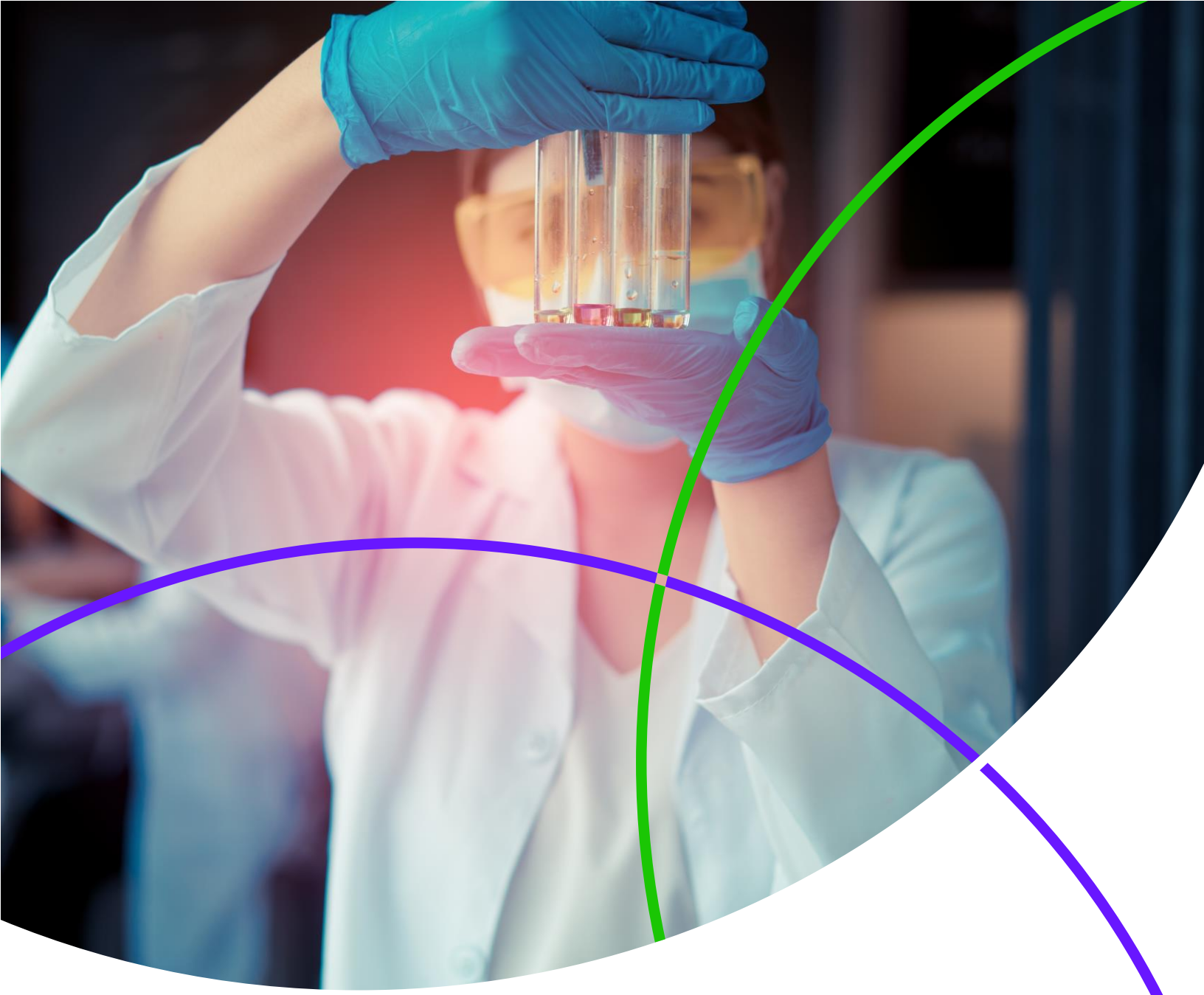

A BioWorld special report

Biopharma news and views from Southeast Asia

Amid challenges, the industry gains traction
in Singapore, Thailand, Malaysia and Indonesia

From the publishers of BioWorld,
a Clarivate Analytics news service

Clarivate
Analytics

A SPECIAL REPORT FROM CPHI AND CLARIVATE ANALYTICS

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"Biopharma news and views from Southeast Asia: Amid challenges, the industry gains traction in Singapore, Thailand, Malaysia and Indonesia" features a series of articles on the region from BioWorld, the Clarivate Analytics biopharma news service.

Both organizations believe that through knowledge-sharing, our industry develops as a whole, opportunities arise and new horizons are uncovered. We see this report as a great way to kick off the exciting CPhI South East Asia event and to highlight the importance of continuous regulatory compliance within Asia Pacific and across the world. Join us on this learning journey as all together we drive the industry forward.

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Table of contents

Decades of investment paying off in Singapore's biotech boom	5
AJ Biologics builds first vaccine manufacturing facility in Malaysia, looks to innovate with partners	8
South Korea's Daewoong moves into Indonesia via academic partnership	10
Thailand's growing market set to attract global pharma firms	12
Duke-NUS brings aboard Novo Nordisk to fund stem cell research program	14
Tackling the blood-brain barrier: Duke-NUS discovery leads to startup Travecta	16
With new development deal, manufacturing site, Wuxi expands global footprint	18
Malaysia's Duopharma to capitalize on growing SEA biosimilars market	20
More news from the region	21

Introduction

Biopharma in Singapore, with a strong investment community and scientific drivers like Duke-NUS Medical School, continues to charge forward. Thailand has invested in its core and is expected to see further industry growth. Advancements in both Malaysia, with a new vaccine manufacturing facility, and Indonesia, where an academic power is likewise partnering on new medicines, have resulted in increased global attention. This collection of feature articles and news briefs, compiled from BioWorld, the daily biopharma news service from Clarivate Analytics, looks at developments across the life sciences in this upcoming region over the last year and more.

Decades of investment paying off in Singapore's biotech boom

By David Ho, Staff Writer

Singapore isn't just becoming a biotech hub. The island nation's biotech ecosystem is at "an inflection point," said Benjamin Seet, executive director of the biomedical research council at A*STAR (The Agency for Science, Technology and Research), a statutory board under the Ministry of Trade and Industry.

"In the past five years alone, close to 50 drug development biotech companies were incorporated in Singapore, and I am highly optimistic that the number of companies will continue to rise," he said.

