UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

OSR HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-41390	84-5052822
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

10900 NE 4th Street, Suite 2300 Bellevue, WA	98004
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (425) 635-7700

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol:	Name of Each Exchange on Which Registered:
Common stock, par value $0.0001 per share	OSRH	The Nasdaq Stock Market LLC
Redeemable warrants, exercisable for shares of common stock at an exercise price of $11.50 per share	OSRHW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the Registrant on December 31, 2025, based upon the closing price of $0.56 of the Registrant's common stock as reported on the Nasdaq Stock Market, was approximately $7.7 million. Common stock held by each officer and director and by each person known to the registrant who owned 10% or more of the outstanding voting and non-voting common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2026, there were 33,124,755 shares of common stock, par value $0.0001 per share issued and outstanding.

INTRODUCTORY NOTE

OSR Holdings, Inc. (the "Company") is a global healthcare company dedicated to advancing healthcare outcomes and improving the quality of life for people and their families. We aim to build and develop a robust portfolio of innovative and potentially transformative therapies and healthcare solutions. Our current operating businesses (through our three wholly owned subsidiaries) include (i) developing oral immunotherapies for the treatment of cancer, (ii) developing design-augmented biologics for age-related and other degenerative diseases and (iii) neurovascular intervention medical device and systems distribution in Korea. The Company's vision is to acquire and operate a portfolio of innovative healthcare-related companies globally.

Prior to the closing of our initial business combination on February 14, 2025 (the "Closing") comprising the merger via share exchange of the Company and our target company OSR Holdings, Co., Ltd. a corporation organized under the laws of the Republic of Korea ("OSR"), previously reported on Form 8-K filed February 14, 2025 and further described below, the Company operated as a blank check company under the name Bellevue Life Sciences Acquisition Corp.

Unless the context indicates otherwise, references in this report to "we," "us" or the "Company" means the OSR Holdings, Inc. and our consolidated subsidiaries, and refer to the historical operations of the Company under the name of Bellevue Life Sciences Acquisition Corp. prior to the Closing (sometimes referred to herein as "*BLAC*") and to the combined OSR Holdings, Inc. and its subsidiaries following the Closing. References to "*OSR*" refer to the legacy historical operations of OSR Holdings, Ltd. and its subsidiaries prior to the Closing. References to our "management" or our "management team" refer to our officers and directors, and references to the "Sponsor" refer to Bellevue Global Life Sciences Investors LLC, a Delaware limited liability company.

This Annual Report on Form 10-K covers the fiscal year ended December 31, 2025, and presents the consolidated results of OSR Holdings, Inc. and its consolidated subsidiaries for that fiscal year.

The Company was formed as a Delaware corporation on February 25, 2020, for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses.

On February 14, 2023, we consummated our initial public offering ("*IPO*") of an aggregate of 6,000,000 units, at $10.00 per unit ("*Units*"), generating gross proceeds of $60,000,000 before underwriting discounts and expenses.

Simultaneously with the closing of our IPO, our sponsor, Bellevue Global Life Sciences Investors, LLC ("*Sponsor*"), purchased an aggregate of 430,000 units at a price of $10.00 per unit, for an aggregate purchase price of $4,300,000 ("Private Placement Units").

In connection with our IPO, the underwriters were granted a 45-day option from the date of our prospectus issued in connection with our IPO (the "*Over-Allotment Option*") to purchase up to 900,000 additional units to cover over-allotments (the "*Over-Allotment Units*"), if any. On February 21, 2023, the underwriters purchased 900,000 Over-Allotment Units fully exercising the Over-Allotment Option. The Over-Allotment Units were sold at an offering price of $10.00 per Over-Allotment Unit, generating additional gross proceeds of $9,000,000 to the Company.

The transaction costs of our IPO amounted to $2,721,126, consisting of $1,380,000 of underwriting discounts and $1,341,126 of other offering costs. Following the closing of our IPO on February 14, 2023, $61,050,000 (approximately $10.175 per Unit) from net offering proceeds of the sale of the Units in our IPO and the sale of the Private Placement Units was placed in a trust account (the "*Trust Account*"). Following the closing of the Over-Allotment Option on February 21, 2023, and including the amount from our IPO, an aggregate amount of $70,207,500 was placed in the Company's Trust Account established in connection with our IPO. The proceeds held in the Trust Account are invested in United States "government securities" within the meaning of Section 2(a)(16) of the Investment Company Act of 1940, as amended (the "*Investment Company Act*") having a maturity of 185 days or less or in money market funds meeting certain conditions under Rule 2a-7 promulgated under the Investment Company Act which invest only in direct U.S. government treasury obligations. Except with respect to interest earned on the funds held in the Trust Account that may be released to the Company to pay its tax obligations, the proceeds from our IPO were not to be released from the Trust Account until the earlier of: (a) the completion of the Company's initial business combination, (b) the redemption of any of our public shares properly submitted in

connection with a stockholder vote to amend our Amended and Restated Certificate of Incorporation (the "*Charter*") (1) to modify the substance or timing of our obligation to allow redemption in connection with our initial business combination or to redeem 100% of our public shares if we do not complete our initial business combination within the time provided in the Company's Charter (as subject to extension), or (2) with respect to any other provision relating to stockholders' rights or pre-initial business combination activity; or (c) absent an initial business combination within the time provided in the Company's Charter (as subject to extension), our return of the funds held in the Trust Account to our public stockholders as part of our redemption of the public shares.

