BIO Collaborate

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DRUGS FOR NEUROLOGICAL DISEASES

神经系统疾病治疗药物

天府生命科技园
Tianfu Life Science Park

人脑是所有器官中最复杂的一部分，并且是所有神经系统的中枢，控制着认知、情感和执行功能，对生命、健康有着至关重要的作用。中枢神经系统（CNS）故障会引发广泛疾病。

The human brain is the most complex organ in the body and the center of all the nervous systems. It controls the function of cognition, emotion, and executive functions and plays a vital role in life and health. Dysfunctions of the central nervous system (CNS) can lead to a wide range of diseases.

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By CDHT Investment Group Biomedicine Industrial Park Management Co. Ltd

内部资料 仅供参考

BIO Collaborate

天府生命科技园
Add. / 地址：成都市高新区科园南路88号 **Tel.** / 电话：028-8605 8168 028-8531 1525

成都前沿医学中心一期
Add. / 地址：成都市高新区新川路2222号 **Tel.** / 电话：028-8532 6166 028-6110 8918

成都前沿医学中心二期
Add. / 地址：成都市高新区新川路2222号东侧 **Tel.** / 电话：028-8605 8168 028-8597 6074

成都前沿医学中心三期
Add. / 地址：成都市高新区新川路2222号西侧 **Tel.** / 电话：028-8605 8168 028-8597 6074

成都高投生物医药园区管理有限公司
成都高新区科园南路88号天府生命科技园管理楼（天府生命科技园办公地址）
成都高新区和民街366号成都前沿医学南中心E1栋（成都前沿医学中心一期办公地址）

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01

卷首语
Preface

PREFACE

CHAPTER I

CNS DISEASES

人脑是所有器官中最复杂的一部分，并且是所有神经系统的中枢，控制着认知、情感和执行功能，对生命、健康有着至关重要的作用。中枢神经系统（CNS）故障会引发广泛疾病，包括多动症和自闭症等神经发育疾病，阿尔兹海默症（AD）、帕金森综合征（PD）等神经退行性疾病，以及焦虑、抑郁等精神类疾病。

The human brain is the most complex organ in the body and the center of all the nervous systems. It controls the function of cognition, emotion, and executive functions and plays a vital role in life and health. Dysfunctions of the central nervous system (CNS) can lead to a wide range of diseases, including neurodevelopmental diseases such as ADHD and autism, neurodegenerative diseases such as Alzheimer's disease (AD) and Parkinson's disease (PD), and mental diseases like anxiety and depression.

其中，精神类疾病治愈率低，复发率高，患者依从性低，且绝大多数精神疾病的病因不明，诊断率和治疗率也相对降低，给社会带来沉重的负担。尤其在我国，精神疾病患者人群庞大，但精神疾病的认知率远低于世界平均水平。对精神类疾病发生发展的基本机制和干预研究已成为科技创新前沿热点和国家重大需求。现阶段，药物维持治疗仍是降低精神类疾病复发和住院风险最有效的方法之一。但在该领域药物开发的临床研究中，存在着研究方法有限，缺少有效的生物标志物，量表评分容易产生偏差，安慰剂效应居高不下等诸多挑战，联合用药和换药带来的安全性和依从性问题也不容忽视。以上诸多难题给这条赛道带来了重重障碍，因此入局者少，赛道宽广。

Among them, mental diseases are characterized by low cure rates, high recurrence rates, poor patient compliance, and a lack of clear etiology in the majority of cases. Moreover, diagnosis and treatment rates for mental diseases also remain relatively low, imposing a heavy burden on society. Particularly in China, there is a large population of patients with mental diseases, while the awareness of these conditions lags behind the global average. Understanding the fundamental mechanisms of mental diseases and conducting intervention research have become hotspots in technological innovation and major national demands. At the present stage, drug maintenance treatment is still one of the most effective measures to reduce the recurrence and hospitalization risks of mental diseases. However, clinical research in drug development in this field faces numerous challenges, such as limited research measures, a lack of effective biomarkers, potential bias in scale ratings, and persistently high placebo effects. Therefore, safety and compliance issues caused by drug combination and dressing change cannot be ignored. These challenges have created numerous obstacles in this field, resulting in limited participation and vast untapped potential.

大多数中枢神经系统疾病需长期用药，因此中枢神经系统治疗药物市场是具备慢性病市场特征的巨大市场，且目前存在大量未被满足的临床需求，是生物技术公司有望以技术优势快速突破并发展为大市值企业的潜力行业。生物制药创新已经带来了重要的新医学里程碑和科学进步，就疾病新靶点的探索也在加速进行，可以预见，未来对于CNS疾病的观念转变，药物开发政策转变，以及临床需求的转变等，或将把CNS药物开发领域推向一个新高峰，在疾病的早期诊断、防治以及临床药物治疗等方面取得跨越式进步。

Most CNS diseases require long-term medication, making the CNS therapeutic drug market a substantial market with characteristics of the chronic disease market. Currently, there are numerous unmet clinical needs in this market, presenting an opportunity for biotechnology companies to quickly break through and develop into high-value enterprises through technological advantages. Biopharmaceutical innovation has already achieved significant medical milestones and scientific progress, with exploration of new disease targets accelerating. It is foreseeable that changes in the concept of CNS diseases, drug development policies, and clinical demands may propel CNS drug development to new heights, leading to great advancements in early disease diagnosis, prevention, clinical drug treatment, etc.

02

行业资讯
Industry News

INDUSTRY NEWS

INDUSTRY NEWS

LIVE

行业资讯

Neuropsychiatric Field

首届中国新疆“一带一路”神经精神领域创新药高峰论坛成功举办

The First China (Xinjiang) "Belt and Road" Neuropsychiatric Innovative Drug Summit Forum Successfully Held

2023年5月26日，由中国科学院新疆分院、新疆科学技术协会和新疆医科大学联合主办的首届中国新疆“一带一路”神经精神领域创新药高峰论坛暨国家十三五“国家重大新药创制·科技重大专项”抗抑郁症1.1类中药创新药“参葛补肾胶囊”获批上市发布会在新疆乌鲁木齐举行。全国200余名神经精神领域专家学者、企业代表参会。

On May 26, 2023, the First China (Xinjiang) "Belt and Road" Neuropsychiatric Innovative Drug Summit Forum & the Launch Event of the Approved Type 1.1 Antidepressant Innovative Traditional Chinese Medicine "Sengge Kidney-Tonifying Capsules" under the 13th Five-Year "National Major New Drug Innovation and Development · Major Science and Technology Program", jointly organized by the Xinjiang Branch of the Chinese Academy of Sciences, the Xinjiang Association for Science and Technology, and Xinjiang Medical University, was held in Urumqi, Xinjiang. Over 200 experts, scholars, and enterprise representatives in the field of neuropsychiatry nationwide attended the forum.

该届高峰论坛以“除抑郁阴霾、享心扉阳光”为主题，旨在助推神经精神领域中医药创新药现代化国际化进程，促进新疆中药创新药高质量融入“一带一路”建设，大力发扬创新药的优势，抓住发展机遇走向国际，从而携手共建人类卫生健康共同体，切实推动神经精神领域中医药服务走向世界。与会者就“一带一路”神经精神领域创新药研发合作贡献特殊力量等重大议题，进行深入探讨与学术交流，出谋献策并发表真知灼见。

Themed "Dispelling the Haze of Depression and Embracing the Sunshine of the Heart", this summit forum aimed to promote the modernization and internationalization of innovative traditional Chinese medicine in the field of neuropsychiatry, promote the high-quality integration of innovative traditional Chinese medicine in Xinjiang into the "Belt and Road" Initiative, vigorously carry forward the advantages of innovative drugs, and seize development opportunities on the international stage to work together to build a community of common health for mankind, thereby effectively facilitating the service of traditional Chinese medicine in the field of neuropsychiatry to the world. During the forum, participants engaged in in-depth discussions and academic exchanges on important topics such as the contribution to cooperation in the research and development of neuropsychiatric innovative drugs of the "Belt and Road" Initiative. They provided valuable insights and recommendations.

美国FDA批准首个产后抑郁症口服药

U.S. FDA Approves the First Oral Medication for Postpartum Depression

2023年8月4日，美国食品药品监督管理局批准了首个用于治疗产后抑郁症的口服药——zuranolone。该药物由专注神经科学领域的生物科技公司Biogen（渤健）和Sage Therapeutics（SAGE）公司开发，两家公司计划在2023年年底前开始以Zurzuvae品牌来销售zuranolone。该药物可用于治疗重度抑郁症、临床抑郁症以及产后抑郁症，患者每天需服用zuranolone一次，并持续服用14天。

On August 4, 2023, the U.S. Food and Drug Administration approved the first oral medication for postpartum depression, known as zuranolone. The medication was developed by the biotech companies Biogen and Sage Therapeutics, both specializing in the field of neuroscience. The companies plan to begin selling zuranolone under the brand name Zurzuvae by the end of 2023. The medication can be used to treat severe depression, clinical depression, as well as postpartum depression. Patients are required to take zuranolone once a day for a continuous period of 14 days.

zuranolone是一种神经活性类固醇，可作为GABA-A受体的正变构调节剂。体内GABA水平较低与抑郁症有关。一项已发表在《美国精神病学杂志》的最新III期临床研究显示，50毫克剂量的zuranolone具有良好的耐受性和有效性。针对196名患有产后抑郁症的女性研究显示，与服用安慰剂的患者相比，连续14天每天服用50毫克zuranolone的患者表现出抑郁症状显著改善超过50%，而服用安慰剂的女性只有38%的症状得到改善。治疗产后抑郁症需要快速起效的抗抑郁疗法，业内认为，zuranolone将是第一个针对产后抑郁快速起效的口服药物制剂，有助于帮助产妇迅速摆脱心理疾病的阴霾。

Postpartuma Depression

Zuranolone is a neuroactive steroid that acts as a positive allosteric modulator of GABA-A receptors. The lower level of GABA in the body is related to depression. The latest Phase III clinical study, published in the American Journal of Psychiatry, demonstrated that a 50-milligram dose of zuranolone is well-tolerated and effective. A study involving 196 women suffering from postpartum depression showed that patients who took 50 milligrams of zuranolone daily for 14 consecutive days experienced a significant improvement by more than 50% in depressive symptoms, compared to patients who took a placebo. In contrast, only 38% of the women who took a placebo showed an improvement in their symptoms. Rapid-acting antidepressant therapy is crucial for the treatment of postpartum depression. It is believed in the industry that zuranolone will be the first oral drug preparation for fast relief from postpartum depression, which will help new mothers quickly get rid of the shadows of mental illness.

丽珠集团精神分裂症治疗药物布南色林片获批上市

Blonanserin Tablets for the treatment of schizophrenia of Livzon Pharmaceutical Group Inc. Approved for Marketing

2023年8月11日，丽珠医药集团股份有限公司（以下简称"丽珠集团"）发布公告称，公司全资子公司丽珠制药厂收到国家药品监督管理局核准签发的《药品注册证书》，公司布南色林片获批上市。截至目前，布南色林片有1家获批进口上市，国产2家（含丽珠集团丽珠制药厂）获批上市，另有3家企业处于注册审评阶段。

On August 11, 2023, Livzon Pharmaceutical Group Inc. (hereinafter referred to as "Livzon") announced that its wholly-owned subsidiary, Livzon Pharmaceutical Factory, had received the Drug Registration Certificate issued by the National Medical Products Administration and granted approval for the marketing of Blonanserin Tablets. As of now, one company's Blonanserin Tablets have been approved for import and market launch, and two domestic companies (including Livzon Pharmaceutical Factory) have received approval for the marketing of Blonanserin Tablets. Additionally, three other enterprises are in the registration and evaluation stage.

根据相关资料显示，布南色林原研来自日本住友制药，是一种新型的非典型抗精神病药。布南色林片属于5-羟色胺和多巴胺受体拮抗剂，是第二代非典型抗精神分裂症药物。与其它抗精神病药物相比，该品种治疗谱更广，对阴性症状效果明显优于传统药物，安全性高，副作用更轻。据悉，丽珠集团针对布南色林片已直接投入的研发费用约为2,987.75万元。本次布南色林片获批上市，既是丽珠集团前沿布局精神领域，不断推进创新研发摘得的硕果，同时也充分展示了该公司的研发实力。

According to relevant information, Blonanserin, originally developed by Sumitomo Pharma Group in Japan, is a novel atypical antipsychotic drug. Blonanserin Tablets belong to 5-hydroxytryptamine and dopamine receptor antagonists and are considered second-generation atypical antipsychotic drugs. Compared to other antipsychotic drugs, this drug has a broader spectrum of treatment, with a more pronounced effect on negative symptoms than traditional drugs, higher safety levels, and fewer side effects. It is reported that Livzon has directly invested approximately RMB 29,877,500 in the research and development of Blonanserin Tablets. The approval for the marketing of Blonanserin Tablets not only signifies Livzon's strategic move into the field of mental health and the fruit of continuous promotion of innovative research and development, but also highlights the company's research and development capabilities.

Livzon Pharmaceutical

研究表明多发性硬化症药物可用于治疗阿尔茨海默病

Research Shows That Multiple Sclerosis Drugs Can Be Used to Treat Alzheimer's Disease

2023 年 9 月 1 日讯，美国肯塔基大学医学院生理系 Erhard Bieberich 教授团队在《柳叶刀 - 发现科学》(The Lancet Discovery Science) 旗下的《电子生物医学》(eBioMedicine) 杂志发表论文，报告他们发现一种已上市药物 ponesimod（商品名 Ponvory）可以减少阿尔茨海默症（AD）的神经炎症。ponesimod 一种美国食品药品监督管理局批准用于治疗复发性多发性硬化症（MS）的口服药物。该药物通过靶向免疫系统中的特定受体来帮助调节身体的反应，防止其攻击中枢神经系统，从而减少大脑中的炎症。这种受体被一种称为 1- 磷酸鞘氨醇的脂质激活，Bieberich 实验室研究了其功能，首次证明 ponesimod 在 AD 小鼠模型中有效。研究人员还与肯塔基大学的桑德斯布朗衰老研究中心合作，获取人脑样本进行研究。从这些测试中收集的数据与小鼠模型一致，也表明 ponesimod 可用于治疗阿尔茨海默病。

According to the report on September 1, 2023, a team of researchers led by Professor Erhard Bieberich from the Department of Physiology at the University of Kentucky College of Medicine published a paper in eBioMedicine, a journal under The Lancet Discovery Science. The paper reported their discovery that a marketed drug called ponesimod (trade name: Ponvory) can reduce neuroinflammation in AD. Ponesimod is an oral drug approved for marketing by the FDA for the treatment of relapsing multiple sclerosis (MS). The drug works by targeting the specific receptor in the immune system to help regulate the body's response and prevent it from attacking the CNS, thereby reducing inflammation in the brain. The receptor is activated by a lipid called sphingosine-1-phosphate, and Bieberich's laboratory studied its function, providing the first evidence that ponesimod is effective in AD mouse models. The researchers also collaborated with the Sanders-Brown Center on Aging of the University of Kentucky to obtain human brain samples for study. Data collected from these tests were consistent with the mouse models, which also indicated that ponesimod could be used to treat AD.