Seet isn't alone in his optimism. The *Scientific American Worldview* placed Singapore as second on its 2016 list of countries with strong biotech potential, just behind the U.S.

"Singapore's biotech ecosystem is becoming increasingly sophisticated, with licensing and acquisition deals and robust pipelines already in place. We now have an increasing number of made-in-Singapore drugs in clinical trials, and we have local biotech companies reaching valuations of hundreds of millions and achieving public listing," Seet told *BioWorld*.

"This is an exciting time to set up a biotech company in Singapore."

But it didn't happen overnight.

The Singaporean government has been investing in R&D efforts since the early 90's, starting with a SG$2 billion (US$1.5 billion) budget for its National Technology Plan 1995. The public investment in R&D currently stands at SG$19 billion (US$14.2 billion) under the Research, Innovation and Enterprise 2020 Plan (RIE2020).

"The initial public investments in the life sciences took place almost 30 years back, and have been sustained over the decades," said Seet.

Teo Chee Hean, deputy prime minister and chairman of the National Research Foundation Singapore, had previously expressed a need to invest in R&D to turn Singapore into a "knowledge-based economy, which thrives on innovation and enterprise." And the government has made health and biomedical sciences a key pillar in the RIE2020. Under the plan's budget, SG$4 billion (US$2.9 billion) has been specifically allocated to health and biomedical sciences. Another SG$3.2 billion (US$2.3 billion) will go toward advanced manufacturing and engineering, which would be beneficial for biotech manufacturing growth.

"This has now resulted in new drugs, devices and diagnostics being discovered and developed in our hospitals, medical schools and research institutes, which have in turn, led to a steady pipeline of commercial activities," said Seet.

Furthermore, five therapeutic areas of focus have been identified as priorities: cancer, cardiovascular diseases, diabetes mellitus and other metabolic or endocrine conditions, infectious diseases, and neurological and sense disorders.

Financial finesse

Singapore's position as a finance hub has also come in useful for developing its biotech industry. State investments in biotech, meanwhile, have bolstered the sector. Examples include Tessa Therapeutics Pte. Ltd., which recently closed an SG$108 million (US$80 million) financing round led by state-owned investment company Temasek Holdings.

The company plans to use the proceeds from that funding round to further advance its clinical pipeline and to bring therapies, based on the company's VST, or virus-specific T-cell, platform, into clinical trials. Tessa is conducting the largest phase III trial of its kind for its lead drug candidate, TT-10, a T-cell therapy specifically aimed at cancer cells harboring the Epstein-Barr virus, a type of herpes virus that stays permanently in certain white blood cells of an infected person. The virus has been linked to many types of cancers. (See *BioWorld*, June 27, 2017.)

The drug has received fast track and orphan designation from the U.S. FDA. Tessa anticipates that the trials may lead to the first T-cell therapy for a solid tumor approved by the FDA.

If not on the home ground, then markets close by in the region have also proved to be viable sources of funding for Singapore based biotech companies.

Among them, the biggest success story would be Aslan Pharmaceuticals Pte. Ltd., which raised NT1 billion (US$33 million) on the Taipei Stock Exchange. The 2.6 million shares offered for the IPO were oversubscribed by 29.4 times. (See *BioWorld*, May. 17, 2017).

The company has a pipeline of five novel compounds and one modybodies (novel stabilized heavy chain human monoclonal antibody fragments that can be assembled into multi-specific formats) platform for the treatment of Asia-prevalent tumors.

"Singapore's pro-business and pro-science policies have helped nurture a thriving biotech industry," Carl Firth, CEO and founder of Aslan, told *BioWorld*. "The commitment to building world-class infrastructure, talent, research and intellectual property protection provides robust support for biotech companies, like Aslan, to succeed,"

Partnerships, infrastructure and manpower

Funding was just one part of the country's efforts.

"A coordinated, intensive, nationwide approach was also essential," according to Lim Chuan Poh, chairman of A*STAR. "Its ministries and public-sector agencies have worked well together and have nimbly made changes over time to boost momentum. In an ever-changing global economic landscape, this integration and coordination have been essential."

Partnerships with research institutions including A*STAR and National Cancer Centre Singapore (NCCS) have enabled Tessa to accelerate its journey to develop next-generation cancer therapies.

"At NCCS, we conducted a phase II trial, which demonstrated one of the highest two-year overall survival benefit of 62.9 percent among trial participants and led to Tessa's phase III trial for nasopharyngeal carcinoma," John Connolly, Tessa's chief scientific officer, told *BioWorld*.

"Tessa is currently operating a joint immuno-oncology lab with A*STAR's Institute of Molecular and Cell Biology," he added. "The collaboration is bringing together Tessa's R&D, clinical and commercial expertise with A*STAR's world-class research facilities to accelerate cancer immunotherapy research. These are examples of Singapore's rapid advancement in medical research over the last decade and are testaments to its position as a hub for biotech discovery and medical excellence in the region."

Partnerships aimed at bridging the gaps between Singapore and other markets, like the Korea-Singapore Healthcare Incubator, have also been useful in helping both Singapore investments and innovations reach a wider audience. (See *BioWorld MedTech*, Oct. 12, 2017.)

The Southeast Asian country also has the infrastructure in place to host biotech companies. It has two major biotech parks, with tax breaks and other incentives provided to encourage companies to settle in those hubs.

The one-north district, a subzone located in Queenstown, is an international research and development center for biomedical sciences, tech and media firms. It is home to institutions such as A*STAR and Takeda Pharmaceutical Co. Ltd. Last year, a $72 million Advanced Medicine Oncology Centre opened in the area.

The other park is the Tuas Biomedical Park.

Besides R&D facilities, Singapore also has a growing manufacturing sector to support biotech companies. Abbvie Inc., for example, opened a 120,000-square-meter biologics manufacturing site in the Tuas Biomedical Park. (See *BioWorld*, Oct. 9, 2017).

The country also has focused on cultivating its human resources.

"Singapore concluded that it must promote strong intellectual capital creation as a basis for developing knowledge-intensive companies and generating high–value-added jobs for Singaporeans," said Deputy Prime Minister Teo.

According to A*STAR, Singapore is now home to more than 50 biomedical sciences manufacturing plants that employ more than 19,000 people and has a market value of SG$15 billion (US$11 billion).

The $293 million plant that Abbvie operates is expected to take in about 250 personnel across different disciplines, with approximately 83 percent being local hires.