On March 14, 2023, the Company announced that, commencing on March 17, 2023, the holders of Units may elect to separately trade the shares of common stock, warrants and rights included in the Units. No fractional shares, warrants or rights would be issued upon separation of the Units and only whole shares, warrants and rights would trade. The shares of common stock, the warrants and the rights traded on the Nasdaq Capital Market under the symbols "BLAC," "BLACW" and "BLACR," respectively, and the Units not separated continued to trade on the Nasdaq Capital Market under the symbol "BLACU" until the closing of our initial business combination on February 14, 2025 as discussed below.

The Company and OSR entered into a Business Combination Agreement dated November 16, 2023 (the "*Business Combination Agreement*") pursuant to which, prior to the Closing each holder of OSR Common Stock that executes a Participating Stockholder Joinder to the Business Combination Agreement on or prior to the Closing (each such Person, a "*Participating OSR Stockholder*"), and each holder of OSR Common Stock that executes a Non-Participating Stockholder Joinder on or prior to the Closing (each such Person, a "*Non-Participating OSR Stockholder*") would be joined as parties to the Business Combination Agreement, pursuant to which at the Effective Time (i) the Company would issue the Aggregate Participating Consideration to the Participating OSR Stockholders, and (ii) the Participating OSR Stockholders would sell, transfer, convey, assign and deliver all of their respective shares of OSR Common Stock to the Company (subclauses (i) and (ii), collectively, the "*Share Exchange*").

As previously disclosed on the Company's Current Report filed on Form 8-K on February 21, 2025, on February 14, 2025 (the "*Closing Date*"), the Company completed its previously announced business combination (the "*Business Combination*") with OSR pursuant to the Amended and Restated Business Combination Agreement, dated as of May 23, 2024, as amended on December 20, 2024 (the "*Business Combination Agreement*"), by and among the Company, OSR, each stockholder of OSR that executed a Participating Joinder thereto (each such person, a "*Participating Stockholder*"), and each stockholder of OSR that executed a Non-Participating Joinder thereto (each such person, a "*Non-Participating Stockholder*", and together with the Participating Stockholders, the "*OSR Stockholders*"). As a subsequent event following the end of the period covered by this Form 10-K, the Non-Participating Stockholders exercised their options to put their OSR shares to exchange them into the shares of the common stock of OSR Holdings, Inc. The effective date of the closing of such share exchange with the Non-Participating Stockholders was January 30, 2026.

In connection with the Closing of the Business Combination, we changed our name from Bellevue Life Sciences Acquisition Corp. to OSR Holdings, Inc. and changed the trading symbols of our common stock and warrants from "BLAC" and "BLACW," to "OSRH" and "OSRHW," respectively. In connection with the Closing, any Units (which were trading under the symbol "BLACU") that had not yet separated, were separated into their component shares of common stock and warrants and ceased trading.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K constitute "forward-looking statements" for purposes of federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this report may include, for example, statements about:

- our expectations around the performance of the Company, including without limitation, the Company's strategy, future operations, financial performance and position, revenues, projected costs, prospects and plans;
- the ability to obtain or maintain the listing of the Company's securities on Nasdaq;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors following our initial business combination;
- our officers and directors allocating their time to other businesses and potentially having conflicts of interest with our business;
- our ability to successfully and efficiently integrate future expansion plans and opportunities and to grow our business in a cost-effective manner;
- future potential change in control;
- the implementation, market acceptance and success of the Company's post-merger business model;
- developments and projections relating to the Company's competitors and industry;
- our expectations regarding the Company's ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our public securities' potential liquidity and trading;
- our expectations regarding the Company's ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- the impact of COVID-19 type pandemics on the Company's business;
- our public securities' potential liquidity and trading;
- changes in applicable laws or regulations;
- expectations regarding the time during which we will be an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act");
- the use of proceeds not held in the trust account or available to us from interest income on the trust account balance;
- the trust account not being subject to claims of third parties; or
- the outcome of any known and unknown litigation and regulatory proceedings.

