

五鼎生技
APEXBIO
T a i w a n

May 2023



Company profile

TSEC 1733

Industry IVD Medical Device

Operation Locations

.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,
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 732 people (upto 3/31/2023)

Milestone

1997-2001

1997 ApexBio set-up
1998 BGM FDA 510K approval
1999 Uric Acid patent granted
2000 IPO listed to Taiwan OTC
2001 Transit IPO listed to TSEC

2002-2006

2002 ISO 9001/13485 notified
2003 CE IVDD notified
2005 Pesticide residues check
product launch

2007-2011

2007 Lactate launch
2008 oice BGM launch
2009 Taoyuan factory set-up
2010 Tele-health tech build-up
2011 AEO certified by Customs Admin

2012-2016

2012 ApexBio Suzhou Corp set-up
2013 1st Taiwan MITTELSTAND
Award from MOEA
2015 .HbA1C/MultiSure GK
products launch
.ISO14001/OHSAS18001
notified

2017-2021

2017 .Acquired Omnis Health LLC
.Brazil ANVISA notified
2018 .ivCGM production set-up
.Getone KET-1 FDA 510K
approval
2019 ISO45001:2018 notified
2020 GCTU CE approval

2022-2023

2022 .Setup Molecular Bio Div
and production line at
TaoYuan factory and passed
TFDA QMS notify

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

Product profile



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



KETOSURE™ POC

BLOOD KETONE MONITORING SYSTEM

Ketone POC barcode scanner + wifi

(EU territory distributed by Roche)



GLUCOSURE POC

Glucose/Ketone POC barcode scanner + wifi



+ 醫院專用



Eclipse PLUS

For Clinic and Hospital

Pre-screening Diabetic Kidney Disease

- 糖化血色素(HbA1c)
- 微量白蛋白(Microalbumin)
- 肌酸酐(Creatinine)
- 微量白蛋白/肌酸酐比值(ACR)



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: 250L 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

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E-mail: info@apexbio.com / Website: www.apexbio.com

CE 0197 FDA CFDA

New pipeline products

■ Rapid test

TFDA QMS passed

Developing items:

- COVID-19 Antigen Rapid Test Kit
- Influenza Rapid Test Kit
- Vector-borne Disease Detection for Mosquito-borne Illnesses
- Economic Animal and Animal Epidemic Prevention Detection

■ Home use CGM

■ Smart POC

Customized projects

- Product platform focus on electrochemistry/photometry/ Lateral flow assay , 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
- Cooperated with Italy customer for ivCGM (ICU use), the clinical trial completed, preparing TFDA & CE notification in 2023.
- Cooperated with customers for Rapid tests

Global sales distribution

Territory	2021	2022	2023/1Q
America	43%	40%	32%
EU	45%	49%	55%
Asia	11%	10%	13%
Africa	1%	1%	0%

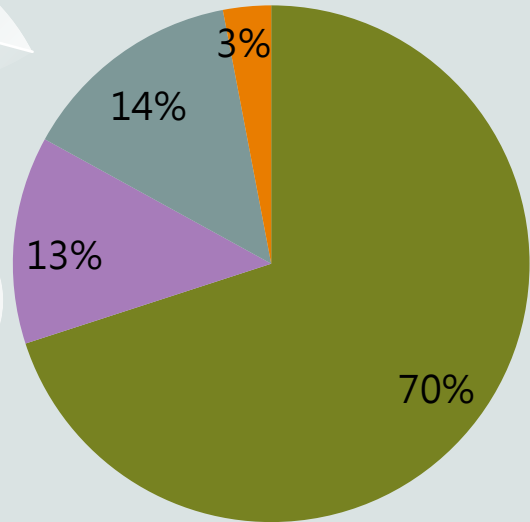
Finance Performance

	2021	2022	2023/1Q
Revenue	2,131,656	2,244,176	436,537
Gross margin	571,512	576,839	134,216
Operation profit	204,949	176,560	42,053
Profit after tax	202,289	181,451	35,748
EPS	2.03	1.82	0.36
G/M ratio	27%	26%	31%
Shipped Meter Qty (kit)	1,677K	1,821K	276K
Shipped Strip Qty(pcs)	1,167M	1,118M	261M

Product ratio

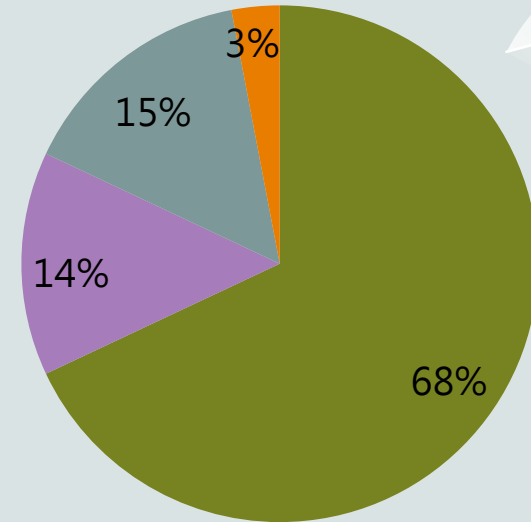
2022

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



2023/1Q

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



Non-BGM
Hemoglobin/Ketone/UricAcid/Lactate/Cholesterol/
Pesticide quick check etc

the 9th Corporate Governance Evaluation (2022)

Category	Total number of indicators		weighting		Points for satisfied indicators		Number of inapplicable indicators		Extra Credit Indicators:	
	2021	2022	2021	2022	2021	2022	2021	2022	2021	2022
Protecting Shareholder Rights and Interests and Treating Shareholders Equitably	16	16	0.2	0.2	15	13	0	0	0	1
Enhancing Board Composition and Operation	26	26	0.33	0.33	22	21	0	0	3	3
Increasing Information Transparency	21	18	0.26	0.23	13	11	0	0	0	0
Putting Corporate Social Responsibility into Practice	16	18	0.21	0.24	14	13	0	0	1	1
others	2	2	-	-	-	-	-	-	-	-

Total score : 79.29

Ranking (SEC): 36%~50%



Thank you

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