"We are participating in the Biologics Overseas Skills Training [BOOST] program to build up a pipeline of skilled manpower for Singapore's biologics manufacturing industry by supporting the execution of its training modules," Marc O'Donoghue, site director of Abbvie Operations Singapore, told *BioWorld*.

"This includes upgrading the skills of experienced professionals as well as equipping fresh graduates with on-the-job training in biologics manufacturing," he added.

The BOOST program is a professional conversion program jointly developed by Workforce Singapore (WSG) and the Singapore Economic Development

Board (EDB) specifically for the local pharmaceutical and biologics sector. So far, more than 350 professionals have benefited from that program since its inception in 2014. Abbvie alone currently has 47 trainees under BOOST.

Overall, the environment of Singapore has proved receptive to the industry.

"Following the establishment of Singapore's first biomedical research institute – the Institute of Molecular and Cell Biology in 1985, Singapore has developed to become a leading biomedical hub with an attractive ecosystem for rapidly growing, ambitious biotechnology companies," said Connolly. "The presence of a large pool of talent in biomedical sciences here also contributes to the advancement of the Singapore's biotech ecosystem," he added.

For its part, A*STAR has contributed to that growth in a number of ways, said Seet, "for example, in creating intellectual property, in nurturing talent and in spinning-off companies."

A*STAR has put in place national platforms like the Experimental Therapeutics Centre and Drug Discovery and Development unit to support development of drug candidates. It also offers incubators such as A*START Central to further house and support startup companies.

Seet claimed that about one-third of local biotech spin-offs in the past decade have come from A*STAR.

"The priority now is to support and sustain this growth," he said. ♦

– January 17, 2018

AJ Biologics builds first vaccine manufacturing facility in Malaysia, looks to innovate with partners

By David Ho, Staff Writer

AJ Biologics Sdn. Bhd., of Malaysia, recently broke ground on the first vaccine manufacturing facility in the country and is going after innovation in the vaccine space with the new plant.

Located in the state of Negeri Sembilan, AJ Biologics's state-of-the-art facility will meet the current good manufacturing practice standards and is funded by its Saudi founders, the Aljomaih Group.

The investment group has pledged an investment of more than RM138.2 million (US$34 million) over the next three to five years toward the building of the plant. AJ Biologics said that investment will also cover the operations and capacity building for the business and their partners; approval and licensing of vaccines in Malaysia, Brunei and Singapore; technology transfer and talent development; and vaccine co-development and partnerships.

"Through this manufacturing facility, AJ Biologics hopes to help Malaysia become self-reliant and reduce its dependency on vaccine imports," Jerome Cabannes, chief operating officer of AJ Biologics, told *BioWorld*. "With domestic production capabilities comes increased vaccine security, which will eliminate the risks of shortages during emergencies or pandemic outbreaks."

The vaccine factory is designed to support the production of 12.5 million units of liquid injection vials, 10 million units of lyophilized injection vials and 10 million units of liquid in pre-filled syringes. AJ Biologics said it believes that production capacity is enough to fill the needs of the Malaysian market as well as ASEAN countries and the Middle East.

"The vaccines produced at the plant will be targeted at diseases endemic to the region," said Cabannes. "It will produce a balanced portfolio of pediatric and adult vaccinations that fit in with Malaysia's current vaccination program, like DTaP and BCG vaccine, that is in line with the World Health Organization's recommendations."

The AJ Biologics facility located in Bandar Enstek is on track to be operational by early 2019. The project was originally conceived in 2013.

AJ Biologics also claims it is eager to tap into disruptive innovations by working with other partners in the area of vaccines. But the pharmaceutical company is unable to disclose any more details until further development has taken place.

Entry-point project

The Malaysian government has been keen to develop the Southeast Asian nation's biotech scene to catch up with neighboring countries like Singapore. The country launched the National Biotechnology Policy (NBP) to further develop three economic sectors, namely agriculture, health care and industrial manufacturing, as well as to support the growth of an enabling ecosystem throughout the scientific, academic and business communities in the country in 2005. The NBP is broken down into three phases: phase I for capacity building (2005-2010), phase II on science to business (2011-2015) and phase III to develop global business (2016-2020).

As part of the government's ongoing initiatives to support biotech growth, AJ Biologics has been awarded the Bionexus status as a company and is recognized as an entry-point project under the National Key Economic Area (NKEA).

"The Bionexus status allows promising biotech companies like us to enjoy a number of privileges, ranging from tax incentives and red tape assistance to access to discussions," said Hannah Nawi, head of corporate communications at parent company AJ Pharma Holdings Sdn. Bhd. "Being recognized as an entry-point project under the NKEA has also been quite helpful, as this means the government recognizes the company's high growth potential in meeting the country's needs.

"Developing the right capabilities through investing in technology, innovation, research and development, and strategic partnerships will place AJ Biologics and Malaysia in good stead to be a significant regional and global vaccine player," Nawi told *BioWorld*.

Earlier this year, AJ Pharma completed its first global vaccine business acquisition in Denmark. The firm now has completely acquired the state-owned Statens Serum Institut under the auspices of the

Danish Ministry of Health.

The new entity has been renamed AJ Vaccines and has a strategic vaccine pipeline, including inactivated polio vaccine, BCG vaccine and tetanus and diphtheria vaccines. It is expected to contribute toward achieving national vaccine self-reliance in Malaysia through tech transfers and manpower once the manufacturing facility is in operation.

Last year, AJ Biologics also signed a deal to market and distribute a leptospirosis vaccine in Malaysia made by French biotech company Imaxio SA.

The European connection remains strong for AJ Biologics as the company said the manufacturing equipment for the plant will come from the region as well.

According to AJ Biologics, Malaysia's vaccine market has strong potential but only a handful of key players. The company hopes to increase its presence in the sector and eventually in the global market, which is expected to grow from $34.3 billion in 2017 to $49.27 billion by 2022 at a compound annual growth rate of 7.5 percent, according to a report by Research and Markets. ♦

– December 1, 2017

'Reverse innovation'

South Korea's Daewoong moves into Indonesia via academic partnership

By Elise Mak, Staff Writer

South Korean company Daewoong Pharmaceutical Co. Ltd. is partnering with Universitas Indonesia (UI), a state university in Jakarta, to jointly develop new biological medicines. The collaboration – the first of its kind in Indonesia – is expected to help Daewoong expand its global manufacturing and R&D network.