The forward-looking statements contained in this report are based on our current expectations and beliefs concerning future developments and their potential effects on us. Future developments affecting us may not be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) and other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are

not limited to, those factors listed under the heading “Risk Factors” elsewhere in this report. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and developments in the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this report. In addition, even if our results or operations, financial condition and liquidity, and developments in the industry in which we operate are consistent with the forward-looking statements contained in this report, those results or developments may not be indicative of results or developments in subsequent periods.

SUMMARY OF RISK FACTORS

Our business, our business sector and investing in our securities involve a number of risks of which you should be aware before making an investment decision. You should read this summary together with the description of each risk factor contained under "Item IA. Risk Factors" in this Annual Report on Form 10-K, as well as other documents filed from time to time with the SEC, for a more detailed discussion of certain risks that could materially adversely affect our financial conditions and the market price of our securities. The following list describes some of the principal risk factors applicable to the Business Combination, BLAC, OSR and the combined Company.

- The price of the Company's Common Stock and warrants may be volatile. The market price of the Company's Common Stock has declined significantly in recent months, making the financing of continuing business operations more difficult and dilutive and increasing the risk of the Common Stock being delisted. These and other factors, including a potential loss of liquidity in the market for the Common Stock may limit your ability to sell the Company Common Stock.
- The Company's limited operating history, the early stage of its development programs and the inherent uncertainties and risks involved in pharmaceutical product development may make it difficult for it to execute on its business model.
- The Company will likely incur significant operating losses for the foreseeable future and may never achieve or maintain profitability.
- We may not be successful in our efforts to acquire, in-license or discover and develop new product candidates.
- We currently have no marketing and sales organization for pharmaceutical products and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our pharmaceutical products, we may not be able to generate pharmaceutical product revenue.
- Our investment strategy and future growth rely on a number of assumptions, some or all of which may not be realized.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts and/or other operations.
- We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to compliance with its public company responsibilities and corporate governance practices.
- The Company's management team has limited experience managing and operating a U.S. public company.
- If economic conditions in South Korea deteriorate, our current business and future growth could be materially and adversely affected.
- Our business includes subsidiaries that are developing oral immunotherapies for the treatment of cancer and design-augmented biologics. These companies have a limited operating history, and their programs are in early stages of development. This may make it difficult to evaluate our prospects and likelihood of success.
- We currently outsource, and intend to continue to outsource, much of our discovery, clinical development, and manufacturing functions to third-party providers or consultants. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business, results of operations, and financial condition.

- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- Conflicts of interest arising from related-party relationships may adversely affect the terms of the Company's licensing arrangements and could delay or reduce royalty revenues.

The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial, may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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PART I

