residual system including Meters, Test Strips and control Solution including the Point of Care and Home use.

This certificate is valid from 25 October 2021 until 23 October 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due before 13 October 2024. Issue 4. Certified since 24 October 2019

The audit leading to this certificate commenced on 22 September 2021
Previous issue certificate validity date was until 23 October 2021

Authorised by



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Product portfolio



Blood glucose monitoring systems

Professional Monitoring systems



■ Uric Acid

■ Hemoglobin

■ Lactate

■ Ketone

■ HbA1C



Multi-functional systems

■ Glucose + Uric Acid

■ Glucose + Ketone

■ Glucose + Cholesterol

■ Glucose + Cholesterol + TG + Uric Acid



GLUCOSURE POC

Glucose/Ketone POC barcode scanner + wifi

KETOSURE™ POC

BLOOD KETONE MONITORING SYSTEM

Ketone POC barcode scanner + wifi

(EU territory distributed by Roche)



+ Hospital



行動推車
操作者ID/患者ID



試片批號
支援1維/2維條碼



POC平台
血糖管理系統



HIS
醫院資訊系統

LIS
檢驗管理系統



APEXBIO

Eclipse PLUS

Eclipse PLUS

MULTI-PURPOSE ANALYZER

- Hemoglobin A1c
- Microalbumin
- Creatinine
- Albumin Creatinine Ratio (ACR)



Specifications

- Display: 5" Full Color LCD
- Display Unit:
 - HbA1c: %, mmol/mol, eAG
 - Microalbumin: mg/dL
 - Creatinine: mg/dL, mmol/L
 - ACR: mg/g, mg/mmol
- Operating/User Interface: Touch Panel Screen
- Data Port: Type-A USB
- Power Supply: 100~240V, 50/60Hz
- Dimension: 290L x 206W x 137H (mm)
- Weight: 1.6kg
- Operating Condition:
 - Temperature: 18~35°C/Humidity: <80%
- Analyzer Storage Condition:
 - Temperature: 4~50°C/Humidity: <80%
- Cartridge Storage Temperature:
 - HbA1c: 2~8°C
 - Microalbumin: 4~30°C
 - Creatinine: 4~30°C
 - ACR: 4~30°C
- Accessories: Optical Control Cartridge, Barcode Scanner, Printer, USB Cable, Power Adaptor

Eclipse PLUS

MULTI-PURPOSE ANALYZER

HbA1c

MICROALBUMIN

CREATININE

ACR



For Clinic
and Hospital

Pre-screening
Diabetic Kidney
Disease



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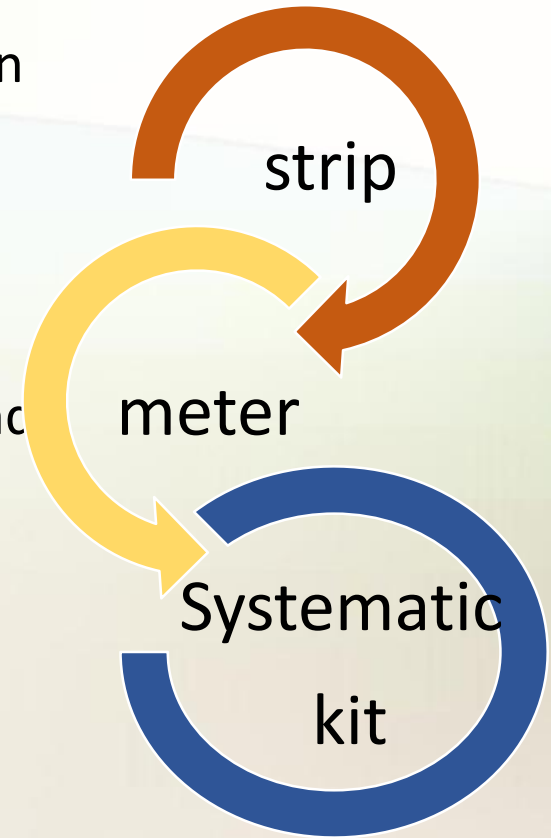


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Customized projects

- Product platform focus on electrochemistry/photometry/ Lateral flow assay; developing a first tool of the world that can monitor liver function test for an ODM customer, and the product had been approved by TFDA in 2022 and published in Analytical and Bioanalytical Chemistry.
- To derive new parameter tests and optimize our core platform.
- Sharing our advantage of regulation/quality control/sales channels/clinical trails/manufacturing to alliance with partners and customers.
- Integrate to IOT with hospitals and healthcare service centers --new model 5G BGM is developing for a US healthcare customer
- Cooperated with Italy customer for ivCGM (ICU use) at 4th phase under clinical trial and CE notification in 2023.