The two parties established the Bio Technology Research Centre UI-Daewoong at the university's integrated research facilities. The center comes with advanced tools in biotechnology, such as capillary electrophoresis, freezer thermoscientific and molecular devices. This laboratory will operate with the concept of smart system, in which the control of all the tools and energy sources is done by automation.

The South Korean pharmaceutical company has already made plans as to what type of biologics it will jointly develop with its new academic partner.

"Our initial product is epidermal growth factor," Nathan Kim, head of Daewoong's communications department, told *BioWorld*. "Next would be other biologic products such as human growth hormone, monoclonal antibody, stem cell products and so forth.

"Daewoong is looking to produce and develop biologic products through its differentiated reverse innovation approach and integrated laboratory," he added.

"Reverse innovation" is a strategy invented by Daewoong to advance into developed markets from developing countries.

Daewoong will use this opportunity to develop biologic products tailored to the Indonesian market at the plant and R&D center it has built in the country; then the company will export those products to developed markets, including its homeland, South Korea. Prior to that move, Daewoong has already developed a hemopoietin in Indonesia.

Given its huge population, Daewoong views Indonesia as a lucrative market and a hub for biologics production and R&D in the future, said Kim. "It is one of the world's biggest countries with vast growth potentials," he said.

Apart from the new laboratory with UI, Daewoong has another research center in Jakarta to develop biotechnology-driven products – Daewoong-Infion, a joint venture between Daewoong and East Java-based PT Infion Pharmaceutical Co. Daewoong also has a manufacturing site in Surabaya to produce erythropoietin, somatropin and vaccines.

But the ambition of the Korean pharma company doesn't stop with Indonesia. Daewoong is looking to extend its reach to other parts of the world. And one way of securing a strong foothold in the markets is collaboration with local partners.

"Although Daewoong has long been engaged in R&D for biologics and has developed advanced technology and analytical methods, in order to produce high quality and beneficial product in each local area, we have to collaborate with experts and professors of that area," said Kim.

As part of its localization strategy, the company launched the open collaboration research program to seek quality partners around the globe, which had connected it to one of Indonesia's top universities.

"As one of the best universities in Indonesia, UI has many experts and professors," said Kim.

To UI, the establishment of this research center means a transfer of science using high biotechnology to support its student academic activities in the field of R&D of biological drugs. It is a form of academic partnership between the two in the field of education, research and development of biological medicine. The center will team up with UI's College of Pharmacy to offer scholarships and training programs for biopharmaceutical expertise.

Both parties hope to contribute to the health care industry in Indonesia through developing biotech infrastructure and innovating pharmaceutical products.

And the collaboration comes at a time when the Indonesian government is also looking to enhance its R&D capacity in biotechnology.

"The collaboration is in line with, and will support, the road map proposed by Indonesia's Ministry of Health regarding the independence of pharmaceutical products. The road map aims to

shift the focus from importing active pharmaceutical ingredients and raw materials to research and development," said Kim.

Headquartered in Seoul, Daewoong has been eyeing the bigger Asian market in recent years.

In October 2014, the company set up a research center in Liaoning, a northeastern city of China, in collaboration with Shenyang Pharmaceutical University to develop generics for the Chinese market. The center also develops oral solutions, suspension products and sustained-release drugs.

In South Asia, it opened a research center in Hyderabad, India, in January 2009. The center focuses on developing global generics for the markets in the U.S. and Europe.

As Daewoong's overseas expansion strategy plays out, it is also trying to tap into the Association of Southeast Asian Nations (ASEAN), including Vietnam, Singapore, Malaysia and the Philippines, and the Islamic markets through Indonesia.

Daewoong now has eight branches overseas, mostly in the Southeast Asia region. ♦

– April 23, 2018

Emerging markets

Thailand's growing market set to attract global pharma firms

By David Ho, Staff Writer

Pharmaceutical companies around the world are eying the Thailand market as it is set to almost double in size over the next few years.

According to a report by consulting firm Globaldata plc, the pharmaceutical market in Thailand is expected to grow from $5.91 billion in 2015 to $9.47 billion by 2020. As the main contributor of that boom, Globaldata cited the rise of chronic diseases, especially in the elderly Thai population.

Thailand's current population of 68.29 million is projected to reach 69.31 million by 2020. According to the Thailand Development Research Institute, the country is one of the fastest aging societies in the world, with estimates that its elderly population will make up 25 percent of the country's population by 2025.

An increasing elderly population and unhealthy lifestyle habits have led to increasing obesity and other noncommunicable diseases such as diabetes, hypertension and cancer. BMI Research forecasts that antidiabetic pharmaceuticals in particular will be a central factor driving the drug market's growth. Figures by the International Diabetes Federation supports that estimate, as the condition affected a startling 7.1 percent of the Thai population in 2015. By 2040, that number is predicted to rise to 7.6 percent, translating to a net increase of 1.2 million patients.

According to cancer research project Globocan by the International Agency for Research on Cancer (IARC), the number of new cancer cases in Thailand also will be an increasing burden. Numbers are predicted to rise from 123,801 in 2012 to 168,039 by 2025, with men being the most affected. Cancers of the liver, lung, breast, colon and cervix are the most dominant forms, accounting for 60 percent of new cases in the country in 2012. That proportion is expected to remain consistent through to 2025.

Another significant factor in the pharmaceutical boom can be attributed to Thailand's medical tourism sector. Since 2003, the Thai government has actively promoted the country as a medical tourism hub, with international roadshows and tax exemptions for investments in health care facilities aimed at medical tourists. With health care costs at only one-fifth of those in Europe and the U.S., the country attracts and treats an average of 2 million foreign patients per year. The pharmaceutical industry has benefited tremendously from that trade.

Optimism despite challenges

Yet, despite healthy forecasts, there are challenges on the horizon.

Given the country's significant spending on pharmaceuticals, price controls by the Thailand FDA are being introduced, which could dampen the market. A draft Drug Bill has already been put forth by the Thailand FDA that requires firms to submit the cost structure of their products. It is currently being considered by the Thai government.

That cost control measure allows the Thai government to reject approvals with a proposed price that it deems unreasonable or inappropriate. That could affect sales of patented drugs and discourage further investments.

The country's unstable politics may also play a part in cooling down pharmaceutical sales. Two army coups in the last decade and the recent passing of the monarch have also made investors slightly nervous.