03

行业洞察
Industry Insight

INDUSTRY
INSIGHT

INDUSTRY INSIGHT

神经系统疾病药物
Neurological system disease drugs

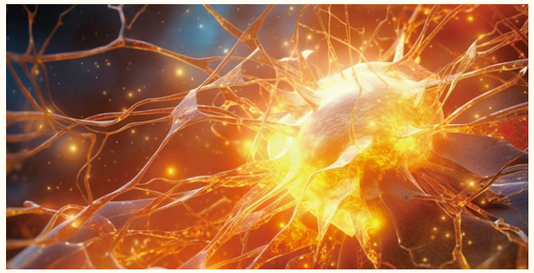
01 引言
Introduction

随着人类寿命的延长、人口老龄化的加剧以及社会压力的日益增大，脑疾病的患病率正在逐年攀升。当大脑、脊髓和/或周围神经系统中的神经元开始出现功能受损或退化时，便会导致神经退行性疾病的发生。这些疾病包括阿尔茨海默病、多发性硬化症和帕金森病等，给患者带来巨大的身体和精神痛苦。随着神经元逐渐退化，患者可能会出现一些相对轻微的症状，例如身体协调问题或记忆力下降等。然而，随着更多神经元受到损害，症状会不断加剧，最终导致一些患者失去行走或独立生活的能力。除了这类疾病，抑郁、焦虑等精神类疾病正在"吞噬"人们的健康。

With the extension of human lifespan, the intensification of population aging, and the increase of social pressure, the prevalence of brain diseases is steadily increasing. Neurodegenerative diseases will occur when neurons in the brain, spinal cord, and/or peripheral nervous system begin to undergo functional impairment or degeneration. These diseases include Alzheimer's disease (AD), multiple sclerosis (MS), Parkinson's disease (PD), and so on, which will cause immense physical and psychological suffering to patients. As neurons progressively degenerate, patients may exhibit relatively mild symptoms, such as coordination issues or memory deterioration. However, as more neurons become damaged, symptoms will worsen, causing some patients to lose the ability to walk or live independently. Apart from these diseases, mental health diseases like depression and anxiety are also taking a toll on people's well-being.

从美国来看，神经退行性疾病已带来了经济上的巨大负担，每年仅这一类疾病就导致医疗费用和经济损失超过6550亿美元。中枢神经系统疾病的需求量巨大且增长迅速，代表了一种未满足且不断增长的健康需求，亟待推动神经科学前沿研究以开发更有效的疗法来改善神经退行性疾病患者的状况。现代药物对许多癫痫、抑郁症、脑损伤和创伤后应激障碍患者的治疗效果并不明显。对于认知方面的治疗如自闭症的核心症状或精神分裂症也缺乏有效的解决方案。许多中枢神经系统疾病患者因为医疗需求和实际有效治疗之间的差距而遭受痛苦。神经系统疾病研究是一个重要的领域，涉及神经科学的多个前沿领域以及潜在应用领域。为解决这些问题，需要布局针对脑功能异常、神经发育、精神/行为异常的神经生物学机理、调控机制、神经再生与修复等方面的研究工作，以满足人类健康事业的巨大需求。

In the United States, neurodegenerative diseases have already imposed a substantial economic burden, resulting in more than USD 655 billion in medical expenses and economic losses each year. The demand for the treatment of central nervous system (CNS) diseases is enormous and growing rapidly, representing an unmet and growing health need. Urgent efforts are required to advance cutting-edge neuroscience research to develop more effective therapies for improving the condition of patients suffering from neurodegenerative diseases. The therapeutic efficacy of modern drugs is not obvious for many patients suffering from epilepsy, depression, cerebral injury, and post-traumatic stress disorder (PTSD). Effective treatment solutions for cognitive aspects, such as the core symptoms of autism or schizophrenia are also lacking. Many patients with CNS diseases suffer due to the gap between medical needs and the actual effective treatment. The study of nervous system diseases is an important field that involves multiple frontier domains and potential applications of neuroscience. To address these issues, research efforts need to be directed toward neurobiological mechanisms, regulatory mechanisms, and neural regeneration and repair related to brain dysfunction, neurodevelopment, and psychiatric/behavioral disorders, which is essential to meet the substantial demands of the undertaking of human health.



02 中枢神经系统药物开发现状及挑战
Current Status of and Challenges in CNS Drug Development

2.1 血脑屏障阻碍药物进入神经中枢
2.1 Blood-Brain Barrier Hinders the Entry of Drugs into the Nerve Center

血脑屏障是高度选择性的屏障，将大脑与身体的其他部分隔开。出于这个原因，血脑屏障是发现有效治疗中枢神经系统相关疾病的新药的主要障碍，能够进入神经中枢的药物分子非常有限。在药物设计中，增加药物分子的亲脂性则会影响其水溶性，造成给药困难，一些抗体药/多肽/核酸药需要设计专门的跨血脑屏障载体才能发挥作用。不仅如此，进入大脑中的药物浓度也无法进行直接的测量，药物浓度与临床终点的联系过于复杂。此外，大部分中枢神经系统疾病缺乏明确的致病机理。任何一种疾病药物的成功研发，都是建立在对疾病机制有着深刻了解的基础上。但中枢神经系统疾病是缓慢的退行性的疾病，大部分的发病机制并不明确，这一方面限制了中枢神经系统药物研发只能针对疾病的症状进行缓解治疗，无法釜底抽薪。

The blood-brain barrier serves as a highly selective barrier that separates the brain from the rest of the body. Thus, the blood-brain barrier is a major obstacle to the discovery of new drugs to effectively treat CNS-related diseases, and the pharmaceutical molecules capable of entering the nerve center are limited. In drug design, increasing the lipophilicity of a pharmaceutical molecule can impact its water solubility, making administration challenging. Some antibody drugs, polypeptide drugs, or nucleic acid drugs, can only exert their efficacy through specialized carriers for crossing the blood-brain barrier. Furthermore, the concentration of drugs that enter the brain cannot be directly measured, and the connection between drug concentration and clinical endpoints is too complex. Additionally, many CNS diseases lack clearly defined disease mechanisms. Successful drug development for any disease relies on a deep understanding of its disease mechanisms. However, most CNS diseases are slow and degenerative in nature, with most of their pathogenesis remaining unclear, which restricts the development of CNS drugs to relieve symptoms of these diseases rather than addressing the root causes.

2.2 神经系统药物临床试验设计困难
2.2 Challenging Clinical Trial Design for Nervous System Drugs

这类药物缺乏可以对疾病进行可观量化和评估的疾病标志物。疾病机制的缺失导致临床试验设计的困难，进而影响下一步的效果。根据1990年至2012年间不同中枢神经系统适应症的试验，III期失败率为53%，缺乏疗效是主要原因（46%）。CNS疾病的表征不够明显，有些甚至没有明显的器质病变，病人自己报告效果带有高度的主观性，得出的数据也难以对疾病进行客观的测量和评估。许多中枢神经系统质量药物在临床前的表现不错，但临床却以失败告终，这和疾病模型的表面效度和结构效度较差有关。耶鲁大学医学院2016年的一篇文章就指出，大多数导致临床失败的模型过于宽松，比如阿尔茨海默病和肌萎缩性脊髓侧索硬化症模型可能会测量错误的指标，或在错误的时间测量正确的指标，导致其与人类疾病相关性差。比如治疗抑郁症的药物，会引起高血压、自杀倾向等副作用，这对于进入市场销售的影响很大，导致收益过低。一些公司的药物效果不错，但是毒副作用过大，最终也导致了临床试验的失败。

There is a lack of disease markers that can be quantified and evaluated effectively for such drugs. The absence of a clear disease mechanism leads to challenges in clinical trial design, which, in turn, affects subsequent outcomes. According to trials for various CNS indications from 1990 to 2012, the failure rate of the Phase III trial was 53%, with lack of efficacy being the primary reason (46%). The manifestations of CNS diseases are not obvious, and in some cases, there may be no evident organic lesions. Patients' self-reported outcomes often carry a high degree of subjectivity, and the data obtained from them makes it challenging to objectively measure and assess the disease. Many quality CNS drugs perform well in preclinical stages but ultimately fail in clinical trials, often due to poor surface and structural validity of disease models. According to an article published by the Yale School of Medicine in 2016, most models leading to clinical failures are often too permissive. For instance, models for diseases like AD and amyotrophic lateral sclerosis (ALS) may measure incorrect indicators or correct indicators at the wrong times, resulting in a poor correlation with human diseases. Additionally, drugs used to treat depression can cause side effects such as hypertension or suicidal tendencies, which will significantly impact market entry and sales, leading to low profits. Some companies have produced drugs that work well, but their big toxic and side effects have ultimately led to the failure of clinical trials.

TARGET SELECTION

2.3 高难度高风险导致资本投资薄弱
2.3 High Difficulty and High Risk Lead to Weak Capital Investment

由于开发治疗脑部疾病的药物比开发其他治疗领域的药物更困难、更耗时、更昂贵，因此一直以来都是投资相对薄弱的领域。目前部分大公司退出这一领域降低了全球神经科学的转化能力，并对社会在改善神经系统疾病影响方面的利益构成了严重挑战。对神经科学研究投资的削减，部分反映了药物开发总体上面临的日益严峻的挑战，因为总体成功率下降，而发现和开发新药的满负荷成本已上升到1.8亿至39亿美元的范围内。尽管中枢神经系统疾病领域有着潜在的巨大市场和令人心动的社会效益，但由于较高的财务风险，该领域现在被广泛认为不如其他治疗领域的研究投资有吸引力。这种较高的风险反映了候选药物开发成功的可能性较低，加上相对较高的项目成本和临床试验开展的复杂性，以及监管机构审查时间远高于平均水平。

Developing drugs to treat brain diseases is more difficult, time-consuming, and expensive compared to drug development in other therapeutic fields. As a result, investment in this field has historically been relatively weak. The departure of some major companies from this field has diminished the global translational capability of neuroscience and posed significant challenges to society's interest in addressing the impact of neurological diseases. The reduction in investment in neuroscience research partly reflects the increasingly serious challenges faced by drug development overall, as overall success rates have declined, and the full load cost of discovering and developing new drugs has risen to a range between USD 180 million and USD 3.9 billion. Despite the vast potential market and compelling social benefits in the field of CNS diseases, the field is now widely perceived as less attractive for research investment compared to other therapeutic fields due to higher financial risks. This higher risk is a reflection of the lower probability of successful development of drug candidates, coupled with the relatively high project costs, complexity of conducting clinical trials, and much longer regulatory review time than the average.

03 神经系统疾病治疗对医疗卫生环境提出高要求
Treatment of Nervous System Diseases Places High Demands on Healthcare Environment

在中枢神经系统疾病中，阿尔兹海默症(AD)、帕金森综合征(PD)等神经退行性疾病已经得到了广大社会群众的重视，而以多动症、自闭症为代表的等神经发育疾病，以及焦虑、抑郁等精神类疾病，还未得到足够的科普和认识，这一系列疾病与心理健康和精神卫生息息相关，其治疗除了依靠药物控制外还对医疗卫生环境提出了更高的要求。

In CNS diseases, neurodegenerative diseases such as AD and PD have garnered widespread attention from the public. However, neurodevelopmental disorders represented by conditions like ADHD and autism, as well as mental diseases including anxiety and depression, have not received sufficient propagation and recognition. These diseases are closely tied to mental health and hygiene, and their treatment not only relies on drug control but also places higher demands on the healthcare environment.

3.1 心理健康和精神卫生需得到广泛重视

3.1 Mental Health and Hygiene Need Widespread Attention

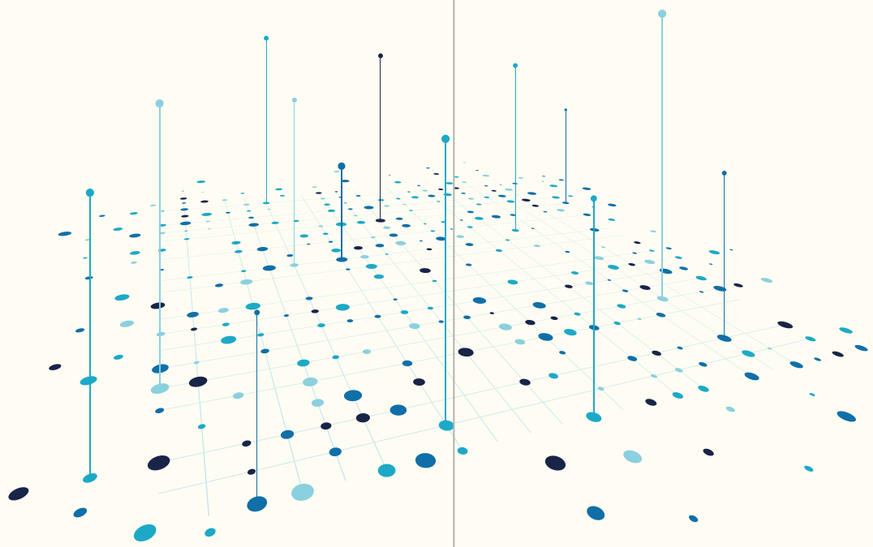
据最新调查数据披露，我国成年人各类精神疾病（不含痴呆）的终生患病率为16.6%，以抑郁障碍为主的心境障碍和焦虑障碍患病率总体呈上升趋势。在我国，由精神障碍造成的疾病负担占所有非传染性疾病负担的13%。由于公众对精神疾病缺乏正确认识，对精神科治疗不了解或误解，精神疾病患者中接受治疗的人数不超过全部患者的20%。我国精神卫生事业起步较晚，精神疾病诊断率低，可能与患者就诊率低、其他科室医生不具备精神疾病知识导致误诊或漏诊等有关。有研究显示，中国15岁以上人群抑郁症发病率4%—8%，但全国地市级以上医院对抑郁症的识别率不到20%，只有不到10%的抑郁症患者接受了正规治疗。2021年底，国家心理健康和精神卫生防治中心成立，从国家层面统筹开展精神卫生相关工作。今年7月，国家卫健委决定在北京市、上海市和湖南省设置国家精神疾病医学中心。我国精神卫生学科起步较晚，虽然近些年在国家的重视和各个部门的推动下、在公众对精神心理健康的日渐了解下快速发展，但与世界上精神医学发展较早的国家相比，仍有一定的差距。面对精神障碍负担不断加重、精神卫生资源分布不均衡、精神障碍防治面临诸多困境的现状，需多措并举促进各地区心理服务和精神卫生体系的协调发展，为提高群众心理健康状况和幸福水平服务。

According to the latest survey data, the lifetime prevalence of various mental diseases (excluding dementia) among adults in China is 16.6%. Mood disorders primarily involving depressive disorder and anxiety disorder are on the rise. In China, the disease burden caused by mental disorders accounts for 13% of the burden of all non-communicable diseases. Due to a lack of proper understanding among the public about mental diseases and misconceptions about psychiatric treatment, less than 20% of individuals with mental diseases receive treatment. China's mental health services started relatively late, with low rates of diagnosis for mental diseases, which could be attributed to a low patient consultation rate, as well as the lack of knowledge about mental diseases among physicians in other departments, leading to misdiagnosis or underdiagnosis. Research indicates that the prevalence of depression among individuals aged 15 and above in China is between 4% to 8%. However, fewer than 20% of hospitals in prefecture-level cities or above in China can correctly identify cases of depression, and less than 10% of individuals with depression receive proper treatment. At the end of 2021, the National Center for Mental Health, China was established to centrally coordinate mental health-related efforts at the national level. In July of this year, the National Health Commission of the People's Republic of China made a decision to establish the National Center for Mental Disorders in Beijing, Shanghai, and Hunan. The discipline of mental health in China started relatively late. Although in recent years, with the increasing attention from the government and the efforts of various departments, it has been rapidly developing as the public's understanding of mental and psychological health grows. However, there still exists a certain gap when compared to countries where psychiatric medicine has a longer history. Faced with the growing burden of mental disorders, unequal distribution of mental health resources, and numerous challenges in mental disorder prevention and treatment, it is necessary to conduct multi-pronged approaches to promote the coordinated development of psychological services and mental health systems in various regions, ultimately improving the mental health and well-being of the masses.