Item 1. Business

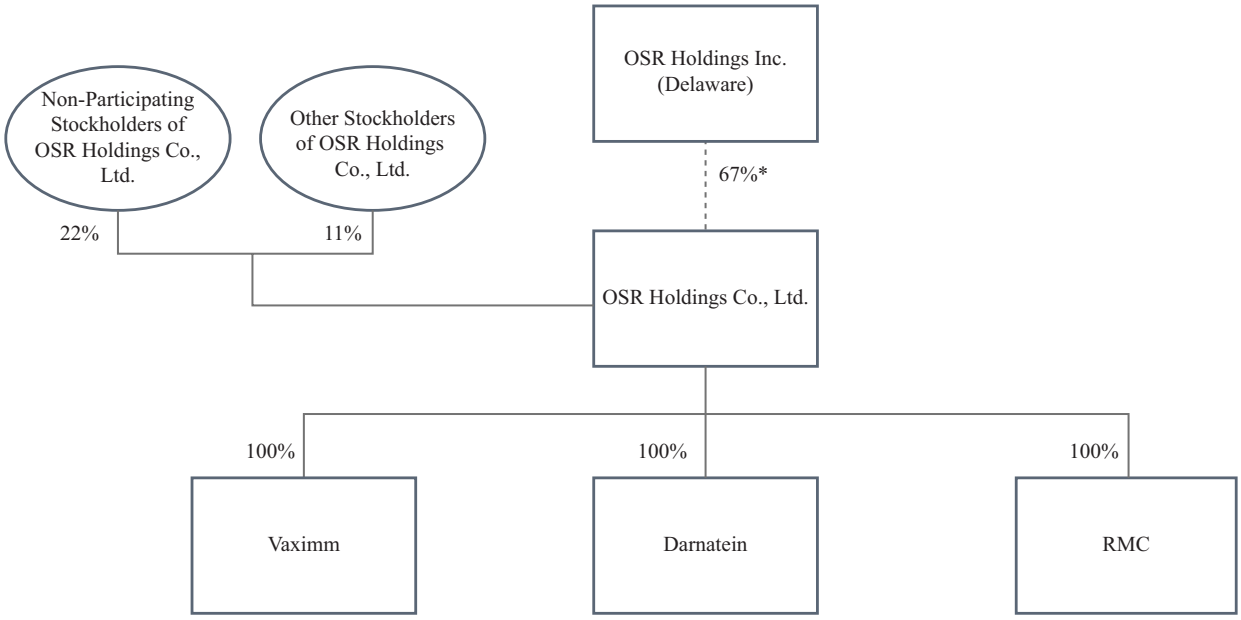
Company and Business Strategy Overview

As a global healthcare holding company, with operations in South Korea and Switzerland and an office in the United States, we intend to leverage our existing and expanding network of academic and industry leaders and investor network, including venture capital and private equity, in major healthcare markets globally to identify, lead and support the growth of our subsidiaries and subsidiary candidates based on innovative research. Subsidiary candidates are companies that are either already existing entities or new companies formed in connection with acquiring or licensing existing assets from industry or academia. We expect to attract industry partners either as co-investors or through technology licensing deals and may raise capital directly from private, strategic or public investors. We seek to chart a potentially more efficient and optimal route by pairing what we believe are the right team and pharmaceutical or medical device technologies that have the potential to treat diseases and improve healthcare outcomes with the necessary financial and other resources. Since our target markets feature large established global businesses with abundant capital that acquire healthcare companies, we hope to realize additional liquidity through the sale of our subsidiaries from time to time.

We are a data-driven company. We evaluate our subsidiary candidate opportunities by better understanding the target indications toward identifying new approaches and technologies to improve treatment outcomes. We collaborate with academic and industry leaders to promote a seamless integration and partnership between entrepreneurial scientists and seasoned business development and leadership teams. These technical and scientific experts from academia and industry bring innovative contributions and a high level of enthusiasm. Our holding company leadership team supports and empowers each subsidiary to transform their potentially breakthrough discoveries into impactful and viable commercial products.

Our company's collective expertise from industry veterans, seasoned scientists, capital market and legal professionals provides the core foundation of our global healthcare holding company. The Company operates as a hub-and-spoke business model with a centralized executive team partnering with subsidiary management teams to ensure overall program and corporate alignment by and between subsidiaries and holding company. Our overarching goal is to enhance value creation for our subsidiaries by continuously assessing optimal development options and exploring partnership and fundraising opportunities. We encourage cooperation and knowledge sharing among our subsidiaries to enhance our synergistic business model. We believe our strong foundational scientific conviction, entrepreneurial acumen and opportunistic approach positions us as a differentiated global company advancing pharmaceutical and medical device technologies in an efficient, cost-effective and meaningful manner. Our interdisciplinary team of accomplished scientists and entrepreneurial business leaders promotes the development and commercialization of a risk diversified portfolio to address unmet medical needs with resilience and efficiency.

Our corporate organization and ownership of subsidiaries is illustrated by the following chart*:



Portfolio Overview

OSR's subsidiaries (other than RMC) have diverse scientific and technological developments, and are engaged in distinct areas of therapeutics research and development, including oral T-cell immunotherapies and recombinant biologics. This approach not only provides the Company with a broader scope of potential therapeutic solutions but also reduces the risks associated with a singular-asset approach.

Figure 2 below summarizes our three subsidiaries, two of which have their own drug development pipelines.

Portfolio Company	Science, Technology and Platform
VAXIMM	T-cell immunotherapies based on a live attenuated, safe, orally, available bacterial vaccine strain, genetically modified to develop and elicit patients' cytotoxic T-cells against specific pre-defined targets
darnatein inventing modular molecules for life	Platform integrating different protein domain sequences linking into a Design-augmented (DA) recombinant biologic with enhanced biological functionality for bone and cartilage regeneration
RM communication	Neurovascular surgical devices

Figure 2. *the Company subsidiary portfolio snapshot.*

Intellectual Property Overview

We own or have in-licensed numerous patents and intellectual property underlying patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of therapeutic product candidates in development by our portfolio companies, including related manufacturing processes and technologies. As of December 31, 2025, the patent portfolio of our subsidiaries includes 10 patent families of issued patents and pending patent applications in various stages of prosecution. Generally, the patents issued and patent applications

pending are in multiple jurisdictions including the United States, Europe, Japan, India, and China, with anticipated expiration between 2032 to 2041, without considering patent term adjustments or patent term extensions. The below table summarizes the seven patent families that have been issued to-date for our subsidiary companies:

Company Assignee	Family	Status	Type	Granted Regions	Expiration Year
Vaximm	Manufacturing (1) WO 2013/091898, Method for Producing High Yield Attenuated Salmonella Strains	Owned	Manufacturing	AU, CA, CN, EP, IN, JP, KR, US, ZA	2032
	VXM01 – dosing (2) WO 2014/005683, DNA Vaccine for Use in Pancreatic Cancer Patients	Owned	Formulation	AU, CN, EP, JP, KR, US, ZA	2033
	VXM06 – WT1 (3) WO 2014/173542, Salmonella-based vectors for cancer immunotherapy targeting Wilms' tumor gene	Owned	Composition of Matter	EP, JP, US	2034
	VXM04-MSLN (4) WO 2015/090584, Novel MSLN targeting DNA vaccine for cancer immunotherapy	Owned	Composition of Matter	EP, JP, US	2034
	VXM01 – combination (5) WO 2016/202459, VEGFR-2 targeting DNA vaccine for combination therapy	Owned	Composition of Matter; Method of Use	AU, CA, CN, EP, IN, US, ZA	2036
	VXM01 Tumor expression (7) WO 2018/149982, Novel VEGFR-2 targeting immunotherapy approach	Owned	Composition of Matter	AU, US	2038
Darnatein	Designer ligands of TGF-ß superfamily (0) WO 2010/099219	Exclusive License	Composition of Matter	EP, KR, JP	2030
	Activin/bmp7 chimeras: super-active sab704 and sab715, and their respective noggin-sensitized variants, nab704 and nab715; and nab204 WO2020/101366	Owned	Composition of Matter	KR, CN, US	2039

Individual patents are in force for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are in force for 20 years from the earliest nonprovisional filing date. In addition, in certain instances, a patent term can be adjusted or extended to recapture a portion of the term effectively lost as a result of the USPTO delay or the FDA regulatory review period (a patent term adjustment or patent term extension, respectively). The restoration period for FDA delay cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest nonprovisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

When appropriate, we seek to protect aspects of our technology and business not amenable to, or that we do not consider appropriate for, patent protection as trade secrets. We seek to protect this intellectual property, in part, as trade secrets, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors.

Vaximm

Vaximm Corporate Overview

Vaximm is developing innovative oral T-cell immunotherapies for the treatment of disorders that require the safe and targeted elimination of specific cell populations. (e.g. neoplasms, other proliferative diseases, chronic infections). Based on over 20 years of research, Vaximm's customizable immunotherapy platform has the potential to be efficiently and effectively adapted to treat various diseases and address specific patient needs. Vaximm currently has three clinical and pre-clinical drug candidates targeting diseases ranging from glioblastoma to gastrointestinal stromal tumor to ocular diseases. Vaximm holds the only clinically tested oral cancer vaccine with proven safety and demonstrated efficacy

Vaximm's flagship asset, VXM01, is a late clinical-stage (NCT037500701) immuno-oncology candidate for glioblastoma, which early-stage clinical trials (NCT02718443 and NCT01486329) suggest may be a potentially specific and effective treatment. VXM01 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for both glioblastoma and pancreatic cancer on August 31, 2017 from FDA and August 23, 2017 from EMA. An Orphan Drug Designation will permit Vaximm to receive additional years of market exclusivity upon regulatory approval, which provides a significant competitive advantage. See "*Government Regulation — Orphan Drug Designation and Exclusivity*." " Based on evolving science, Vaximm is developing the VXM01 v 2.0. While meant to improve efficacy, it leverages the proven vector safety data from VXM01 to move into late-stage development at speed.

While VXM01 (including version 2.0) moves into planned phase 2, phase 2/3 clinical trials, we are continuing to evaluate Vaximm's other preclinical candidates for further development in investigational new drug (IND)-enabling studies.

Importantly, the live, attenuated *S.* typhi strain Ty21a, presents a proprietary platform for inducing an immune response to other antigens beyond the here chosen VEGFR-2, such as Carcinoembryonic Antigen (CEA), Fibroblast Activation Protein (FAP) expressed in the tumor stroma, or Multiple Drug Resistance 1 (MDR-1). We have since tested in preclinical models a variety of other antigens with success.

- VXM04: A preclinical-stage oral T-cell vaccine targeting mesothelin (MSLN)
- VXM06: A preclinical-stage oral T-cell vaccine targeting Wilms Tumor Protein (WT1)
- VXM08: A preclinical-stage oral T-cell vaccine targeting CEA(Carcinoembryonic antigen)
- VXM10: A preclinical-stage oral T-cell vaccine targeting PD-L1 (Programmed death-ligand 1)

These products are currently undergoing preclinical studies to evaluate their safety, immunogenicity, and anti-tumor efficacy. Vaximm will need to complete these preclinical studies and submit Investigational New Drug (IND) applications to the relevant regulatory authorities before initiating clinical trials for each of these product candidates.

While Vaximm has direct experience advancing a therapeutic candidate from preclinical to late-stage clinical trials and developed a pipeline of other preclinical therapeutic candidates, other than receiving Orphan Drug Designation for VXMO1, Vaximm has limited experience in applying for regulatory or marketing approval for any of its product candidates specifically. That said, this experience exists within the team. As Vaximm continues to advance its line of oral immunotherapies, it will remain flexible and opportunistic to explore partnering options.