However, industry experts remain optimistic about the outlook of the Thai pharmaceutical industry. Companies like Evonik Health Care have expanded their offices to Thailand and set up applied technology laboratories.

Evonik, a global specialty chemical company, recently opened its first applied technology laboratory in Bangkok. The facility will be the company's first laboratory that caters to the health care business in Southeast Asia. It is equipped with a drum coater and fluidized bed for drying, granulation and coating, and it has analytical capabilities for conducting drug release tests. Those resources will enable Evonik to train customers and partners on the use of its polymer excipients, to develop oral formulations and to provide production support.

"Southeast Asia is an important growth region for Evonik Health Care. As local technical and regulatory requirements become more stringent, we felt it was timely to invest to strengthen our customer support in the region," Stefan Randl, vice president of sales and services at Evonik Health Care Asia, told *BioWorld Asia.*

"After being active in Thailand for more than 30 years, our newly expanded office premises in Bangkok will allow us to further grow and enhance our presence in the country," added Peter Meinshausen, regional president of Evonik Southeast Asia, Australia and New Zealand.

"In light of this development, and the newly established laboratory, I am very much looking forward to continuing to build on our momentum in this dynamic and prosperous region." ♦

– April 19, 2017

Duke-NUS brings aboard Novo Nordisk to fund stem cell research program

By Elise Mak, Staff Writer

Denmark's Novo Nordisk A/S has teamed up with Singapore's Duke-NUS Medical School to provide funding for the next three to five years for stem cell-based research aimed at growing heart muscle and retinal cells to treat heart failure and vision loss.

The exact amount was not disclosed but "there are both significant research funding and milestone payments depending on the progress of the work," Serene Ong, media specialist at Duke-NUS, told *BioWorld*. "Novo Nordisk has the rights to license the technologies for generating therapeutic cells for the diseases."

The Singaporean medical school called it "one of the biggest partnerships in its history." The funding provides the much-needed support to further develop its stem cell-based therapeutics.

Over the years, the school's researchers have come up with a novel way for growing cells in chemically defined culture systems, which supports stem cell self-renewal and directs differentiation of the cells.

The method is also free from animal products and has been shown to form new heart muscle tissue in injured mouse hearts.

The research was led by the school's professor, Karl Tryggvason, who is also a co-founder of Biolamina AB, a Swedish biotech firm that has a proprietary technology built on laminins and will produce the laminins to be used in this research partnership.

"The advancement in the technique to grow better-quality cells is a significant step in developing stem cell-based therapies," said Tryggvason. "The next step for us will be to assess their suitability for human use in the appropriate preclinical models."

His effort in spearheading that cell-growing technique paid off and caught the attention of global pharma giant Novo Nordisk.

"Novo Nordisk approached Duke-NUS as a partner as Professor Tryggvason's team harbors unique expertise in stem cell-derived therapies for eye diseases and heart failure," said Ong.

"Such knowledge dovetailed with Novo Nordisk's objectives," she added. "The two are collaborating on stem cell differentiation protocols for making clinical quality cells."

According to Ong, Tryggvason's research concerns broad studies on the protein components and diseases of basement membranes that are protein scaffolds to which most organized cells in the body are attached. The components of those scaffolds such as laminin proteins influence stem cell differentiation and behavior.

Tryggvason's team has produced most of the proteins such as the laminins using gene technology methods and made it possible to study how they influence cells in detail.

During the past five years at Duke-NUS, the team has been focusing on developing methods to generate different kinds of cells such as heart, eye retina, blood vessel or skin cells, while the cells are placed on different laminin types. Studies have demonstrated positive results.

What is groundbreaking about Tryggvason's work is that the laminins allow highly controllable and reproducible differentiation of stem cells into the target cells, and that the cell culture systems are defined and free of animal components.

From a therapeutic point of view, it is important that the differentiation methods do not contain any animal components and that they are extremely reproducible, such that the therapeutic cells work the same way in a highly reproducible manner.

Almost four decades of research work has come to a turning point, when Novo Nordisk stepped in to help advance the technology into application.

"Novo Nordisk visited Duke-NUS back in September 2017 to learn about Professor Tryggvason's project," said Ong. "Having the intention to invest heavily in stem cell-based therapeutics, they rapidly decided to get rights to our technology."

Duke-NUS is also working on other potential applications of the cell therapy. Further collaborations may become of interest for Novo Nordisk.

For the school, if the collaboration with Novo Nordisk goes well, it may see itself turning into a cell therapy center in Singapore.

"The company has established research laboratories and centers at other major collaboration and production sites such as Oxford University, University of San Francisco, and in North Carolina," said Ong. "Therefore, it is not impossible that a cell therapy center in Singapore could become a reality later."

Established in 2005, Duke-NUS was a strategic collaboration between the Duke University School of Medicine in North Carolina and the National University of Singapore. One of its research focuses is on cancer and stem cell biology. ♦

– May 17, 2018

Newco news

Tackling the blood-brain barrier: Duke-NUS discovery leads to startup Travecta

By David Ho, Staff Writer

Travecta Therapeutics Pte Ltd. is the latest startup to join Singapore's biotech block. The newly formed drug discovery company is based on intellectual property derived from discoveries made at Duke-NUS Medical School (Duke-NUS).

Travecta is based on the findings of its scientific founder, David Silver, who published research in 2014 that established a path and transport system that specifically takes lipids such as the omega-3 fatty acid – docosahexaenoic acid (DHA) – to the brain. Silver discovered that a transporter protein called Mfsd2a carries DHA in the chemical form of lysophosphatidylcholine (LPC) to the brain.

"The challenge of delivering central nervous system drugs lies in the blood-brain barrier, which prevents 98 percent of small-molecule drugs from entering the brain," said Silver, who is also deputy director of the cardiovascular and metabolic diseases program at Duke-NUS. "MSfd2a is a lysolipid transporter that is highly expressed at the blood-brain barrier and enables the exploitation of its natural transport mechanism to deliver therapeutics conjugated to lysolipid scaffolds for delivery across the blood-brain barrier.

"The pathway we found can be exploited to deliver new or existing drugs which have proven ineffective due to their lack of transport across the blood-brain barrier," he told *BioWorld*. "This offers many opportunities, including the revitalization of dormant candidates, the repurposing of existing drugs and the development of new therapies for currently untreatable diseases."