3.2 心理健康和精神卫生服务体系待完善

3.2 Mental Health and Hygiene Services System Need to Be Improved

在制度层面，要完善精神卫生心理健康服务体系的顶层设计，提高精神卫生资源的利用效率，拓宽基层精神障碍康复体系覆盖面，平衡不同地区医疗资源的分配，提升精神心理卫生服务能力。与此同时，还需完善精神卫生相关政策法规。一方面，规范精神卫生诊疗服务，保护精神障碍患者的合法权益；另一方面，完善社区对重性精神疾病的防治和管理能力。在人才队伍建设方面，需提升精神卫生专业的人才培养，完善精神科医师、临床心理治疗师及职业康复师的培养体系和考核标准，提升精神卫生从业人员临床诊疗技能、综合素质、知识储备、就业待遇以及社会认可度。在医学领域中，精神科是个冷门专业，社会认可度低、职业风险高，导致其对优秀医学生的吸引力明显不足。有统计显示，我国医学院毕业生选择从事精神专科的不到1%，这不利于精神科的长远发展。相关部门应加大财政投入，提高精神卫生专业人员的待遇，从根本上解决精神科医护人才队伍面临的后继乏力问题。此外，还需加强相关科室和硬件设施建设。国内大部分三甲医院主要关注患者的躯体健康，对心理健康关注不够。一些综合性医院甚至没有设立精神心理科，部分省市没有精神卫生中心和精神病专科医院，将近50%的县医院没有精神卫生专业机构、精神科床位或精神科医生，农村和边远地区的精神卫生资源较为薄弱。未来应构建精神卫生专科医院联体和联盟，充分利用互联网、大数据平台，积极开展远程会诊，推动基层首诊、双向转诊、急慢分治、上下联动的分级诊疗模式，提升基层诊治能力。



STRENGTHENING

At the institutional level, there is a need to enhance the top-level design of the mental hygiene and health services system, improve the utilization efficiency of mental health resources, expand the coverage of the grassroots rehabilitation system for mental disorders, balance the distribution of medical resources in different regions, and enhance the capacity of psychological and mental health services. Additionally, mental health-related policies and regulations need to be further developed. On one hand, efforts should be made to regulate mental health diagnosis and treatment services to protect the legal rights of individuals with mental disorders. On the other hand, efforts should be made to improve the prevention and management capabilities of communities for severe mental diseases. In terms of talent building, efforts should be made to enhance the training of professionals in mental health, which includes improving the training system and assessment standards for psychiatrists, clinical psychologists, and occupational therapists, as well as enhancing the clinical diagnosis and treatment skills, overall qualifications, knowledge base, employment treatment, and social recognition of mental health professionals. Psychiatry is considered a less popular specialty in the medical field, with low social recognition and high occupational risks, which significantly reduces its attractiveness to outstanding medical students. Statistics show that less than 1% of medical school graduates in China choose to specialize in psychiatry, which is not conducive to the long-term development of psychiatry. Relevant authorities should increase financial investments and improve the remuneration for mental health professionals to fundamentally address the problem of insufficient successors in the mental health workforce. Furthermore, it is also necessary to strengthen the development of related departments and facilities. Most tertiary hospitals in China primarily focus on patients' physical health while paying insufficient attention to their mental health. Some comprehensive hospitals do not even have a psychiatry department, and in some provinces and cities, there are no mental health centers or psychiatric specialized hospitals. Nearly 50% of county hospitals are not equipped with mental health specialized institutions, psychiatric beds, or psychiatric doctors. Mental health resources are relatively weak in rural and remote areas. In the future, it is essential to establish networks and alliances of mental health specialized hospitals and make full use of the internet and big data platforms to actively conduct remote consultations and promote a tiered diagnosis and treatment model involving initial diagnosis at the grassroots level, bidirectional referrals, distinguishing between acute and chronic cases, and coordination between higher-level and lower-level healthcare facilities, aiming to enhance the diagnosis and treatment capabilities at the grassroots level.

3.3 突发事件心理干预应对能力亟需加强

3.3 Psychological Intervention Ability to Cope with Emergencies Needs to Be Strengthened

目前，公众对精神心理问题的认识还存在不少误区，需要消除精神障碍的污名化问题，形成关爱精神障碍患者的社会氛围。很多人将精神疾病等同于"意志薄弱"，认为精神疾病是"矫情""娇气"，认为"扛一扛就过去了"。还有一些人对精神疾病认识较为片面，认为精神疾病"治不好"。在这样的情况下，不少精神障碍患者有"病耻感"，害怕被贴上精神病标签，不敢或不愿寻求专业帮助，常常导致病情延误。抑郁症像高血压、糖尿病一样有其生物学基础，是大脑的神经递质发生了改变。抑郁症本身并不可怕，可怕的是不能正视它，不能及时得到专业的治疗和帮助。近十年来，我国对突发事件的心理干预工作经历了从无到有、建章立制的过程。精神卫生法、基本医疗卫生与健康促进法等法律和制度规定和保障了对突发事件开展心理救援的工作。应加强对普通医务人员心理健康知识培训制度，提高他们对精神心理问题的识别和处置能力。同时，精神专科医院应提高自身的调度能力，应能快速抽调人员、物资，快速精准地解决突发紧急事件。

Currently, there are still many misconceptions among the public regarding mental and psychological issues. It is essential to eliminate the stigma associated with mental disorders and foster a social atmosphere that cares for individuals with mental disorders. Many people equate mental diseases with "weak willpower" and consider them as being "pretentious" or "sensitive". They think that one can simply "tough it out" to overcome mental diseases. There is also a partial understanding of mental diseases among some individuals who believe that they are "incurable". In such a context, many individuals with mental disorders feel a sense of "shame" and fear of being labeled as mentally ill. As a result, they are afraid or unwilling to seek professional help, often leading to delays in receiving treatment. Depression, like hypertension and diabetes, has a biological basis, involving changes in neurotransmitters in the brain. Depression itself is not terrifying. What is terrifying is the failure to face it and the inability to receive timely professional treatment and assistance. In the past decade, China has made significant progress in psychological intervention for emergencies, transitioning from an absence of such services to the establishment of comprehensive regulations and systems. Laws and regulations such as the Mental Health Law, the Basic Medical Health and Health Promotion Law, provide legal and institutional support for conducting psychological rescue work during emergency events. Efforts should be made to enhance the knowledge and training of ordinary medical staff in mental health to improve their ability to recognize and handle psychological and mental issues. Simultaneously, specialized psychiatry hospitals should enhance their dispatch capabilities, thus enabling them to rapidly deploy personnel and resources to address sudden and urgent events effectively.

04 中枢神经系统疾病药物代表性企业概览
Overview of Representative Companies for CNS Drugs

4.1 渤健
4.1 Biogen

渤健（Biogen）是一家典型的科学驱动研发的生物技术公司，由五位来自全球顶尖大学的教授1978年组团创建。初创团队阵容十分豪华，其中两位创始人Walter Gilbert、Phillip Sharp在公司成立不久就接连获得诺贝尔化学奖以及生理学或医学奖，掌门人之一Charles Weissmann在1979年成功合成出具有生物活性的人类白细胞干扰素。1991年，渤健在纳斯达克上市。1996年，治疗复发性多发性硬化症（MS）的干扰素β-1a（商品名：Avonex）获美国食品药品监督管理局批准上市，这是首款被证明能够减缓残疾进展、降低病情恶化频率的药物，日后为渤健赚取丰厚利润的同时也奠定了其在神经科学领域领军地位的关键一步。渤健为全球罹患严重神经和神经退行性疾病的患者探寻、研发和提供创新疗法和相关方案。当前，渤健拥有治疗多发性硬化的领先药物组合，推出了第一个批准用于脊髓性肌萎缩症的治疗药物，并提供先进生物制剂的生物类似药。渤健除了MS以外，也在积极投资临床巨大未满足需求的脊髓性肌萎缩症（SAM）、肌萎缩侧索硬化（ALS）、产后抑郁症（PPD）、重度抑郁症（MDD）、天使症候群、帕金森病等神经学疾病新药开发。

Biogen is a representative science-driven R&D biotechnology company. It was founded in 1978 by five professors from top global universities. The impressive founding team included two Nobel laureates, Walter Gilbert and Phillip Sharp, who received Nobel Prizes in Chemistry and Physiology or Medicine soon after the company's establishment. One of the heads, Charles Weissmann, successfully synthesized biologically active human leukocyte interferon in 1979. In 1991, Biogen went public on NASDAQ. In 1996, interferon -1a (trade name: Avonex) for relapsing multiple sclerosis (MS) was approved for marketing by the FDA. Avonex was the first drug proven to slow down the progression of disabilities and reduce the frequency of disease exacerbation. Subsequently, it has not only generated substantial profits for Biogen but also played a pivotal role in establishing its leadership in the field of neuroscience. Biogen is dedicated to exploring, developing, and providing innovative therapies and relevant solutions for patients worldwide who suffer from severe neurological and neurodegenerative diseases. Currently, Biogen has a leading combination of drugs for treating MS, has launched the first drug approved for spinal muscular atrophy (SMA), and offers biosimilar drugs of advanced biologics. In addition to MS, Biogen is actively investing in the development of new drugs for SMA, ALS, PPD, MDD, AS, PD, and other neurological diseases with huge unmet clinical needs.

4.2 灵北制药
4.2 Lundbeck

灵北制药有限公司是一家专注于发现和开发脑部疾病创新治疗方案的国际制药公司，总部设在丹麦，业务遍及全球50多个国家，在丹麦、法国和意大利拥有生产基地，并在丹麦和美国设有研发中心。已在神经科学领域深耕70多年，产品惠及全球数百万的患者。灵北制药以开发脑部疾病药物为核心，在精神、神经领域建立有药物开发平台，药品品种涉及小分子、抗体、疫苗，适应症主攻抑郁、精神分裂、帕金森、偏头痛、阿尔茨海默等；其中，以抑郁症和精神分裂领域药品开发数量较多。抗抑郁药是灵北于药品行业受关注度最高的开发方向之一，在全球已上市的数十个抗抑郁药当中，很容易看到灵北的身影。灵北的另一重要产品管线，为精神分裂药物品种。灵北制药获得国家药品监督管理局批准上市的代表药物有治疗抑郁障碍的草酸艾司西酞普兰（来士普®）、氟哌噻吨美利曲辛片（黛力新®）、氢溴酸西酞普兰片（喜普妙®），用于原发性帕金森病患者单药治疗的甲磺酸雷沙吉兰片（安齐来®），以及用于治疗中重度至重度阿尔茨海默型痴呆的盐酸美金刚片（易倍申®）等。

Lundbeck is an international pharmaceutical company headquartered in Denmark, specializing in discovering and developing innovative treatment solutions for brain diseases. Lundbeck operates in over 50 countries, with production bases in Denmark, France, and Italy, as well as R&D centers in Denmark and the United States. With more than 70 years of dedicated work in the field of neuroscience, Lundbeck's products have benefited millions of patients worldwide. Lundbeck, with a focus on the development of drugs for neurological diseases, has established a drug development platform in the fields of psychiatry and neurology. The company's drug variety includes small molecules, antibodies, and vaccines, targeting indications such as depression, schizophrenia, PD, migraine, and AD, among which, the number of drugs developed for depression and schizophrenia is larger. Antidepressant drugs represent one of the most highly regarded development directions of Lundbeck in the pharmaceutical industry and among the dozens of antidepressant drugs that have been launched worldwide, it's easy to spot the presence of Lundbeck. Another important product pipeline of Lundbeck is the drug for schizophrenia. Lundbeck has received approvals from the National Medical Products Administration for the marketing of representative drugs such as Escitalopram Oxalate (Lexapro®), Flupentixol and Melitracen Tablets (Deanxit®), and Citalopram Hydrobromide Tablets (Celexa®) for depression, Rasagiline Mesylate Tablets (Azilect®) for patients with primary PD, and Memantine Hydrochloride Tablets (Ebixa®) for moderate to severe AD.

4.3 恩华药业
4.3 Nhwa

江苏恩华药业股份有限公司始建于1978年，前身为徐州第三制药厂，经过系列改制、重组和整合，发展为国内优秀的中枢神经系统专科用药领军企业。2008年在深圳证券交易所上市。公司主要生产经营中枢神经系统用药，战略定位于中枢神经药物领域市场，主要从事中枢神经系统药物的开发、生产和销售，主要药物类别包括麻醉类、精神类和神经类，是国家定点麻醉类和精神类药品生产基地。主要的利润是来源于精神类、神经类和麻醉类药物。公司设有企业院士工作站、国家博士后科研工作站、江苏省神经药物工程技术研究中心、江苏省中枢神经药物研究重点实验室，还分别在苏州和上海筹建了苏州恩华生物医药科技有限公司和上海枢境生物科技有限公司，已建立中枢神经系统药物新分子实体研究与开发平台、高端中枢神经递药系统研究与开发平台、中枢神经系统新药筛选及药理学评价研究与开发平台、精麻类药品防滥用技术研究与开发平台。公司在研项目70余项，分别处于药品研发的各个阶段，储备了一定数量的新产品，保证了企业的可持续性发展。

Jiangsu Nhwa Pharmaceutical Co., Ltd., founded in 1978, formerly known as Xuzhou No. 3 Pharmaceutical Factory, has developed into an outstanding Chinese leader in specialized drugs for CNS through a series of restructuring, reorganization, and integration efforts. In 2008, it went public on the Shenzhen Stock Exchange. The company primarily manufactures and operates CNS drugs, with a strategic focus on the CNS drug market. It engages primarily in the development, production, and sales of CNS drugs, which are categorized as anesthetic, psychotropic, and neurologic drugs. It serves as a designated production base for anesthetic and psychotropic drugs in China. The majority of its profits are derived from psychotropic, neurologic, and anesthetic drugs. The company has established various R&D platforms, including Enterprise Academician Workstation, National Postdoctoral Research Workstation, Jiangsu Engineering Research Center for Neurologic Drugs, and Jiangsu Key Laboratory of CNS Drug Research. It has also set up subsidiaries in Suzhou and Shanghai, namely Suzhou Nhwa Biomedical Technology Co., Ltd., and Shanghai Shujing Biotechnology Co., Ltd. It has established R&D platforms for new molecular entities for CNS drugs, advanced central nervous drug delivery systems, CNS drug screening, and pharmacological evaluation, and anti-abuse technologies of psychotropic and anesthetic drugs. The company has over 70 ongoing research projects, with each at different stages of pharmaceutical development, and has accumulated a certain number of new products, ensuring the sustainable development of the enterprise.