Opportunity

Current approaches to targeted immunotherapies have various limitations, such as drug biodistribution, off-target effects, immunotolerance, and evasion. The complex and diverse makeup of tumor microenvironments creates further difficulties. Production of targeted immunotherapies is expensive and time-intensive, making tailor-made therapies challenging to produce and manufacture at scale and, thus, not readily accessible. Optimally, the development of innovative new strategies can overcome drug resistance, enhance druggability, and improve drug biodistribution to maximize treatment efficacy.

Vaximm seeks to overcome these limitations by leveraging our foundational science and innovative platform of attenuated bacterial strains to produce effective, customizable, oral vaccines efficiently and cost-effectively. Vaximm's lead product candidate, VXM01, targets the tumor vasculature and specific tumor antigens. It differs decidedly from other vaccine approaches, since VXM01 does not have to overcome local immune suppression/encapsulation. The target, further, does not allow for mutations and immune escape. VXM01 and the underlying proprietary platform, further, has the potential to target multiple indications, even beyond oncology.

VXM01 has recently completed a Phase 2 clinical trial in Europe for the treatment of recurrent glioblastoma, where activity has been observed to date. Vaximm also plans to initiate a new clinical trial of VXM01 in recurrent glioblastoma patients in the United States.

If VXM01 demonstrates efficacy in the treatment of recurrent glioblastoma, Vaximm intends to expand by developing oral cancer vaccines targeting other solid tumor indications. The company's strategy generally involves the following key steps:

1. Identify novel tumor-specific antigens: Vaximm will leverage its expertise in antigen discovery to identify new tumor-specific antigens that can be targeted by Vaximm's platform. This will include, as per precedent, targets which are expressed by cancer supporting tissue.

   The safety profile and the mode of action of the platform make it a prime candidate for combination with standard of care treatments. Thus, currently envisioned clinical development will initially focus on add-on trials, avoiding initially combinations of non-approved assets. This presents a straight forward way to approval.

2. Conduct preclinical studies with the FDA's good laboratory practice ("GLP" regulations): Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. Vaximm will perform preclinical studies to evaluate the safety, immunogenicity, and anti-tumor efficacy of its oral cancer vaccine candidates in line with the GLP regulations that the FDA requires.

3. File an Investigational New Drug (IND) application: Upon the successful completion of preclinical studies, Vaximm will submit an IND application to regulatory authorities such as the FDA. IND is a request for authorization from the FDA to ship an investigation product and then administer it to humans and must be allowed to proceed by the FDA before human clinical trials may begin. This submission includes all relevant data from preclinical studies and outlines the proposed clinical trial protocols. The IND review period typically takes 30 days, during which the regulatory agency evaluates the submission to ensure the safety of proceeding to human trials.

4. Initiate clinical trials: Based on the preclinical data and IND approval, the company will design and conduct additional Phase 2 clinical trials to assess the safety, tolerability, and preliminary efficacy of its oral cancer vaccines in other cancer indications.

5. Conduct Phase 3 clinical trials: Phase 3 trials are large-scale, randomized, controlled studies designed to provide additional supporting evidence of the efficacy and safety of therapeutic candidates. These trials typically involve hundreds of patients and are conducted at multiple sites worldwide. Vaximm will work closely with clinical investigators, regulatory authorities, partners and patient advocacy groups to design and execute Phase 3 clinical trials for its oral cancer vaccine candidates.

6. Seek regulatory approval: Following the successful completion of Phase 3 clinical trials, the result of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, and proposed labeling, among other things, are submitted to authorities, such as the FDA or EMA. This stage is known as the New Drug Application (NDA) review.

Regulatory Steps

New Drug Application

A New Drug Application (NDA) tells the full story of a drug. Its purpose is to demonstrate that a drug is safe and effective for its intended use in the population studied.

A drug developer must include everything about a drug — from preclinical data to Phase 3 trial data — in an NDA. Developers must include reports on all studies, data, and analyses. Along with clinical results, developers must include proposed labeling, safety updates, drug abuse information, patent information, any data from studies that may have been conducted in other countries, institutional review board compliance information and directions for use. Vaximm has that information largely readily available due to past work. Especially, there seems no need for expensive and long-lasting animal safety studies.

NDA Review

Once each authority such as FDA or EMA receives an NDA, the review team decides if it is complete. If it is not complete, the review team can refuse to file the NDA. If it is complete, the review team has 6 to 10 months to make a decision on whether to approve the drug. The process includes the following:

- Each member of the review team conducts a full review of his or her section of the application. For example, the medical officer and the statistician review clinical data, while a pharmacologist reviews the data from animal studies. Within each technical discipline represented on the team, there is also a supervisory review. All expertise needed with a proven track record are available within the team
- FDA or EMA inspectors travel to clinical study sites to conduct a routine inspection. The Agency looks for evidence of fabrication, manipulation, or withholding of data.
- The project manager assembles all individual reviews and other documents, such as the inspection report, into an "action package." This document becomes the record for NDA review. The review team issues a recommendation, and a senior official makes a decision.