Travecta now plans to use the Duke-NUS technology to develop therapeutic agents that can be selectively delivered across the blood-brain barrier through a Mfsd2a-directed drug delivery platform for treatment of diseases of the brain, eye and central nervous system, with the aim of providing improved treatment with reduced side effects.

Michael Shleifer, a co-founder of Travecta, told *BioWorld* the team has found "key indications and targets that have promising outcomes, based on the characteristics of the MFSD2a transporter," though he declined to divulge any specific indications.

However, Shleifer did say that the clinical studies of proprietary compounds will be conducted in the U.S. As Travecta is based in Singapore, it will additionally work on clearing China's regulatory path.

"The prioritization of the pipeline is based on many factors, including the regulatory path, which will depend on some specific aspect of each molecule. The platform aims at accelerating drug development by integrating a multidisciplinary approach, which means that we will be careful with drug candidates that bear a high regulatory risk," said Shleifer.

Laurent Benissan, another co-founder of Travecta, said their conversations with industry partners "show a significant interest due to Travecta's innovation and the large portfolio of drug candidates which could benefit from it."

"We can work on direct conjugation of existing molecules by designing synthetics and execute synthesis," Benissan told *BioWorld*. "As an alternative, in situations where direct conjugation is not optimal, we offer suitable analogues and work with our partners' teams to explore the right candidates."

Once the platform is developed, Travecta plans to develop both an internal pipeline and partnerships with the industry.

"Our programs are usually based on risk-sharing models where we receive funding and resources, while offering know-how and support of the clinical plans. Our strengths derive from the partnership with Duke-NUS, a world class research institution, and the agility of being a well-funded early stage company," said Benissan, who also works at Sprim, a global health research and information consulting firm that will provides insights for clinical and regulatory development to Travecta.

"This model supports the effective translation of R&D and preclinical research to commercial discussions with industry partners," added Benissan.

The license agreement between Duke-NUS and Travecta was facilitated by the Duke-NUS' Centre for

Technology and Development (CTeD), which is part of an innovation and entrepreneurship initiative focused on commercializing research carried out at Duke-NUS.

CTeD and Silver have worked together for the past several years to develop and commercialize that discovery. That includes the founding of Vanteres (formerly known as Babynostics US, Inc.) that is also based on the same research by Silver.

Travecta is backed by TKS I, a health care and life science-focused venture fund by Tikehau Investment Management in Singapore. It is the strategic investment arm of Tikehau Capital, which manages around €12.6 billion (US$16 billion) in assets.

David M. Epstein, Duke-NUS' vice dean of innovation and entrepreneurship, said that "developing a platform around the LPC and Mfsd2a transport system for targeted drug delivery represents among the best of our bench-to-bedside innovations." ♦

– March 22, 2018

With new development deal, manufacturing site, Wuxi expands global footprint

By Elise Mak, Staff Writer

China's contract drugmaking giant, Wuxi Biologics Inc., of Wuxi city, is actively expanding its global footprint, announcing plans to work with its Canadian partner on a brain cancer drug and opening its 10th global manufacturing facility in Singapore.

One of the largest CROs in the world, Wuxi provides biologics discovery, development and manufacturing services.

The company's latest partner, Bioasis Technologies Inc., which specializes in treating neurological diseases, inked an initial strategic collaboration with Wuxi, under which the latter will help Bioasis develop and manufacture its lead investigational biological candidate, xB^3-001, to treat brain cancer.

xB^3-001 is an innovative drug candidate designed to overcome the biggest challenge to treat brain disease – namely, delivering biologics across the blood-brain barrier (BBB) and into the brain. It is being developed with Bioasis' delivery platform technology xB^3, but manufacturing xB^3-001 would require a tailor-made approach, with expertise and agility in cell line, process and formulation development, all of which Wuxi can offer.

"This is a challenging product to develop and manufacture," Chris Chen, CEO of Wuxi Biologics, told *BioWorld*. "It is a novel class of products that requires more sophisticated development and manufacturing.

"We are providing service for now. We hope to bring the drug candidate into clinics in 18 months," said Chen, adding that the partners are eyeing the U.S. and European markets first. China is not yet in the plan.

The potential of xB^3-001 is vast. Bioasis is aiming to go beyond brain cancer with the drug candidate. "We look to advance our lead program in HER2-positive breast cancer brain metastases," said Mark Day, president and CEO at Bioasis. "The initiation of manufacturing for xB^3-001 is a pivotal milestone for us."

Going global

Besides speaking with *BioWorld* about Bioasis partnership, Chen also spoke of the company's new facility in Singapore, which is slated to open in 2021.

Choosing Singapore as its second drug substance manufacturing facility outside of China, as well as its first overseas site in Asia, is of strategic significance to Wuxi Biologics.

"It allows access to local talents and emerging biotech companies that need to use our platform," Chen said. "It also enables ASEAN companies to discover and develop biotherapeutics.

"The new site will undoubtedly meet Wuxi Biologics' growing need for biologics development and manufacturing in the near future, and expedite biologics development in Asia," he added.

Ge Li, chairman of Wuxi Biologics, said he believes Singapore is leading in the biopharmaceutical industry and can help the company enhance its biomanufacturing capacity. "The new site plays a key role in Wuxi Biologics' global biomanufacturing network to ensure that biologics are manufactured ... to benefit patients worldwide," said Ge.

Just three weeks ago, Wuxi Biologics said Dundalk, Ireland, would be where the first global site would be. It is expected to be completed by 2021, at about the same time as the Singaporean site.

With an investment of €325 million (US$392 million), the drug substance manufacturing facility in Ireland comes with a total of 48,000-liter fed-batch and 6,000-liter perfusion bioreactor capacity, making it the world's largest facility using single-use bioreactors.

And this time in the ASEAN country, the facility will be of smaller scale, though. It will come with a total of 4,500-liter bioreactor capacity with two 2,000-liter traditional fed-batch and one 500-liter perfusion-based continuous processing, after pouring in S$80 million (US$60 million).

Similar to the facility in Ireland, the Singaporean site will be able to run continuous bioprocessing. It will handle both clinical and small volume commercial production and will include an early stage bioprocess development laboratory.

"[The establishment of the drug manufacturing site] will introduce Wuxi Biologics' next-generation bioprocessing technology platform to this region,"

said Beh Swan Gin, chairman of Singapore Economic Development Board, which backed the company's new manufacturing site in the country.

"Wuxi Biologics' presence here will also strengthen our ecosystem for supporting biotech companies from Singapore and beyond," said Beh.