4.4 绿叶制药

4.4 Luye Pharma

绿叶制药集团隶属于绿叶生命科学集团旗下，是一家致力于创新药物的研发、生产和销售的国际化制药公司，以全球研发、全球制造、全球市场为三大战略重心，聚焦中枢神经系统、肿瘤、心血管、代谢等疾病领域。现阶段，绿叶制药在中枢神经系统领域的在研管线有7条，针对的疾病包括精神分裂症、阿尔茨海默病、抑郁症、焦虑症和帕金森病等。其中治疗精神分裂症和双相障碍I型的Rykindo®（利培酮缓释微球注射制剂）已在中美获批上市，是首个由中国药企自主研发并在美国获批上市的中枢神经系统治疗领域的新药。目前，绿叶制药正在积极推进Rykindo®在美国的商业化布局，同时也在欧洲开发Rykindo®，并计划将其推广至全球更多市场。在既往的国际化进程中，其已通过思瑞康®、利斯的明透皮贴剂等已上市产品的全球化推广，在该领域内建立起一定的学术影响力。在研管线方面，另有包括已分别在美国和中国临近商业化阶段的棕榈酸帕利哌酮缓释混悬注射液（LY03010），在中国和海外市场同步开发的注射用罗替戈汀缓释微球（LY03003），以及已在中国获批上市并在美国处于新药上市审评阶段的一类创新药若欣林®(盐酸托鲁地文拉法辛缓释片）等在研产品，有望在上市后与Rykindo®形成差异化的产品组合。

Luye Pharma Group, a subsidiary of Luye Life Sciences, is an international pharmaceutical company dedicated to the research, development, production, and sales of innovative drugs. It takes global research, global manufacturing, and global markets as its three major strategic priorities, with a specific focus on CNS, tumor, cardiovascular, and metabolic diseases. At present, Luye Pharma has seven ongoing research pipelines in the field of CNS, targeting schizophrenia, AD, depression, anxiety, PD, and other diseases. Rykindo® (Risperidone Microspheres for Injection), used to treat schizophrenia and bipolar I disorder, has been approved for marketing in both China and the United States. It is the first CNS drug independently developed by a Chinese pharmaceutical company and approved for marketing in the United States. Currently, Luye Pharma is actively promoting the commercial layout of Rykindo® in the United States while also developing Rykindo® in Europe and planning to expand it to more global markets. In the past process of internationalization, it has established a certain level of academic influence in the field through the global promotion of marketed products, such as Seroquel® and Rivastigmine Transdermal Patch. In terms of the ongoing research pipeline, there are also other ongoing research products, including Paliperidone Palmitate Extended-release Suspension Injection (LY03010), which has entered the near-commercialization stage in both the United States and China, Rotigotine Extended-release Microspheres for Injection (LY03003), which was developed simultaneously in China and overseas markets, and the innovative drug Roxinlin® (Toludesvenlafaxine Hydrochloride Extended-release Tablets), which has been approved for marketing in China and is in the new drug marketing review stage in the United States. These ongoing research products have the potential to form a differentiated product portfolio with Rykindo® after their market launch.

4.5 先声药业

4.5 Simcere

先声药业是一家创新与研发驱动的制药公司，拥有"神经与肿瘤药物研发全国重点实验室"，重点聚焦肿瘤、神经系统、自身免疫及抗感染领域。近三年在肿瘤、神经系统、抗感染等领域上市了四款创新药。2020年7月，先声药业神经领域一类创新药先必新®（依达拉奉右莰醇注射用浓溶液）获批在国内上市，可显著改善脑卒中患者愈后，减少患者致残率，目前已惠及百万患者。今年7月，先声药业与瑞士Idorsia公司合作的新型抗失眠药物盐酸Daridorexant，获得国家药品监督管理局签发的药物临床试验批准通知书，拟用于治疗症状持续存在至少3个月且对日间功能产生影响的成人失眠患者。海外临床研究显示，Daridorexant可显著改善失眠人群入睡和睡眠维持，延长睡眠时间，支持安全长期用药，有望为国内数量庞大的慢性失眠患者带来更佳疗法。Daridorexant进入临床试验阶段，有望进一步扩充先声药业神经科学产品管线，更好满足患者需求。

Simcere is an innovative and research-driven pharmaceutical company with a "State Key Laboratory of Neurology and Oncology Drug Development". The company focuses on fields such as tumor, nervous system, autoimmunity, and anti-infection. In the past three years, Simcere has launched four innovative drugs in tumor, nervous system, anti-infection, and other fields. In July 2020, Simcere received approval for the marketing of Xianbixin® (Edaravone and Dexborneol Concentrated Solution for Injection), an innovative drug in the neurology field that can significantly improve the recovery of stroke patients and reduce the disability rate. It has benefited millions of patients so far. In July of this year, Simcere obtained clinical trial approval from the National Medical Products Administration for Daridorexant Hydrochloride, a new type of anti-insomnia drug developed in collaboration with Swiss Idorsia. Daridorexant is intended for the treatment of adult insomnia patients who have symptoms that persist for at least three months and affect daytime functioning. Overseas clinical studies have demonstrated that Daridorexant can significantly improve sleep onset, maintenance, and duration in individuals with insomnia. It supports safe long-term use and is expected to provide a better treatment option for the large number of chronic insomnia patients in China. As Daridorexant progresses into clinical trials, it has the potential to further expand Simcere's neuroscience product pipeline and better meet the needs of patients in this therapeutic field.

05 展望

Outlook

中枢神经系统疾病领域具有巨大的市场潜力和临床需求，其竞争态势远比肿瘤等疾病领域要温和。国内已经有一些生物科技公司开始涉足这个领域，而资本市场对于中枢神经系统药物研发的关注度也日益提高。从研发成功率的角度来看，尽管AD药物的研发成功率相对较低，但其他适应症的研发风险则并不算高。这为中枢神经系统药物研发企业提供了指导，以便在整体风险控制方面进行管线布局。此外，表型筛选结合靶点筛选是神经系统药物开发的有效策略。在具体适应症方面，以精神分裂症为代表，现有的药物已经具有一定的靶点依据和疗效，但仍存在改善阴性症状和认知症状的需求，以及减少现有药物的副作用问题。因此，仍需要通过开发新的药物来提高临床疗效。对于抑郁症患者，目前的治疗手段主要是三环类抗抑郁药，但有效性不足，因此需要探索新的机制以提供更好的疗效。对于成瘾治疗，目前的治疗方法主要是阿片类药物，但复吸率仍然较高，因此需要从成瘾环路调控策略出发，而非仅仅依赖靶点策略来开发新的治疗方法。神经退行性疾病是另一个需要关注的领域。全球范围内阿尔茨海默病患病人数为千万级，而在美国食品药品监督管理局近二十年的批准药物中，仅有一款针对Aβ寡聚体靶点的药物阿杜那单抗上市。因此，对于新靶点和新机制的探索是当务之急。

The field of CNS diseases holds tremendous market potential and clinical demand, with a competitive situation that is much milder compared to fields such as tumors. Some biotechnology companies in China have already started venturing into this field, and there is a growing interest from the capital market in CNS drug research and development. From the perspective of R&D success rates, although the success rate for AD drugs is relatively low, the R&D risks for other indications are not high. This provides guidance for companies engaged in CNS drug research and development to strategically plan their pipelines in terms of overall risk control. Furthermore, combining phenotype screening with target screening is an effective strategy in the development of neurologic drugs. In specific indications, such as schizophrenia, existing drugs already have certain target-based evidence and efficacy. However, there is still a need for improvement in negative symptoms and cognitive symptoms, as well as a reduction of the side effects associated with existing drugs. Therefore, exploring new drugs to provide better efficacy is still essential. For patients with depression, the current treatment primarily relies on tricyclic antidepressant drugs. However, their efficacy is limited, resulting in a need to explore new mechanisms to provide better efficacy. For addiction treatment, the current therapy primarily involves opioid drugs, while the relapse rate remains high. Thus, it is necessary to develop new therapies by focusing on addiction circuit regulation strategies rather than solely relying on target-based approaches. Neurodegenerative diseases are another field that requires attention. There are tens of millions of patients with Alzheimer's disease worldwide. However, according to FDA data, only one drug (aducanumab) targeting the A oligomer has been approved for marketing in the past two decades. Therefore, it is urgent to explore new targets and new mechanisms.

综上所述，我们相信，类似于心血管疾病、肿瘤、自身免疫性疾病治疗药物的研发过程，中枢神经系统疾病药物研发也正处于爆发的前夜。在研究人员的不懈努力和资本的助力下，未来不仅在精神分裂症等需要提升治疗效果的适应症上取得突破，甚至在AD、ALS等较难攻克的疾病方面也会取得进展。

In summary, we believe that drug development for CNS diseases is on the verge of a breakthrough, similar to the research and development process of drugs for cardiovascular diseases, tumors, and autoimmune diseases. With the relentless efforts of researchers and support from capital, we expect breakthroughs not only in indications like schizophrenia where treatment efficacy needs improvement but also in more challenging diseases such as AD and ALS.

04

深度对话
In-depth Interview

IN-DEPTH INTERVIEW CORPORATE STYLE

IN-DEPTH INTERVIEW

专访

四川科瑞德制药股份有限公司 陈功政

Chen Gongzheng,
Deputy General Manager of Sichuan Credit Pharmaceutical Co., Ltd.

专家简介： PROFILE OF THE EXPERT

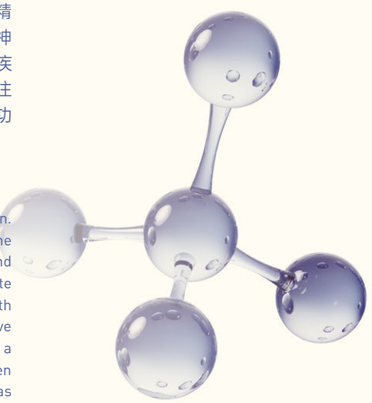
陈功政，四川科瑞德制药股份有限公司副总经理，擅长化学药品分析及专利设计，多次获得四川省专利奖，先后被评为四川省知识产权先进个人、四川省技术创新突出贡献人物。公司主要聚焦中枢神经系统药物研发、高端仿制药研究及产业化、系统性检测及个体化给药研究。

Chen Gongzheng, Deputy General Manager of Sichuan Credit Pharmaceutical Co., Ltd., specializes in chemical drug analysis and patent design. He has received several patent awards in Sichuan Province and has been recognized as an Advanced Individual in Intellectual Property in Sichuan Province and an Outstanding Contributor to Technological Innovation in Sichuan Province. Sichuan Credit Pharmaceutical Co., Ltd. primarily focuses on the research and development of central nervous system (CNS) drugs, the research and industrialization of high-end generic drugs, and the research of systematic testing and individualized drug administration.

专注精神疾病领域
以疾病为中心解决实际临床需求

Focusing on Mental Disorders and Addressing Practical Clinical Needs with Disease-Centric Approaches

据世界卫生组织2023年统计，全世界大约有3.8%的人患有抑郁症。2023年7月5日，饱受抑郁症所苦的华人歌手李玟自杀去世，让抑郁症这一精神类疾病被推至公众眼前。在我国，心理健康和精神卫生领域整体发展目前仍存在患者基数大、疫情后患病率持续上涨、疾病治疗率不足，以及精神卫生服务机构/人员增速远不及患者增速等问题，精神类疾病也已经成为严重的社会问题。这类疾病的治疗药物开发挑战大，但也有着潜在的巨大市场和令人心动的社会效益。本期我们邀请到专注于中枢神经系统疾病治疗药物的四川科瑞德制药股份有限公司（以下简称"科瑞德"）副总经理陈功政，结合企业对疾病领域的选择、管线部署、转化应用等进行领域介绍和观点分享。



According to the WHO's statistics in 2023, approximately 3.8% of the world's population suffers from depression. On July 5, 2023, Chinese singer Li Wen, who had suffered from depression, passed away by suicide, bringing the spotlight onto the mental disorder of depression. In China, the overall development of psychological health and mental health still faces challenges, including a large patient base, a continuous increase in the prevalence rate after the COVID-19 pandemic, an insufficient disease treatment rate, and a significant gap between the growth rate of mental health service institutions and personnel and the growth rate of patients. Mental disorders have become a serious social issue. Developing drugs for such disorders is challenging, but meanwhile, there is a potentially enormous market and exciting social benefits. In this interview, we are honored to have invited Chen Gongzheng, Deputy General Manager of Sichuan Credit Pharmaceutical Co., Ltd. (hereinafter referred to as "CREDIT"), a company dedicated to drugs for CNS diseases, to introduce the field and share his views by presenting an overview of the company's selection of disease fields, pipeline deployment, and translational applications.

科瑞德在二十多年前开始涉足中枢神经系统疾病领域，是什么契机选择了这一方向？

CREDIT entered the field of CNS diseases over two decades ago.
What prompted this decision?

BIO Collaborate

陈功政 Chen Gongzheng

科瑞德于二十一世纪初成立，当时面临着发展资金有限、实力相对较弱以及资源匮乏等客观限制。出于这些考虑，我们选择专注于竞争相对较少的精神疾病领域，选择几款独家产品推广。在这一过程中，我们逐渐积累了药物管线的推广经验和市场资源，同时我们在推广过程中看到越来越多的患者用我们的产品后逐渐康复，也坚定了在精神神经这一疾病领域的持续投入和发展。我们不仅仅通过治疗来减轻患者躯体上的痛苦，更重要的是通过解决患者的情绪障碍，改善其心理健康状况，从而让他们重新拥抱快乐和充实的生活。

CREDIT was established in early 21st century. It was facing objective limitations such as limited development funds, relatively weaker capabilities, and scarce resources at that time. Based on these considerations, we chose to focus on the relatively less competitive field of mental disorders and promote a select few exclusive products. In this process, we gradually accumulated promotion experience in the drug pipeline and market resources. At the same time, we also witnessed more and more patients gradually recovering after using our products in the promotion process, which reinforced our commitment to continued investment and development in psychoneurosis. We not only aim to alleviate the physical suffering of patients through treatment but, more importantly, to address their emotional disorders and improve their mental health status, thereby enabling them to embrace a happy and fulfilling life once again.