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New pipeline products

- Continuous Glucose monitoring system (CGM)
- Lipid panel monitoring system
- Rapid test –
 - Flu A/B test
 - Vector-borne disease test and
 - Economic animal and animal quarantine test

Global sales distribution



Territory	2020	2021	2022/1-3Q
America	42%	43.5%	41%
EU	46%	45%	49%
Asia	11%	11%	9%
Africa	1%	0.5%	1%

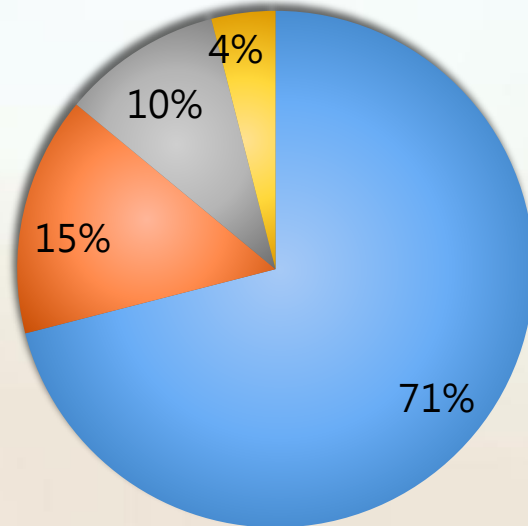
Finance Performance

	2020	2021	2022/1-3Q
Revenue	2,005,337	2,131,656	1,735,537
Gross margin	452,224	571,512	418,971
Operation profit	103,328	204,949	125,879
Profit after tax	94,629	202,289	138,582
EPS	0.95	2.03	1.39
G/M ratio	22%	27%	24%
Shipped Meter Qty (kit)	1,731K	1,677K	1,471K
Shipped Strip Qty(pcs)	1,061M	1,167M	846M

Product ratio

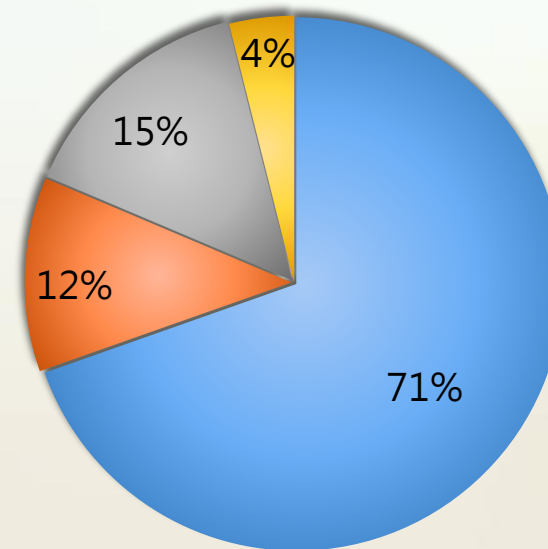
2021

■ BGM & A1C ■ Electrode
■ Non-BGM ■ Others



2022/ 1-3Q

■ BGM & A1C ■ Electrode
■ Non-BGM ■ Others



Non-BGM

Hemoglobin/Ketone/UricAcid/Lactate/Cholesterol/
Pesticide quick check etc

the 8th Corporate Governance Evaluation (2021)

Category	Total number of indicators		weighting		Points for satisfied indicators		Number of inapplicable indicators		Extra Credit Indicators:	
	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021
Protecting Shareholder Rights and Interests and Treating Shareholders Equitably	16	16	0.19	0.2	14	15	0	0	0	0
Enhancing Board Composition and Operation	28	26	0.34	0.33	20	22	0	0	3	3
Increasing Information Transparency	21	21	0.26	0.26	12	13	0	0	0	0
Putting Corporate Social Responsibility into Practice	17	16	0.21	0.21	15	14	0	0	3	1
others	2	2	-	-	-	-	-	-	-	-

Total score : 85.14

Ranking (SEC): 21%~35%

Thank you