Other than building manufacturing sites overseas, Wuxi Biologics is also expanding its presence in its home country, China. Last week, the company said it is to build an integrated biologics development, clinical and commercial manufacturing center in the city of Shijiazhuang in northern China, which will be the largest biologics center in the region. ♦

– May 29, 2018

Biosimilars

Malaysia's Duopharma to capitalize on growing SEA biosimilars market

By Carmen Ho, Staff Writer

Malaysia-based CCM Duopharma Biotech Bhd is positioning itself to capitalize on the growing biosimilars market in Southeast Asia (SEA), following the success of a phase III trial of its erythropoietin (EPO) biosimilar for kidney dialysis. The Kuala Lumpur-based company is set to commence registration of the drug and further strengthen its position in the Malaysian market.

"The completion of the phase III trials is a significant milestone for us as we expand our focus on biosimilars while indirectly assisting in the development of the Malaysian biopharmaceutical industry. It will also enable us to offer more affordable treatment options for patients without compromising their safety and efficacy," said En Leonard Ariff Abdul Shatar, managing director at Chemical Company of Malaysia Bhd, the parent company of CCMD.

"The biosimilar will be beneficial in the treatment of anemia in end-stage kidney failure patients," the company said.

Recombinant versions of EPO are used as a therapeutic agent for anemia patients, kidney dialysis patients and patients who need blood transfusion. CCMD's subsidiary Duopharma and Korea-based Pangen Biotech Inc. jointly produced PDA10, an EPO biosimilar and Pangen's first commercial biosimilar finished product.

The two-year double-blind, randomized, active-controlled parallel-group joint clinical trial to assess the safety and efficacy of PDA10 cost MYR17.5 million (US$3.9 million) and was undertaken in 24 sites in Malaysia and South Korea, with 228 patients involved in Malaysia and 70 in South Korea. PDA10 demonstrated equivalence to the reference produce in terms of pharmacokinetics, pharmacodynamics and toxicity.

CCMD will be the first Malaysian company to co-develop a biotherapeutic product, and PDA10 is the second EPO biosimilar to be developed globally. CCMD has commercialization rights for marketing and distribution of the biosimilar in Malaysia, Singapore and Brunei, assuming the National Pharmaceutical Regulatory Agency (NPRA) grants approval.

"In the face of faltering revenues, CCM will look to its biosimilar developments to buttress its financials," noted an analyst's report from BMI Research.

Publicly listed since 1966, CCM claims to be the largest producer of generics in Malaysia, with close to 200 products targeting a wide range of conditions. However, the company's revenues have been falling for several years now. In 2015, CCM reported overall revenues of MYR997.8 million (US$256.8 million), an 8.4 percent drop year-on-year.

The CCM Pharmaceuticals Division has shown improvements, with a five-year revenue increase of 27.6 percent since 2011. However, CCM reported preliminary 2016 revenues for the division worth MYR312.9 million, a 6.5 percent drop from 2015. The decline was partly caused by an increase in production costs, according to CCM. The company said demand in the Malaysian pharmaceutical sector is expected to remain stable in 2017. However, the industry faces increasing challenges from foreign exchange instabilities affecting the local currency as well as uncertainties in the economy. ♦

– March 22, 2017

More news from the region

From staff reports

Chugai Pharmaceutical Co. Ltd., of Tokyo, said it is expanding Chugai Pharmabody Research Pte. Ltd. (CPR), its research subsidiary in Singapore, to further improve drug discovery capabilities of the Chugai Group, in which the operation period of CPR is to be extended for another five years with an investment of SG$282 million (US$206.88 million) from 2022 to 2026. CPR was established in 2012 to conduct research focused on the discovery of antibody drugs by utilizing innovative antibody engineering technologies owned by Chugai. The operation period of CPR was initially planned to be five years until 2016, and then extended for five additional years.

– July 27, 2018

Eden Prairie, Minn.-based **CHF Solutions Inc.** received registration from FDA Thailand to allow the sale of Aquadex Flex Flow. The product will be sold through the company's current distributor in Southeast Asia, Transmedic.

– *BioWorld MedTech*, August 22, 2018

Histoindex Pte. Ltd., of Singapore, said it is collaborating with Cymabay Therapeutics Inc., of Newark, Calif., to evaluate the efficacy of seladelpar in a phase IIb study of 175 subjects with biopsy-confirmed nonalcoholic steatohepatitis (NASH). Histoindex will use its Genesis200 imaging technology to scan unstained tissue samples from liver biopsies and quantify the NASH characteristics within.

– May 21, 2018

Indivumed GmbH, of Hamburg, Germany, and A*STAR's Institute of Molecular and Cell Biology in Singapore have signed an agreement to perform proteomic and phosphoproteomic analysis of thousands of tissue samples from Indivumed's biobank. The move contributes to Indivumed's global cancer database solution Indivutype, funded by the European Investment Bank and private investors. Indivutype combines cell biological information such as genomic, transcriptomic, proteomic, precision proteomic and digital histopathology data with extensive clinical information from thousands of patients, the company said.

– July 5, 2018

Menarini Asia-Pacific Holdings Pte. Ltd., of Singapore, a member of the Menarini Group, and **Orion Corp.**, of Espoo, Finland, said they signed a multiyear licensing deal for Menarini Asia-Pacific to distribute and commercialize several of Orion's Easyhaler products in 10 countries in the Asia-Pacific region. Terms were not disclosed.

– July 5, 2018

Nkarta Therapeutics Inc., of South San Francisco, said it entered a worldwide exclusive license agreement for proprietary natural killer cell engineering technology jointly owned by the National University of Singapore and St. Jude Children's Research Hospital. The license includes several issued patents and patent applications related to methods to generate large numbers of fully functional NK cells as well as compositions of chimeric receptors for targeting NK cells to tumors and extending their life span.

– June 12, 2018

Rich Pharmaceuticals Inc., of Beverly Hills, Calif., said it filed its submission package to the institutional review board of Phramongkutklao Hospital in Bangkok, Thailand, as part of a process that will lead to a study for the treatment of acute myelocytic leukemia in refractory patients in a phase I/II trial.

– June 9, 2017

Sanofi Pasteur Ltd.'s dengue vaccine has been granted a conditional registration for two years in Malaysia while phase IV studies are carried out. The vaccine, named Dengvaxia, will now be the focus of a joint study between the Malaysian Drug Control Authority (DCA) and the French vaccine maker. The details of the study are currently being worked out between the company and the DCA. Meanwhile, a representative from the company confirmed that Dengvaxia is expected to be available in private vaccination clinics over the next six months for Malaysians between the ages of 9 and 45.