在上世纪六七十年代，人们普遍认为只有躯体的疾病才是真正的疾病，而忽略了精神健康的重要性。心情不好、焦虑抑郁等心理问题常常被忽视，甚至被视为个人弱点的表现。随着时间的推移，人们逐渐意识到精神疾病和躯体疾病之间的区别，也慢慢开始意识到心理治疗和心理咨询的必要性。2013年，国家颁布《精神卫生法》，填补了中国精神卫生领域的法律空白，加强心理健康和促进精神障碍预防工作，提高公众心理健康水平作为各级政府的工作之一，以法律形式明确了心理健康和精神健康的重要性。直至今日，以抑郁症来看，它的门诊量每年至少增长20%，这也意味着精神领域产品的发展仍然有很大的潜力和空间，精神类疾病治疗药物的市场份额也将继续扩大。

In the 1960s and 1970s, it was widely believed that only physical diseases were genuine diseases, while the importance of mental health was often overlooked. Psychological problems like bad moods, anxiety, and depression were frequently ignored or even seen as signs of personal weakness. Over time, people began to recognize the distinction between mental and physical diseases and the necessity of psychological therapy and counseling. In 2013, China enacted the Mental Health Law, filling the legal gap in the field of mental health. Strengthening mental health, promoting the prevention of mental disorders, and improving the public's mental health status started to be regarded as the tasks of governments at all levels, clarifying the importance of psychological health and mental health in legal form. Until today, the outpatient caseload of depression has been increasing by at least 20% annually, indicating that there is still significant potential and room for development in mental health products, and the market share of drugs treating mental disorders will continue to expand.

NEUROLOGIC DRUGS

目前，科瑞德几个拳头产品的市场占有率都很高，请问当初是基于哪些考虑进行选品的？

Currently, several competitive products of CREDIT hold a significant market share. Can you explain the considerations that led to the selection of these products in the first place?

BIO Collaborate

陈功政 Chen Gongzheng

在那时，我们主要注重产品作用机制的先进性，没有关注产品的成熟度，认为对临床有用的产品，发展不会太差；当然，在发展过程中也遇到很大的挑战，毕竟我们发展之初资源有限，去推广一个新概念是非常难的。最终的成功是偶然中的必然，主要的是陈刚董事长对产品和市场的洞察力；他对精神领域的坚定判断，在决策中发挥了关键作用。他有意识地选择了一些竞争相对较小且未受到过多关注的品种。在当时，我们开发的这些产品在国内市场上都是独家，从零开始进行学术推广，逐渐赢得了市场的认可，建立了市场存在感。在发展过程中，我们不断对上市产品进行质量升级，使疗效和安全性得到进一步提高，同时也提高了产品的技术门槛，为市场的发展赢得了充分的时间。我们重点关注精神科、神经科等临床科室，科瑞德始终秉持以患者为中心的发展理念，积极分析该领域的各个疾病，积极与临床专家进行深度交流，寻求最有助于疾病治疗的方案，争取从诊断、治疗、康复全过程提供立体式治疗疾病的系列产品。现阶段，我们还增加了肌松药品的研发和生产，并计划在未来进一步拓展到镇静领域。

At that time, our primary focus was on the advancement of mechanisms of action of the products, rather than their maturity. We believed that products with clinical utility wouldn't perform poorly in development. Of course, during the development process, we also encountered huge challenges, considering our limited resources at the outset. It was extremely challenging to promote a new concept. The ultimate success was a result of both chance and necessity, primarily attributed to Chairman Chen Gang's keen insight into products and markets. His firm judgment in the spiritual domain played a crucial role in decision-making. He made a conscious decision to choose product varieties that were relatively less competitive and had received less attention. At that time, the products we developed were exclusive to the domestic market. We started from scratch with academic promotion and gradually gained market recognition, establishing a strong market presence. Throughout our development, we have continually upgraded the quality of our marketed products, improving both efficacy and safety, and also raised the technical threshold of products, allowing us to gain ample time for market development. With a focus on the psychiatry department, neurology department, and other clinical departments, CREDIT has always adhered to a patient-centric development philosophy. We have actively analyzed various diseases in the field and engaged in in-depth discussions with clinical experts to seek the most effective treatment solutions, aiming to provide a series of products for the comprehensive treatment of diseases from the whole process of diagnosis, treatment, and rehabilitation. At this stage, we are also increasing our research and production of muscle relaxants and plan to further expand into the sedative field in the future.

中枢神经领域药物开发的难点有哪些？

What are the challenges in drug development in the CNS field?

BIO Collaborate

陈功政 Chen Gongzheng

药物开发面临诸多挑战。对于治疗焦虑、抑郁等情绪障碍疾病的药物开发难度尤其突出，因为这些疾病多数的发病机制尚未明晰，动物药效结果与临床试验结果差异巨大。焦虑抑郁的动物模型虽然存在全球公认的标准，但将其推导到人身上的有效性却很低，甚至有时完全无效。其次，焦虑抑郁药物的个体化用药差异明显，当其进入人体实验阶段后，不同人群的反应也可能存在差异，从而导致这类药品临床试验失败率很高。焦虑抑郁药物临床试验周期长，临床指标以主观评价为主，这也是该类药品开发难度大的原因。针对这些难题，我们认为在药物后期开发中，应注重焦虑抑郁发病机理的研究，利用转化医学研究焦虑抑郁的生物学评价客观指标，提高药物评价的准确性和及时性。

Drug development faces numerous challenges, particularly in the development of drugs for emotional disorders such as anxiety and depression, as most pathogenesis of these diseases remains unclear, and there is a huge difference between the results of animal efficacy outcomes and clinical trial outcomes. Although there are globally recognized standards for animal models of anxiety and depression, their applicability to humans is often low, and sometimes even completely ineffective. Moreover, there is an obvious difference in individualized drug administration of drugs for anxiety and depression. After these drugs enter the human experiment phase, different crowds may react differently, leading to a high failure rate in clinical trials. The lengthy duration of clinical trials for drugs for anxiety and depression, along with the reliance on subjective evaluations as primary clinical indicators, also leads to the difficulty in developing such drugs. In response to these challenges, we believe that in the late-stage development of drugs, emphasis should be placed on the study of the pathogenesis of anxiety and depression and the accuracy and timeliness of drug evaluations should be enhanced by utilizing translational medicine to study objective indicators of biological evaluations of anxiety and depression.

此外，通常情况下精神疾病药物开发难度大的原因之一，是药物透过血脑屏障率低，因此需要以高剂量给药，剂量大了后，副作用又增加了。由于这类疾病的治疗周期漫长，多数情况下无法完全治愈，需要长期服药。如果药物副作用较大，会对患者造成新的健康问题，甚至不可逆的伤害。在开发相关药物和选择药物治疗时，都需要仔细权衡其患者收益和可能得风险。因此，新的药物递药系统需要解决如何更好透过血脑屏障这一难题，这也是当前制药领域的热点和突破点。

Additionally, one of the common reasons for the difficulty in developing drugs for mental disorders is the low penetration rate of drugs through the blood-brain barrier. Thus, high doses are often required, which will lead to increased side effects. Since these disorders require long-term treatment and may not be fully curable in most cases, patients need to take drugs for a long time. If the side effects of the drugs are large, they can cause new health problems for the patients or even irreversible harm. It is essential to carefully weigh the benefits to patients against potential risks when developing relevant drugs and selecting drug therapies. Therefore, the new drug delivery system that can address the challenge of improving drug penetration through the blood-brain barrier is the current focus and breakthrough point in the pharmaceutical field.

科瑞德在泸州起步，发展到今天，在成都也建立了研发基地，您认为成都或天府生命科技园的产业生态如何？

CREDIT began its development history in Luzhou and has established a research and development base in Chengdu. What do you think of the industrial ecology in Chengdu or the Tianfu Life Science Park?

BIO Collaborate

陈功政 Chen Gongzheng

科瑞德制药的注册地和工厂在泸州，但大部分研发能力放在成都，主要归因于成都的产业环境和人才环境确实远优于川内其他地区。特别在园区内，我们经常参加到一些行业内的高质量论坛和会议，和同行及时探讨遇到的困难，相互启发、借鉴，这对科瑞德非常重要。我认为，扶持企业健康发展，不仅要关注产业政策，更重要的是要为企业搭建起相互交流的平台，比如园区组织分享会，企业之间可以分享好的做法和经验，降低投资风险。尤其是针对不同类型、不同阶段的企业，需求可能各不相同，比如初创企业需要资金和资源支持，而发展相对成形的企业则更注重发展前景和上市等问题，我也希望政府和园区未来能够出台更加个性化的扶持政策。通过搭建平台、组织交流、提供资源等措施，整合生物医药产业发展的各种要素，形成良性的产业环境，让企业更有归属感，从而吸引更多的优质企业入驻园区。

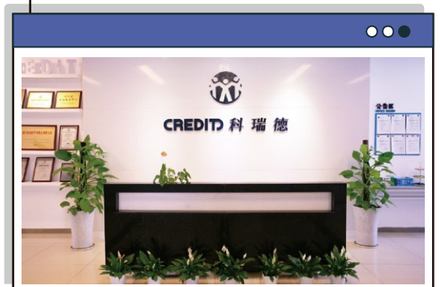
Although the registration place and factory of CREDIT are in Luzhou, most of our research and development capabilities are concentrated in Chengdu. This is primarily because Chengdu offers a superior industrial and talent environment compared to other areas in Sichuan Province. Especially in the Tianfu Life Science Park, we frequently participate in high-quality industrial forums and conferences, allowing us to engage in timely discussions about challenges with peers and inspire and learn from each other, which is of great importance to CREDIT. I believe that supporting the healthy development of enterprises requires not only a focus on industrial policies but, more importantly, a platform for mutual communication for enterprises, such as sharing sessions organized by the park, where enterprises can share good practices and experience, thereby reducing investment risks. Different types and stages of enterprises may have varying needs. For instance, startups may require financial and resource support, while more established enterprises may prioritize growth prospects and IPOs. I hope that the government and the park can issue more personalized support policies in the future. A conducive industrial environment can be established by creating platforms, organizing exchanges, providing resources, and integrating various elements of the biopharmaceutical industry, which will make enterprises feel a sense of belonging and, in turn, attract more high-quality enterprises to the park.

NEUROLOGIC DRUGS

CORPORATE STYLE
企业风采

关于科瑞德

四川科瑞德制药股份有限公司成立于 2000 年，是一家集研发、生产、销售于一体的高新技术企业。公司位于四川省泸州市国家高新区医药产业园酒香大道 8 号，占地面积 260 亩，在职员工 1500 余人。目前拥有胶囊、片剂、冻干粉针剂、水针剂、抗肿瘤固体制剂、中药提取生产线。公司专注于中枢神经系统领域，下辖泸州科瑞德制药有限公司、四川中领创拓医药科技有限公司、费德礼迪生物制药(美国)公司、四川科瑞德美地亚医疗器械有限公司和四川瑞德中枢数字医疗科技有限公司。公司 2022 年投入研发的费用占销售收入的 14% 以上，拥有专职研发团队近 200 人，其硕士研究生以上学历 60 余人。公司目前拥有 67 项已授权专利、注册商标 46 个，19 个药品生产批件、10 个原料药登记号、3 个医疗器械注册证及 18 个围绕中枢神经系统疾病的主要在研项目，包括 7 种改良型新药和 11 种高端仿制药。公司始终坚持"质量为先，创新驱动"不动摇，努力实践"合规、专业、诚信、感恩"价值观，致力"成为驰誉国际的优秀中国医药企业，成为中国中枢神经领域的产品领跑者"，正阔步踏上新征程。



ABOUT CREDIT

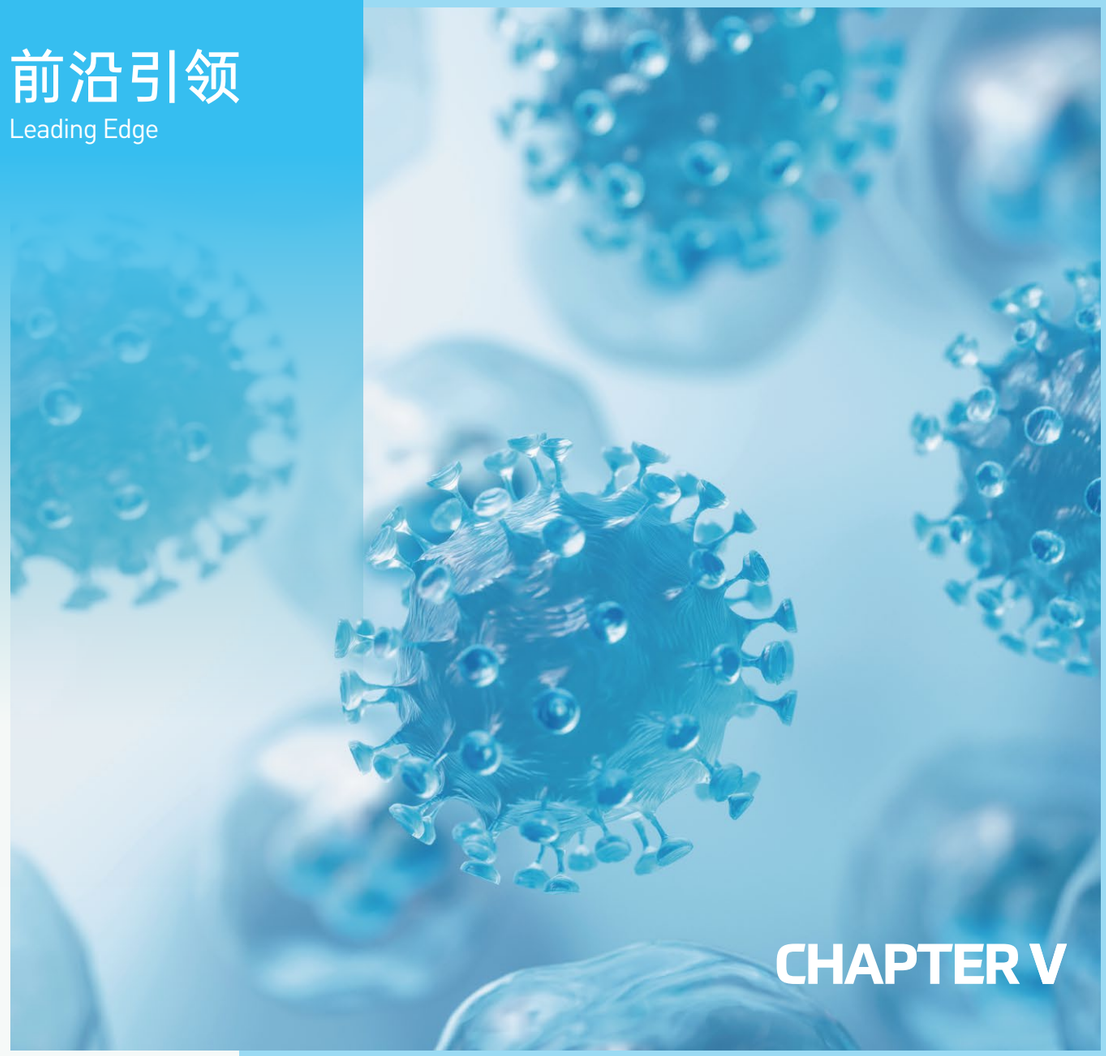
CREDIT 科瑞德

Established in 2000, Sichuan Credit Pharmaceutical Co., Ltd. is a high-tech enterprise that integrates research and development, production, and sales. The company is located at No. 8, Jiuxiang Avenue, Pharmacy Industrial Park of Luzhou National Hi-tech Industrial Development Zone, Sichuan. It covers an area of 260 acres and employs more than 1,500 staff members. CREDIT boasts a wide range of production lines, including capsules, tablets, freeze-dried powder injections, liquid drug injections, anti-tumor solid preparations, and extraction of Chinese traditional medicine. The company specializes in CNS and operates subsidiaries including Luzhou Credit Pharmaceutical Co., Ltd., Sichuan Zhongling Chuangtuo Pharmaceutical Technology Co., Ltd., Fidelity Biopharma (USA) Co., Ltd., Sichuan CreditMedeia Medical Equipment Co., Ltd., and Sichuan Ruide Zhongshu Digital Medical Technology Co., Ltd. In 2022, the company allocated more than 14% of its sales revenue to research and development. It has a dedicated research and development team of nearly 200 full-time researchers, among which over 60 researchers hold a master's degree or above. The company currently holds 67 authorized patents, 46 registered trademarks, 19 drug production licenses, 10 bulk drug registration numbers, 3 medical device registration certificates, and 18 major ongoing projects focused on CNS diseases, including 7 improved new drugs and 11 high-end generic drugs. CREDIT consistently upholds the principle of "Quality First and Innovation-driven Development" and adheres unwaveringly to the values of "Compliance, Professionalism, Integrity, and Gratitude". The company is dedicated to becoming an "outstanding Chinese pharmaceutical enterprise renowned worldwide and a leader in products for CNS in China". It is stepping confidently into a new era of growth.