NDA Approval

In cases where FDA or EMA determines that a drug has been shown to be safe and effective for its intended use, it is then necessary to work with the applicant to develop and refine prescribing information. This is referred to as "labeling." Labeling accurately and objectively describes the basis for approval and how best to use the drug.

FDA Advisory Committees

Often, the NDA contains sufficient data for FDA or EMA to determine the safety and effectiveness of a drug. Sometimes, though, questions arise that require additional consideration. In these cases, FDA or EMA may organize a meeting of one of its Advisory Committees to get independent, expert advice and to permit the public to make comments. These Advisory Committees include a Patient Representative that provides input from the patient perspective.

The estimated timeframe for this process is as follows:

- If applicable: Antigen discovery and vaccine formulation: About 1year.
  (This step is not necessary for VXM01 including 2.0, but may have to in part be executed for new targets)
- Preclinical studies: About 1 year
- IND filing and review: 1 month
- Phase 1/2 clinical trials: 2-3 years
- Phase 3 clinical trials: 2-3 years
- Regulatory approval (including NDA review): 1 year

Based on this timeline, Vaximm anticipates that its next oral cancer vaccine candidate beyond VXM01 could enter clinical trials within the next 3-5 years, with potential regulatory approval in less than 7 years.

In case of the improved version of VXM01, these timelines are expected to be significantly shorter (about 4years).

Clinical Trials

Overview of VXM01 clinical trial

VXM01 was clinically tested in two trials in advanced pancreatic cancer and in Glioblastoma:

- VXM01 Phase I Dose Escalation Study in Patients With Locally Advanced, Inoperable and Stage IV Pancreatic Cancer (NCT01486329)
- VXM01 Phase I Pilot Study in Patients With Operable Recurrence of a Glioblastoma (NCT02718443)

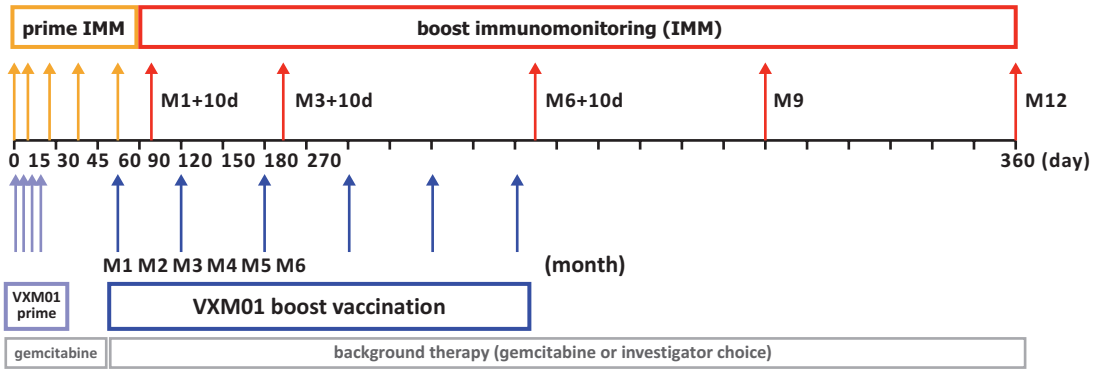
In both studies, VXM01 was found to be extremely safe and found to consistently elicit the expected immune response including biomarkers and indication of efficacy.

1. A randomized, double blinded, placebo phase 1/2 trial in pancreatic carcinoma (NCT01486329):

VXM01 Phase I Dose Escalation Study in Patients With Locally Advanced, Inoperable and Stage IV Pancreatic Cancer.

NCT01486329 was a randomized, placebo-controlled, double-blinded dose-escalation study included a total of 72 treated patients with locally advanced and stage IV pancreatic cancer. The patients received in this trial VXM01 or placebo (S. typhi carrying a non-coding DNA plasmid) in addition to gemcitabine as standard of care. In addition to safety as primary endpoint, the VXM01-specific immune reaction, as well as clinical response parameters were evaluated. After the initial doses, patients received up to six monthly boost vaccinations, or placebo treatment. Vaccinations were applied orally, and concomitant treatment with standard-of-care gem-citabine during the priming phase (first 4 weekly doses):