– April 24, 2017

Financings

Singaporean biotech startup **Dotbio Pte. Ltd.** launched this week with seed capital of $2.3 million. The new player on the biotech scene is focused on the development of immuno-oncology drugs based on humanized domain antibodies.The independent biotechnology company was spun out from Singapore's Nanyang Technological University (NTU) and was incorporated in the Southeast Asian city state last June. The seed financing was led by the Heungkong Group via Futec Biomedical Investments Ltd. Dotbio aims to develop a broad pipeline of drug candidates for new oncology treatments based on its Dotbody technology.

– August 15, 2018

Shanghai-based biopharmaceutical firm **Harbour Biomed Therapeutics Ltd.** completed a series B financing of $85 million, "slightly above" its target, with the round led by Singapore's wealth fund GIC Private Ltd. Harbour anticipates more fundraising in 2019. The company, which specializes in therapeutics concerning immuno-oncology and inflammatory diseases, will use the funds "to continue the development and growth of our portfolio, namely development of clinical projects and discovery projects as well as potential opportunities for in-licensing and partnerships that have synergy to our pipeline," a spokesperson from Harbour told *BioWorld*. GIC invested in **Hua Medicine (Shanghai) Ltd.**, China's diabetes drugmaker, earlier this year in its combined series D and E financing of $117.4 million. The Singaporean investment firm also backed **Cstone Pharmaceuticals Co. Ltd.**, another Chinese R&D company in immuno-based combination therapeutics for oncology, cardiovascular diseases, rheumatoid arthritis, hematology and autoimmune disease, in its $260 million series B financing.

– September 5, 2018

Lion TCR Pte. Ltd., of Singapore, said it raised $20 million in a series A financing round. The proceeds will be primarily used to advance its ongoing clinical trials of lead candidate Liocyx (personalized HBV specific TCR T-cell therapy against HCC) in major hospitals in China and Singapore, as well as for broadening its products pipeline to fight viral-related solid tumors and clearance of chronic hepatitis B.

– May 30, 2018

M&A

Singapore-based **Accuron Medtech Group**, has completed divestment of its shares in molecular detection test maker, **Veredus Laboratories Pte. Ltd.**, also of Singapore, to Sekisui Chemical Co. Ltd., a Japanese public company and owner of **Sekisui Medical Co. Ltd.**, a global diagnostics company. Accuron acquired a controlling stake in Veredus in 2014 and has grown by approximately 30 percent in revenue, doubled its R&D staff, moved its global bio-chip manufacturing facility from Italy to Singapore, and expanded into new markets including Indonesia and China. Accuron recently entered a partnership with the Singapore Government in its SGD$100 million (US$76.24 million) investment into the Health and Biomedical and Sciences sector. The investment is part of a government-initiated scheme to catalyze the growth of Singapore-based deep technology startups in which the Singapore government matches private capital invested by co-investment partners.

– *BioWorld MedTech,* April 4, 2018

Regulatory front

The Medical Device Authority of Malaysia said it will extend the deadline for labeling of medical devices by three years, with a new deadline of Aug. 5, 2021. The agency had declared in 2016 that the labeling requirements would take force in two years, although some exemptions were provided for investigational/ experimental devices. The labeling requirements were described in legislation passed by the Malaysian parliament in 2012.

– *BioWorld MedTech,* August 10, 2018

Appointments & advancements

Engine Biosciences Pte Ltd., of Singapore and San Francisco, appointed Stephen Harrison chief scientific officer and senior vice president. Harrison most recently served as chief scientific officer and senior vice president at Relypsa, Inc. He has also served in executive and leadership roles at Nektar Therapeutics Inc., KAI Pharmaceuticals Inc., Chiron Corp. and Thios Pharmaceuticals Inc. Harrison received his Ph.D. from Cambridge University and was a post-doctoral fellow at University of California at Berkeley.

– May 16, 2018

Histoindex Pte. Ltd., of Singapore, appointed Poon Thong Yuen CEO. He has more than a decade of corporate experience with healthcare services, therapeutic drugs and medical devices and was most recently chief investment officer of Zicom MedTacc.

– July 11, 2018

Travecta Therapeutics Pte Ltd., of Singapore, appointed Douglas C. Hicks chief business officer. He will serve on the executive leadership team and lead business development and corporate strategy for the company. Hicks joins the company from Ibio Inc., where he was the senior vice president of business development and strategy. Prior to joining Ibio in 2010, he was the executive director of business development and strategic analysis at Clearview Projects Inc. He began his career as a consultant for Bristol-Myers Squibb Co.

– September 19, 2018

Diagnostics extra

Research points to quantitative phase microscopy for RBC morphology

Many years have passed since a microscope was just a microscope, but diagnoses that depend on a clear understanding of red blood cell morphology have suffered for want of better information. Researchers in Singapore, India and the U.S. have come up with a method for fixing that problem, however. The problem up to now has been that bright field microscopy and waveguide trapping offer little quantitative information about any structural changes inside an RBC, but these researchers devised a method that begins with recording of time-lapsed interferometric images of RBCs in real time. These RBCs exhibited a drop in maximum phase values, an increase in surface area, and a decrease in volume and sphericity during the planar trapping step, at which point the scientists used quantitative phase microscopy (QPM) to obtain the values for the annular rim and the central donut of each RBC. The results demonstrated that the phase value of the annular rim fell as the phase value of the central donut rose, changes said to correspond with redistribution of cytosol, a reaction attributed to planar trapping and transportation. The article spelling out this research appeared in the Aug. 22, 2018, issue of Lab on a Chip under the title, “Quantitative phase microscopy of red blood cells during planar trapping and propulsion.”

– *BioWorld MedTech,* August 24, 2018

Who we are

BioWorld delivers actionable intelligence on the most innovative drug development science that drives the business, which funds the means to heal disease. With writers and editors stationed around the globe, *BioWorld* reports the breaking news — and provides key perspective — on hundreds of medicines in development, the companies behind those therapeutic candidates, the business development transactions that evolve the market, and the regulatory hurdles that both challenge and guard the process.

Daily news coverage includes:

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- Scientific milestones
- Global regulatory updates
- Profiles of new and drug development innovators
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