05

前沿引领
Leading Edge

LEADING
EDGE



中枢神经系统疾病或将成为肿瘤之后新药研发领域新风口

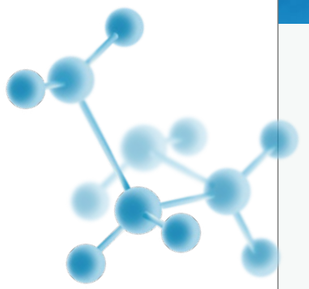
CNS Diseases May Become a New Trend in New Grug Development Following Tumors

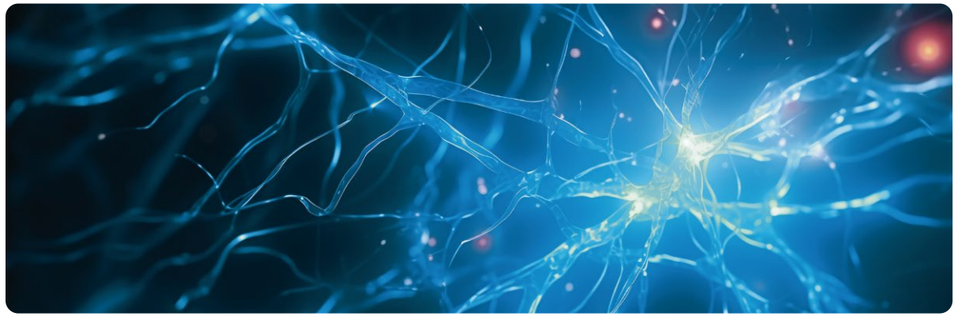
NEUROLOGICAL SYSTEM
DISEASE DRUGS

与肿瘤领域相比，中枢神经系统疾病研究受脑科学发展的限制，在全球范围内起步较晚，研究人员数量较少，过去获得的科研资金支持也相形见绌。然而，伴随人类生活环境的改变和寿命的延长，中枢神经系统疾病正逐渐成为全球最大的疾病负担之一，超十亿患者正在经受不同神经系统疾病所带来的痛苦，他们迫切需要精准有效的治疗手段和药物。我国“十四五”规划明确提出加强抑郁障碍、焦虑障碍、睡眠障碍、儿童心理行为发育异常、老年痴呆等常见精神障碍和心理行为问题干预。这些常见的中枢神经系统疾病被提升到了国家层面的高度，成为需要重点关注的疾病类型。中国科学院院士、北京大学第六医院院长陆林表示：“脑疾病诊疗的突破符合人民对健康的需求和国家战略的需求。”在过去的二十年里，全球许多国家纷纷推出脑计划，我国也于2018年分别成立了北方和南方脑科学与类脑研究中心。在领域专家们的积极推动下，2021年“中国脑计划”正式启动。陆林院士作为脑疾病领域召集人，擘画脑疾病领域研究的宏伟蓝图。中国脑计划的最终目标是解决包括中枢神经系统疾病在内的各种脑疾病，其总体目标是以涵盖健康人群和脑疾病患者的全生命周期为特点，结合基因组学、影像学、症状学等多模态数据，打造集采集、分析、共享于一体的中国人脑健康多维度大数据平台，制定疗效评价体系，研发新型治疗手段。陆林院士强调，中国脑计划为人工智能与精神医学的深度融合提供了契机，必将带来精神病学研究的重大突破，同时促进相关学科的发展和进步。

NEUROLOGICAL SYSTEM DISEASE DRUGS

Compared to the field of oncology, the study of central nervous system (CNS) diseases has been limited by the development of brain science and started later globally with fewer researchers and less scientific research funding in the past. However, with changes in human living environments and increased life expectancy, CNS diseases are gradually becoming one of the largest disease burdens worldwide. Over a billion patients are suffering from various neurological diseases and they urgently need precise and effective treatment methods and drugs. China's "14th Five-Year Plan" has clearly put forward the need to strengthen interventions for common mental disorders and psychological and behavioral problems such as depressive disorders, anxiety disorders, sleep disorders, children's abnormal psychological and behavioral development, and senile dementia. These common CNS diseases have been highlighted at the national level and have become disease types that require special attention. "Breakthroughs in the diagnosis and treatment of brain diseases are in line with the people's needs for health and national strategic needs," said Lu Lin, Academician of the Chinese Academy of Sciences and Director of Peking University Sixth Hospital. Over the past two decades, many countries around the world have launched brain projects, and China established the Northern and Southern Research Centers for Brain Science and Brain-inspired Intelligence in 2018. With the active support of experts in the field, the "China Brain Project" officially launched in 2021. Academician Lu Lin, as the convener of the brain disease field, has outlined an ambitious blueprint for research in this field. The ultimate goal of the China Brain Project is to address various brain diseases, including CNS diseases. Its overall objective is to create a comprehensive Chinese brain health multidimensional big data platform that encompasses the entire lifecycle of healthy individuals and patients with brain diseases and integrates multimodal data, including genomics, imageology, and symptomatology, for data collection, analysis, and sharing, and develop an evaluation system of clinical effect and new treatment methods. Academician Lu Lin emphasized that the China Brain Project provided an opportunity for deep integration between artificial intelligence and psychiatry, which would lead to great breakthroughs in the research of psychiatry, while also promoting the development and advancement of related disciplines.





早在2018年世界生命科学大会上，中国科学院院士、复旦大学脑科学转化研究院院长段树民就谈到，神经系统方面的疾病，包括各种神经精神疾病，对人类身心健康所造成的危害是非常严重的，甚至超过了癌症对人类的影响。近年来，全球对中枢神经系统疾病的关注度逐渐提高，资金和研发也呈现迅速上升的趋势。可以预见，中枢神经系统或将成为肿瘤之后新药研发领域的下一个风口。在科学研究方面，过去几年人类在生物医学领域取得了许多进步，尤其是在干细胞、基因编辑、类器官等方面的技术突破，给中枢神经系统疾病的创新药物研发带来了更多机会。在临床诊断方面，寻找精神疾病客观标志物、研发新型诊疗技术势在必行，已成为精神医学的重要研究方向。随着脑成像技术、电生理学方法等神经生物学技术的进步，以及信息科学、人工智能和脑机接口技术的飞速发展，精神疾病的诊疗也迎来新的发展契机。在新药创制方面，目前对于中枢神经系统疾病新药研发也是一个难得的历史性机遇，面对日趋高发的中枢神经系统疾病和未满足临床需求，国家接连出台政策鼓励，监管机构持续支持。我们期待中枢神经系统疾病新药研发释放活力、增强实力，以临床价值为导向，聚焦未满足临床需求，研发出患者亟需的新药物和新技术。

As early as the 2018 World Life Science Conference, Duan Shumin, Academician of the Chinese Academy of Sciences and Director of the Institute for Translational Brain Research, Fudan University, pointed out that diseases related to the nervous system, including various neurological and psychiatric diseases, would pose a significant threat to human physical and mental health, even surpassing the impact of cancer. In recent years, the global attention to CNS diseases has gradually increased, accompanied by a rapid rise in funding and research and development. It is foreseeable that the CNS may become the next trend in new drug development, following cancer. In terms of scientific research, many advancements have been made in the biomedical field over the past few years, particularly in technological breakthroughs related to stem cells, gene editing, organoids, and so on, which have brought more opportunities for innovative drug development for CNS diseases. In terms of clinical diagnosis, the exploration of objective markers for psychiatric diseases and the development of new diagnosis and treatment technologies have become imperative as an important research direction in psychiatry. With the advancements in brain imaging technology, electrophysiological methods, and other neurobiological technologies, as well as the rapid development of information science, artificial intelligence, and brain-computer interface technology, there are new opportunities for the diagnosis and treatment of psychiatric diseases. In terms of new drug innovation and development, there is currently a rare historic opportunity for new drug development for CNS diseases. In response to the increasing prevalence of CNS diseases and unmet clinical needs, the government has issued a series of encouragement policies, with continuous support from regulatory agencies. Guided by clinical value, with a focus on unmet clinical needs, the new drug development for CNS diseases is expected to unleash vitality and enhance strength, thereby developing new drugs and technologies urgently needed by patients.

06

园区动态
Park Dynamics

PARK
DYNAMICS

CHAPTER VI

PARK
DYNAMICS

LIVE
园区动态

园区6家企业入选 四川省“专精特新”中小企业名单

Six Enterprises in the Park Are Included in the List of Specialized, Refined, Special, and Innovative SMEs in Sichuan

四川省经济和信息化厅发布2023年度四川省专精特新中小企业拟通过名单，成都高新区37家生物医药企业进入名单，总量占成都市拟通过生物医药企业（77家）的48%。

The Sichuan Provincial Economic and Information Department has released the list of specialized, refined, special, and innovative small and medium-sized enterprises in Sichuan Province in 2023. Thirty-seven bio-pharmaceutical enterprises in Chengdu Hi-tech Zone are included in the list, accounting for 48% of the total number (77) of bio-pharmaceutical enterprises to be included in Chengdu.

其中天府生命科技园和成都前沿医学中心共有6家园区企业入选该名单，具体企业名单如下：

Among them, six enterprises in Tianfu Life Science Park and Chengdu Advanced Medical Science Center have been included in the list. The specific list of enterprises is as follows:

序号	市州	区县	企业名称	申报类型
01	成都市	高新区	成都柏奥特克生物科技股份有限公司	新认定
02	成都市	高新区	成都格纯生物医药有限公司	新认定
03	成都市	高新区	成都可恩生物科技有限公司	新认定
04	成都市	高新区	成都欧林生物科技股份有限公司	复核
05	成都市	高新区	成都微芯药业有限公司	新认定
06	成都市	高新区	成都优赛诺生物科技有限公司	新认定
07	成都市	高新区	迈克生物股份有限公司	新认定
08	成都市	高新区	迈克医疗电子有限公司	新认定
09	成都市	高新区	四川汇利实业有限公司	新认定
10	成都市	高新区	四川制药制剂有限公司	新认定
11	成都市	高新区	四川合泰新光生物科技有限公司	新认定
12	成都市	高新区	成都博恩思医学机器人有限公司	新认定
13	成都市	高新区	四川国纳科技有限公司	新认定
14	成都市	高新区	成都瀚辰光翼科技有限责任公司	复核
15	成都市	高新区	马太科技有限公司	新认定
16	成都市	高新区	成都华西公用医疗信息服务有限公司	新认定
17	成都市	高新区	成都柏开图医疗系统科技有限公司	新认定
18	成都市	高新区	成都智数医联科技有限公司	新认定
19	成都市	高新区	四川福济生鸿医疗科技有限公司	新认定
20	成都市	高新区	四川美康医药软件研究开发股份有限公司	新认定
21	成都市	高新区	四川卫宁软件有限公司	复核
22	成都市	高新区	药融云数字科技（成都）有限公司	新认定
23	成都市	高新区	成都阿帕洁生物科技有限公司	新认定
24	成都市	高新区	成都二十三魔方生物科技有限公司	新认定
25	成都市	高新区	成都华西临床研究中心有限公司	新认定
26	成都市	高新区	成都凌泰氢生物技术有限公司	新认定
27	成都市	高新区	成都诺和晟泰生物科技有限公司	复核
28	成都市	高新区	成都赛璟生物医药科技有限公司	新认定
29	成都市	高新区	成都施贝康生物医药科技有限公司	新认定
30	成都市	高新区	成都西岭源药业有限公司	复核
31	成都市	高新区	成都雅途生物技术有限公司	新认定
32	成都市	高新区	成都医路康医学技术服务有限公司	复核
33	成都市	高新区	四川至善唯新生物科技有限公司	新认定
34	成都市	高新区	中核中同蓝博（成都）医学检验有限公司	新认定
35	成都市	高新区	成都金瑞基业生物科技有限公司	新认定
36	成都市	高新区	舒美奇成都生物科技有限公司	新认定
37	成都市	高新区	四川嘉博文生物科技有限公司	新认定

此次名单中，园区企业成都雅途生物技术有限公司，舒美奇成都生物科技有限公司，四川合泰新光生物科技有限公司3家企业为新认定企业。成都西岭源药业有限公司，成都医路康医学技术服务有限公司，成都诺和晟泰生物科技有限公司3家企业通过复核。

In this list, three enterprises in the park, Yacht Biotechnology Co., Ltd., Shumeiqi Chengdu Biotechnology Co., Ltd., and Sichuan SYNLIGHT Biotechnology Co., Ltd., are newly designated. Three enterprises, Xiling Lab, Chengdu Yilukang Medical Technology & Service Co., Ltd., and Chengdu Sintanovo Biotechnology Co., Ltd., passed the review.

成都前沿医学中心
成都分迪药业有限公司自主研发产品顺利获临床批准！

FenDi Pharmaceutical in Chengdu Advanced Medical Science Center Successfully Obtains Clinical Approval for an Independently Developed Product!

2023年6月，成都前沿医学中心成都分迪药业有限公司自主研发的首个口服分子胶药物FD-001，顺利获得国家药监局的临床试验批准。

In June 2023, FD-001, the first oral molecular gel drug independently developed by FenDi Pharmaceutical in Chengdu Advanced Medical Science Center, has successfully obtained clinical trial approval from the National Medical Products Administration (NMPA).

成都分迪药业自主研发的首个口服分子胶药物FD-001经过CDE专家科学严谨的审评，顺利获得国家药监局的临床试验批准。FD-001拟用于急性髓系白血病（AML）、多发性骨髓瘤（MM）和非霍奇金淋巴瘤（NHL）等血液肿瘤的治疗。

The FD-001 has obtained clinical trial approval from NMPA through rigorous scientific evaluation by CDE experts. It is intended for the treatment of hematologic malignancies such as Acute Myeloid Leukemia (AML), Multiple Myeloma (MM), and non-Hodgkin's Lymphoma (NHL).

FD-001是利用分迪药业专有的"ProDeDrug"分子胶合理设计平台开发的一种口服分子胶药物。临床前研究显示，其具有治疗AML、MM和NHL等血液肿瘤的潜力。小鼠异种移植肿瘤模型体内药效研究表明，间断给药可以显著减少肿瘤体积，进一步确定了患者的给药频率。

FD-001, created using FenDi Pharmaceutical's proprietary "ProDeDrug" molecular gel rational design platform, has shown potential in preclinical studies for treating AML, MM, NHL, and other hematologic malignancies. Efficacy studies in mouse xenograft tumor models have indicated that intermittent administration can significantly reduce tumor volume, further establishing the administration frequency for patients.

CLINICAL TRIAL APPROVAL

重要的是，FD-001给药不到两周即可完全消除肿瘤，并在研究结束前动物体内肿瘤不复发。这是由于FD-001可降解血液肿瘤中的转录因子GSPT1靶蛋白，从而诱导AML、MM和NHL等肿瘤细胞的凋亡，并能清除肿瘤干细胞且不影响正常造血干细胞，可克服维奈克拉（Venetoclax）的不足。

What counts is that FD-001 can achieve complete tumor elimination in less than two weeks of administration, with no tumor recurrence observed in animal models by the end of the study. This is attributed to FD-001's ability to degrade the transcription factor GSPT1 target protein in hematologic malignancies, thereby inducing apoptosis in tumor cells like AML, MM, and NHL, while removing tumor stem cells without affecting normal hematopoietic stem cells, overcoming the limitations of Venetoclax.

临床前研究还表明，FD-001具有优异的口服吸收能力，使得其在动物体内的药效优于BMS的CC900009和BiotheryX的BTX-1188。FD-001在同剂量下体内药效是CC900009的25倍，完全清除肿瘤的剂量是BTX-1188的1/13。动物安评研究显示，其安全剂量略高于CC90009。因此，FD-001相对于前两者具有更宽的安全窗口。

Preclinical studies have also demonstrated FD-001's excellent oral absorption capabilities, resulting in superior efficacy in animals compared to BMS's CC900009 and BiotheryX's BTX-1188. At an equivalent dosage, the in vivo efficacy of FD-001 is 25 times that of CC900009, and the dosage required for complete tumor removal is 1/13 of that of BTX-1188. Animal safety assessment studies reveal that the safe dosage of FD-001 is slightly higher than that of CC90009. Therefore, FD-001 possesses a wider safety margin compared to the former two.

分迪药业CEO蔡鑫博士表示，"FD-001与CC90009等单独降解GSPT1的分子胶不同，除主要降解GSPT1，后续研究证明其也降解IKZF1/3，双靶点的降解结合了对肿瘤细胞的有效杀灭和对免疫系统的调节作用，有望成为同类最优的药物分子，可产生更好的疗效和更少的潜在毒副作用。我们将快速推进该分子胶的临床试验，鉴于AML在美国属于罕见病，而在中国具有患者优势，FD-001有望成为该靶点全球首家获批上市药物。我们也正在通过合作方式积极探索分子胶偶联抗体药物，希望拓展分子胶药物的疾病治疗领域。"

Dr. Cai Xin, CEO of FenDi Pharmaceutical, stated, "FD-001, unlike molecular gels that solely degrade GSPT1 such as CC90009, has been shown in subsequent research to also degrade IKZF1/3. The dual-target degradation combines the effective eradication of tumor cells with modulation of the immune system, making it a promising candidate for the most optimal drug molecule in its class, offering better efficacy and fewer potential side effects. We will rapidly advance the clinical trials of this molecular gel, considering AML as a rare disease in the United States but having a patient advantage in China. FD-001 is poised to become the world's first approved drug for this target. We are also actively exploring molecular gel antibody-drug conjugates through collaborative efforts, aiming to expand the therapeutic scope of molecular gel drugs."

本次分迪药业自主研发的首个口服分子胶药物FD-001顺利获得国家药监局的临床试验批准，不仅实现了从PCC到获临床试验默示许可仅11个月的"分迪速度"，更铸造了分迪药业首个口服分子胶新药的重要里程碑。

The successful clinical trial approval by NMPA for FD-001, FenDi Pharmaceutical's first independently developed oral molecular gel drug, has not only achieved the "FenDi speed" from PCC to clinical trial implied license in just 11 months but also forged a crucial milestone for FenDi Pharmaceutical's first oral molecular gel new drugs.

园区开展"不七而遇，缘系今夕——七夕游园会"文化活动

The Park Hosts "Serendipity on Qixi Festival, Destiny Tonight - Qixi Garden Party" Cultural Event

8月22日和8月23日，天府生命科技园&成都前沿医学中心开展"不七而遇，缘系今夕——七夕游园会"特别活动，为园区员工的工作生活增添乐趣.七夕游园会活动分别在天府生命科技园中庭广场与成都前沿医学中心举行，众多园区企业员工在午休时间结伴来到现场，积极体验园区文化活动。

On August 22 and 23, Tianfu Life Science Park and Chengdu Advanced Medical Science Center organized a special event titled "Serendipity on Qixi Festival, Destiny Tonight - Qixi Garden Party" to add fun to the work and life of park employees. The Qixi Garden Party took place at the Atrium Square of Tianfu Life Science Park and Chengdu Advanced Medical Science Center during lunch hours, with numerous employees from various park enterprises actively participating in the cultural activities.

本次活动共设置五个环节，分别是“穿珠乞巧”“鹊桥相会”、“一见倾心”、“极限拉扯”和“爱的圈套”。“穿珠乞巧”环节中，员工们手工制作串珠手链体会“穿七孔针”这一七夕传统习俗的独特魅力，在“鹊桥相会”环节，员工们在信息卡片上写下自己的“七夕宣言”，互换联系方式、结交新朋友。在其他游戏环节，参与者两两组队，共同完成游戏任务，并收获“专属”小礼物。

The event featured five segments: "Begging for Ingenuity through Bead-threading", "Meeting on the Magpie Bridge", "Love at First Sight", "Extreme Tug", and "Love's Trap". In the "Begging for Ingenuity through Bead-threading" segment, employees handcrafted beaded bracelets to experience the unique charm of the traditional Qixi custom of "threading seven needles with colored threads". In the "Meeting on the Magpie Bridge" segment, employees wrote their Qixi declarations on information cards, exchanged contact information, and made new friends. In other game segments, participants worked in pairs to complete game tasks and obtain "exclusive" small gifts.

CULTURAL YEAR SERIES ACTIVITIES




本场园区七夕游园会活动不仅有竞技趣味，也为园区企业员工提供了交流互动的契机。通过互动小游戏和互换信息卡片收获了愉悦和友谊，七夕游园会活动在浪漫和美好的氛围中圆满结束。

This Qixi Garden Party not only provided competitive and entertaining activities but also served as an opportunity for interaction and communication among park employees. The interactive games and the exchange of information cards fostered joy and friendship, concluding the Qixi Garden Party in a romantic and delightful atmosphere.




由成都高投生物医药园区管理有限公司打造的园区文化活动品牌“BioTianfu文化年系列活动”，将持续结合园区文化氛围需求和企业诉求，在活动中柔性植入当前宣传热点和传统节日相应主题，积极营造贴心、舒适、轻松的园区氛围。

The park's cultural event brand, "BioTianfu Cultural Year Series Activities", created by CDHT Investment Group Biomedicine Industrial Park Management Co., Ltd., will flexibly incorporate current promotional hot topics and themes corresponding to traditional festivals by continuing to combine the needs of the cultural atmosphere in the park with corporate demands, to actively create an intimate, comfortable, and relaxed park atmosphere.

专利检索利用与知识产权融资培训活动顺利举办

Successful Hosting of Patent Retrieval Utilization and Intellectual Property Financing Training Event

8月25日，2023年天府生命科技园&成都前沿医学中心专利检索利用与知识产权融资培训活动在天府生命科技园顺利举行。本次活动由成都高投生物医药园区管理有限公司主办，成都技转创业孵化管理有限公司执行承办。活动旨在围绕园区企业需求，针对早中期生物医药企业对知识产权开发及运营的疑难困惑，发挥天府生命科技园&成都前沿医学中心"一站式科技服务"功能作用，常态化、多维度地辅导企业成长。

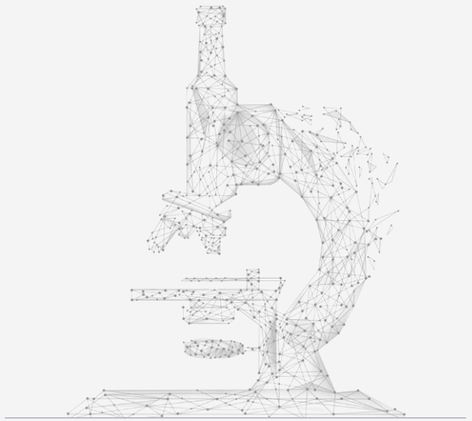
On August 25, the 2023 Tianfu Life Science Park & Chengdu Advanced Medical Science Center Patent Retrieval Utilization and Intellectual Property Financing Training Event was successfully held at Tianfu Life Science Park. The event, hosted by CDHT Investment Group Biomedicine Industrial Park Management Co., Ltd. and undertaken by Chengdu Technology Transfer and Entrepreneurship Incubation Management Co., Ltd., aimed to provide regular and multidimensional guidance to facilitate the growth of early and mid-stage biopharmaceutical enterprises by focusing on their demands, addressing their challenges and puzzlement in intellectual property development and operation, and giving full play to the "one-stop technology service" function of Tianfu Life Science Park & Chengdu Advanced Medical Science Center.

活动邀请了知识产权领域专业讲师——四川九鼎天元集团有限公司副总经理、正高级知识产权师房云，以及成都知识产权交易中心运营服务部/金融服务部负责人、高级知识产权师覃文鸷为参会企业作主题分享。

The event featured professional speakers in the field of intellectual property, including Fang Yun, Deputy General Manager and Senior Intellectual Property Engineer of Sichuan Jiuding Tianyuan Group Co., Ltd., and Qin Wenzhi, Head of Operation Services Department/Financial Services Department of Chengdu Intellectual Property Exchange and Senior Intellectual Property Engineer, who delivered theme presentations to the participating enterprises, respectively.

培训会上，主讲老师房云从专利检索实务、意义及价值等方面进行了重点解析，并总结生物医药企业在专利检索利用中的重点关注事项；主讲老师覃文鸷从知识产权托管及运营、知识产权质押贷款流程及政策进行了详细介绍，并逐一分享了生物医药企业在质押贷款方面的案例和注意事项。分享结束后，讲师与现场企业进行了深入沟通，为参会企业答疑解惑。

During the training session, Fang Yun provided a focused analysis of the practice, significance, and value of patent retrieval, and concluded by summarizing the key considerations for biopharmaceutical enterprises in the utilization of patent retrieval. Additionally, Qin Wenzhi gave a detailed introduction to intellectual property trusteeship and operation and the process and policies of intellectual property pledge loans and systematically shared specific cases and considerations of biopharmaceutical enterprises in pledge loans. Following the presentations, the speakers engaged in in-depth discussions with the participating enterprises and answered their questions.



成都高新区促进医药健康产业新赛道发展政策研讨会召开

Holding of the Seminar on the Policy of Chengdu Hi-tech Zone to Foster the Development of New Tracks in the Pharmaceutical and Health Industry

7月10日，成都高新区促进医药健康产业新赛道发展政策研讨会在成都前沿医学中心成功召开。

On July 10, the Seminar on the Policy of Chengdu Hi-tech Zone to Foster the Development of New Tracks in the Pharmaceutical and Health Industry was successfully held at the Chengdu Advanced Medical Science Center.

强化医药健康产业政策支撑，推动新赛道形成新优势

Strengthening Policy Support for the Pharmaceutical and Health Industry and Fostering New Advantages of New Tracks in the Industry

本次活动由成都高新区生物产业局主办，成都高投生物医药园区管理有限公司协办，吸引了高新区生物产业专家联合会、成都电子科技大学、精准医学产业创新中心、成都京东方医院、成都智算中心等科研机构，以及倍特药业、海创药业、优赛诺、齐碳科技等创新药械企业参加。

Hosted by the Biotechnology Industry Bureau of Chengdu Hi-tech Zone and co-organized by CDHT Investment Group Biomedicine Industrial Park Management Co., Ltd., the seminar attracted participants from the Biotechnology Industrial Expert Federation of Hi-tech Zone, University of Electronic Science and Technology of China, National Industrial Innovation Center of Precision Medicine, Chengdu BOE Hospital, Chengdu AI Computing Centre, and other research institutions, as well as innovative medical instrument enterprises such as Brilliant Pharmaceuticals, Hinova, UCELLO, Qitan Tech.

活动现场，生物产业局相关负责人介绍了当前《成都高新区促进医药健康产业新赛道发展政策》的制定推进情况，同时表示高新区将致力于解决新赛道企业面临的行业发展痛点。

During the event, officials from the Biotechnology Industry Bureau introduced the progress of the formulation and implementation of the Policy of Chengdu Hi-tech Zone to Foster the Development of New Tracks in the Pharmaceutical and Health Industry and Health Industry. They emphasized the commitment of the Hi-tech Zone to addressing the industrial development pain points faced by enterprises in the new tracks.

据了解，为深入推进落实产业建圈强链行动，进一步促进医药健康产业高质量发展，成都高新区不断强化医药健康产业政策支撑，2022年的出台《成都高新区技术产业开发区医药健康产业建圈强链发展政策》，获评成都市2022年"十大重大行政决策示范案例"。

To further advance the implementation of the initiative of building the industrial circle and strengthening the industrial chain, and to promote the high-quality development of the pharmaceutical and health industry, Chengdu Hi-tech Zone has consistently reinforced policy support. In 2022, the Development Policy of Chengdu Hi-tech Industrial Development Zone to Build the Industrial Circle and Strengthen the Industrial Chain in the Pharmaceutical and Health Industry was introduced, earning recognition as one of Chengdu's "Top 10 Major Administrative Decision-making Demonstration Cases" in 2022.

在此基础上，为推动新赛道形成新优势，计划制定《成都高新区促进医药健康产业新赛道发展政策》，拟从创业、投融资、高水平基础研究及关键技术突破、临床研究、产品应用、人才汇聚、企业政务服务等多维度进行支持，助推高新区数字疗法、基因测序设备、细胞和基因治疗、基于人工智能的新药研制、核酸药物、手术机器人、脑机接口等新赛道发展。

Building on this foundation and aiming to foster new advantages of new tracks, Chengdu Hi-tech Zone plans to formulate the Policy of Chengdu Hi-tech Zone to Foster the Development of New Tracks in the Pharmaceutical and Health Industry, which will provide support across multiple dimensions, including entrepreneurship, investment and financing, high-level basic research, breakthroughs in key technologies, clinical research, product applications, talent attraction, and government services for enterprises, aiming to boost the development of new tracks such as digital therapy, gene sequencing equipment, cell and gene therapy, AI-based new drug development, nucleic acid drugs, surgical robots, and brain-machine interfaces.

作为成都市医药健康产业发展主阵地，成都高新区秉持产业建圈强链理念，持续推进创新药、医疗器械等重点产业链高质量发展，推动全国唯一国家精准医学产业创新中心、天府锦城实验室(前沿医学中心)、国家卫健委科技发展中心全国首个示范平台（卫生健康科技成果转移转化示范平台）落地等。

As the main front for the development of the pharmaceutical and health industry in Chengdu, Chengdu Hi-tech Zone adheres to the concept of building the industrial circle and strengthening the industrial chain. It continues to promote the high-quality development of key industrial chains such as innovative drugs and medical devices, driving the establishment of the National Industrial Innovation Center of Precision Medicine, Tianfu Jincheng Laboratory (Advanced Medical Science Center), and the first national demonstration platform of the Science and Technology Development Center of National Health Commission of the People's Republic of China (Demonstration Platform for the Transfer and Transformation of Health Scientific and Technological Achievements).

今年以来，成都高新区“抓关键”“求突破”，持续打造一流营商环境，在医药健康产业稳增长核心支撑、科技创新等方面取得诸多突破，顺利推动威斯克生物全球首个针对XBB等新冠变异株的3价疫苗获批紧急使用，吸引费森尤斯奥美德集团中国西南区总部及国际医院等跨国500强企业，以及投资100亿元的绿叶生命科学研发及产业创新基地等重大项目纷纷落地，实现世界500强赛诺菲的“度普利尤单抗注射液”成为全省首个通过保税物流模式通关的进口单抗类生物制品……

Since the beginning of this year, Chengdu Hi-tech Zone has been focusing on critical aspects and seeking breakthroughs, continuously building a first-class business environment, with numerous breakthroughs made in core support for the stable growth of the pharmaceutical and health industry, scientific and technological innovation, and other aspects. It has successfully promoted the global approval for emergency use of WestVac Biopharma's trivalent vaccine targeting new variants such as XBB in COVID-19, attracted multinational Fortune Global 500 companies, including Southwest China Headquarters of Fresenius VAMED Group and international hospitals, implemented major projects, including the 10-billion-yuan R&D investment of Luye Life Sciences and industrial innovation bases, achieved Sichuan Province's first import clearance through the bonded logistics model for the monoclonal antibody product "Dupilumab Injection" by Sanofi, a Fortune Global 500 company, etc.

下一步，成都高新区生物产业局将持续聚焦产业建圈强链，紧盯科技创新和产业发展前沿，着力解决新赛道企业发展问题，不断优化新赛道发展政策，强化医药健康产业政策支撑，推动新赛道形成产业发展新优势。

In the next phase, the Biotechnology Industry Bureau of Chengdu Hi-tech Zone will continue to focus on building the industrial circle and strengthening the industrial chain by closely following the forefront of scientific and technological innovation and industrial development, addressing the development issues of companies in new tracks, continuously optimizing policies for the development of new tracks, and strengthening policy support for the pharmaceutical and health industry, to foster new advantages of new tracks in industrial development.

MEDICAL CENTER

园区企业西岭源1类新药临床试验获批！

Clinical Trial Approval Granted for Category 1 New Drug Developed by Xiling Lab in the Park!

园区企业西岭源药业全资子公司自主研发的1类新药注射用SMP-656临床试验获批。

The wholly-owned subsidiary of Xiling Lab, a company in the park, has received approval for the clinical trial of the independently developed Category 1 new drug, injectable SMP-656.

2023年8月24日，成都西岭源药业有限公司（以下称“西岭源药业”）全资子公司成都科岭源医药技术有限公司（以下称“科岭源”）自主研发的治疗用生物制品1类新药“注射用SMP-656”，收到国家药品监督管理局（NMPA）批准签发的《药物临床试验批准通知书》。

On August 24, 2023, Chengdu Kelingyuan Pharmatech Co., Ltd. (Kelingyuan for short), a wholly-owned subsidiary of Xiling Lab Co., Ltd. (Xiling Lab for short), received the Notice of Approval of Drug Clinical Trials approved and issued by the National Medical Products Administration for "Injectable SMP-656", a Category 1 new drug developed independently.

SMP-656是科岭源基于创新XL-XDC平台自主开发的HER2-ADC，HER2靶点成熟且全球已有3款创新ADC获批上市，因此未来临床开发成功率高。

SMP-656 is a HER2-ADC developed by Kelingyuan based on the innovative XL-XDC platform. The HER2 target is mature, and three innovative ADCs have been approved for marketing globally, indicating a high success rate in future clinical development.

毒素选用机制新颖、合成技术壁垒超高且已获批上市的艾立布林，在适应症筛选方面有其固有差异化优势，且非临床体内外药效也显著优于同类标杆产品。

Eribulin, characterized by a novel toxin selection mechanism, high synthetic technology barriers, and marketing approval, boasts inherent differentiation advantages in indication selection. Additionally, its non-clinical in vivo and in vitro efficacy is significantly superior to similar benchmarking products.

优选具有自主知识产权的独特亲水性和稳定性的SuperHydra linker，显著降低分子聚集度和免疫原性，且分子血液循环稳定性优异，从而极大拓宽ADC的治疗指数，安全窗显著优于同靶点同毒素的ADC。此外，SMP-656在非临床体内药效持久，极具转化为临床上的持久获益的潜力。

The preferred SuperHydra linker with independent intellectual property rights, characterized by unique hydrophilicity and stability can significantly reduce molecular aggregation and immunogenicity, and its molecular blood circulation stability is outstanding, greatly expanding the therapeutic index of ADC, with a safety window that is greatly superior to ADCs with the same target and toxin. Furthermore, SMP-656 exhibits prolonged non-clinical in vivo efficacy, demonstrating significant potential for sustained benefits in clinical settings.

关于西岭源药业 About Xiling Lab

成都西岭源药业有限公司以催化合成技术为锚点，开发高壁垒仿制药和差异化创新药，致力于打造国际领先的小分子创新药研发平台、造影剂药物开发平台、催化技术平台和偶联药物平台，开发诊断和治疗肿瘤的高端仿制药和创新药。公司已完成化学药研发、临床研究、产业化（MAH）和商业化（合作）全产业链发展的初步布局。

Xiling Lab focuses on catalytic synthetic technology to develop high-barrier generic drugs and differentiated innovative drugs. It is committed to building an internationally leading platform for the research and development of small molecule innovative drugs, contrast agent drug research and development platform, catalytic technology development platform, and ADC platform to develop high-end generic and innovative drugs for the diagnosis and treatment of tumors. The company has completed the preliminary layout of the entire industrial chain development, including chemical drug research and development, clinical research, industrialization (MAH), and commercialization (cooperation).

西岭源药业率先攻克史上最高门槛原料药之一，被誉为药物合成领域“珠穆朗玛峰”—艾立布林的关键合成技术。公司已提交甲磺酸艾立布林中、美、欧原料药（DMF）备案；中国制剂、美国制剂（ANDA）已受理，已向多家海内外药企提供高质量艾立布林原料药用于仿制药或合作ADC开发。

Xiling Lab has pioneered one of the highest-threshold bulk drugs in history, acclaimed for the key synthetic technology for Eribulin, known as the "Mount Everest" of the pharmaceutical synthesis field. The company has submitted filings for DMF of Eribulin Mesilate in China, the United States, and Europe. The Chinese formulation and U.S. formulation (ANDA) have been accepted, and its high-quality Eligulin bulk drugs have been supplied to numerous domestic and international pharmaceutical enterprises for generic drugs or cooperative ADC development.

07

创新生态
Innovation Ecology

INNOVATION
ECOLOGY

CHAPTER VII

天府生命科技园和成都前沿医学中心
圆满完成“迎大运，保安全”专项安全管理工作任务

Tianfu Life Science Park and Chengdu Advanced Medical Science Center Successfully Complete the "Embrace the Games, Ensure Safety" Special Safety Management Task

天府生命科技园和成都前沿医学中心（以下简称园区）作为具有大量危险化学品、危险废弃物的重点产业园区，是大运会期间安全管理工作的重中之重。结合高新区对园区大运会期间安全管理工作的重要指示，成都高投生物医药园区管理有限公司（以下简称“高投生物园公司”）主动作为、攻坚克难，圆满完成大运会期间园区安全管理工作，确保园区安全形势稳定。

As a key industrial park with a significant quantity of hazardous chemicals and hazardous waste, Tianfu Life Science Park and Chengdu Advanced Medical Science Center (hereinafter referred to as the Park) is of utmost importance in the safety management work during the Chengdu 2021 FISU World University Games (hereinafter referred to as the Games). Following the important directives of the Hi-tech Zone regarding safety management work in the Park during the Games, CDHT Investment Group Biomedicine Industrial Park Management Co., Ltd. (hereinafter referred to as "Gaotou Biomedical Park Management Co., Ltd.") successfully completed its safety management task by taking proactive actions and tackling challenges, ensuring the stable safety situation of the Park.

Chengdu World University Games

创新生态

01 统一思想，主动担当，高效率推动工作部署

Unified Thinking and Proactive Fulfillment of Responsibility for Efficient Progress of Work Deployment

园区建筑面积约52万平方米，入驻生物医药类企业200余家，商业配套13家，聚集生物医药从业人员超7000人。为确保园区安全管理工作高效开展，高投生物园公司科学部署、精准施策。**一是强化组织领导**，从2023年4月起即开展工作动员，铺排计划，制定方案，于7月上旬主动对接相关职能部门和园区所有重点企业，召开大运会前安全管理工作专项会议，确保全员协同作战。**二是压实责任链条**，梳理关键节点，厘清责任边界，集结专业力量组建工作专班，确保任务到人、责任到岗、要求到位。

Covering a building area of about 520,000 square meters, the Park is home to over 200 biomedical enterprises, 13 commercial facilities, and over 7,000 biomedical practitioners. To ensure the efficient execution of safety management work in the Park, Gaotou Biomedical Park Management Co., Ltd. scientifically planned and precisely executed its strategies. First, it strengthened organizational leadership by initiating work mobilization, laying out plans, and formulating schemes from April 2023. In early July, it proactively connected with relevant functional departments and all key enterprises in the Park and held a special meeting on safety management work before the Games, ensuring a unified effort from all staff. Second, it solidified the chain of responsibility by identifying key nodes, clarifying responsibility boundaries, and assembling professional forces to establish a dedicated team, ensuring that tasks were assigned to individuals, responsibilities were allocated to positions, and requirements were in place.

创新生态

02 齐抓共管，挂图作战，高标准完成工作任务

Joint Management and Plan-based Operations for High-standard Task Completion

由于大运会期间危化品车辆限制入城等规定，园区企业需提前储备足量危化品，且危废品转运工作受限，导致园区危化品和危废品存储量远超日常，安全管理工作面临巨大考验，高投生物园公司迎难而上，尽锐出战。**一是紧盯重点保安全**，协调90家危化品使用企业安全储备危化品、合理开展日常实验；每日上门巡查企业危化品使用情况，向危化品存储条件差的企业提供园区标准危化品暂存间；一对一上门协调28家重点涉危企业重新制定实验计划，涉危企业均未在大运会期间开展危险实验。**二是多措并举克难关**，制定园区安全全覆盖检查计划，采取安全隐患大排查和重点企业上门巡查相结合的方式，确保全盘掌握园区危废品使用及转运情况，打造24小时值守的标准化危废集中暂存点，并于7月21号完成园区危废清零。**三是多级联控快处置**，迅速开展园区安全生产工作摸底，建立风险预判台账，划定26处重点管控点位，实现"定时、定点、定人"应急处理机制，安排24小时应急救援小组，确保安全风险及时化解处理。

Due to regulations during the Games restricting the entry of hazardous chemical vehicles into the city, enterprises in the Park needed to stockpile a sufficient quantity of hazardous chemicals in advance. Additionally, the transport of hazardous waste was restricted, resulting in a much higher volume of hazardous chemicals and waste stored in the Park than usual, which posed an enormous challenge to safety management work. However, Gaotou Biomedical Park Management Co., Ltd. pressed ahead courageously. First, it kept an eye on the key points to ensure safety by coordinating with 90 enterprises using hazardous chemicals in the safe storage of hazardous chemicals and the reasonable implementation of daily experiments. It also conducted daily door-to-door inspections of the use of hazardous chemicals by enterprises and provided temporary standard hazardous chemical storerooms for enterprises with poor storage conditions. In addition, it conducted one-to-one door-to-door coordination with 28 key hazardous chemical enterprises to redesign their experimental plans, ensuring that none of them conducted dangerous experiments during the Games. Second, it adopted multiple measures to overcome difficulties. By devising a comprehensive safety inspection plan for the Park, with the combination of a thorough investigation of potential safety hazards and door-to-door inspections of key enterprises, it aimed to ensure a full grasp of the use and transport of hazardous waste in the Park. It also established temporary standardized hazardous waste storage points with 24-hour surveillance and successfully achieved zero hazardous waste in the Park on July 21. Third, it implemented multi-level joint control and rapid response. It quickly conducted an assessment of safety production in the Park, established a risk prediction ledger, designated 26 key control points, implemented a "time-based, location-specific, and personnel-designated" emergency response mechanism, and arranged a 24-hour emergency rescue team, ensuring the timely resolution of safety risks.

创新生态

03 推陈出新，完善机制，高质量巩固工作成效

Innovating and Refining Mechanisms to Consolidate Work Achievements with High Quality

为更好地实现园区安全管理工作精细化、制度化、智能化，结合本次大运会安全管理工作的经验，高投生物园公司下一步将重点从以下三方面入手进一步提升园区安全管理成效。**一是打造危化品集中管理平台**，通过线上管理系统在线管控企业危化品实时情况、重点区域重点设备运行情况、企业履职情况、日常巡查整改情况等，提升园区对危化品管理的精准性和智能化程度。**二是深化全过程管控体系**，以线上和线下手段结合实现"危化品集中配送入园+在园标准化管理+危废集中转运出园"的全过程管理流程。**三是制定行业标准化管理准则**，联合天府生命科技园安全生产联合会及行业专家共同编制《成都高新区医药研发场所安全管理手册》（暂定名），形成生物医药行业全生命周期安全管理体系。

To achieve more precise, systematic, and intelligent safety management work in the Park, building on the safety management experience gained during the Games, Gaotou Biomedical Park Management Co., Ltd. will focus on the following three key areas to further enhance the effectiveness of safety management in the Park. First, it plans to establish a centralized management platform for hazardous chemicals, which involves developing an online management system to monitor real-time information about hazardous chemicals used by enterprises, the operation of key equipment in critical areas, enterprise compliance, and the situations of daily inspections and remediation, to improve the precision and intelligence of hazardous chemical management in the Park. Second, efforts will be made to deepen the whole-process control system, which involves combining online and offline methods to establish a whole-process management procedure, covering "centralized distribution of hazardous chemicals into the Park + standardized in-park management + centralized transport of hazardous waste out of the Park". Third, it will endeavor to develop industrial standardized management guidelines. It will collaborate with the Safety Production Association of Tianfu Life Science Park and industrial experts to draft the Safety Management Manual for Chengdu Hi-tech Zone Pharmaceutical R&D Sites (tentative name), to establish a safety management system for the full life circle of the biomedical industry.

下一步，高投生物园公司将持续做好各板块安全管理工作，不断思考安全管理新模式，提升安全管理能力，为高新区建设世界一流高科技园区贡献力量。

In the next phase, Gaotou Biomedical Park Management Co., Ltd. will continue to excel in all aspects of safety management work, explore new safety management models, and enhance safety management capabilities, thereby contributing to establishing a world-class high-tech park in the Hi-tech Zone.

GAOTOU BIOMEDICAL PARK