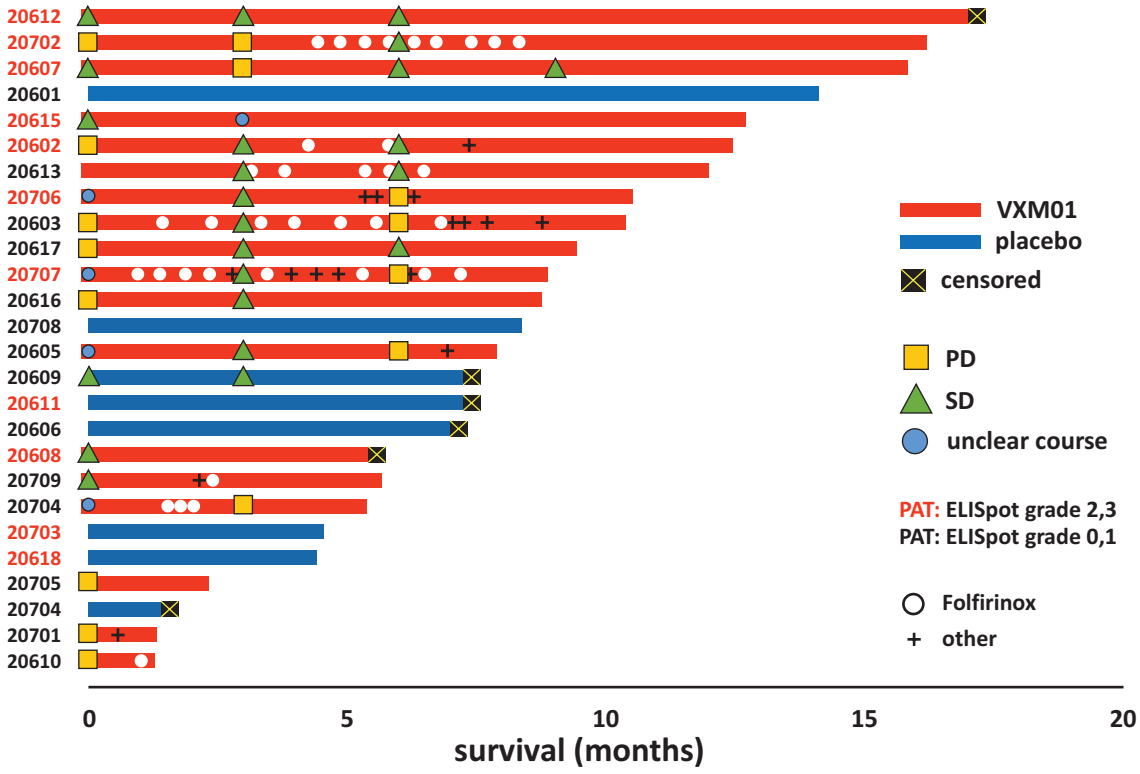
- Part 1 (n=45, 5 dose levels) initiation treatment only in the first week on days 1, 3, 5, and 7 at doses ranging from 106 colony forming units (CFU) up to 1010 CFU of VXM01 or placebo (2:1 randomization).



- Part 2 (n=27, 2 dose levels) at two alternative doses of either 106 colony-forming units (CFU) or 107 CFU with up to 6 monthly boosts after initiation treatment. Immune monitoring involved interferon-gamma (IFN-γ) ELIspot analysis with long overlapping peptides spanning the entire VEGFR-2 sequence. (Designation: VXM01 has received orphan drug designation from the U.S. Food and Drug Administration (FDA) and the European Commission.

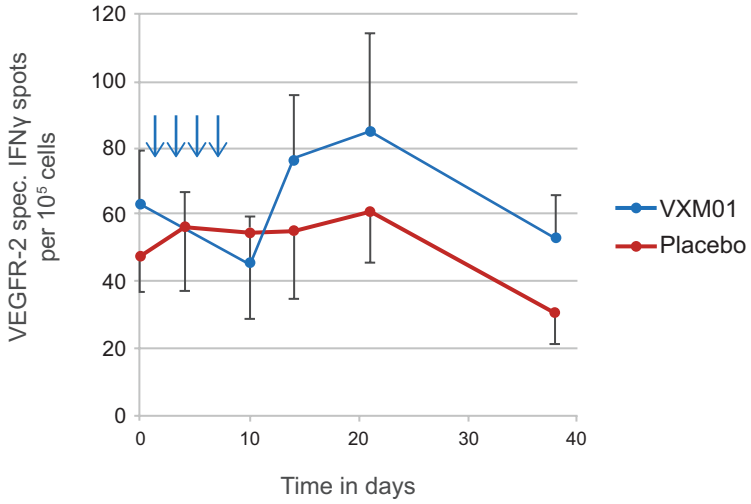
This trial was completed at the University of Heidelberg and the German Cancer Research Center (DKFZ).

Overall survival (all comers):



Importantly, target specific T cell activation over placebo was noted in both, periphery and tumor tissue.

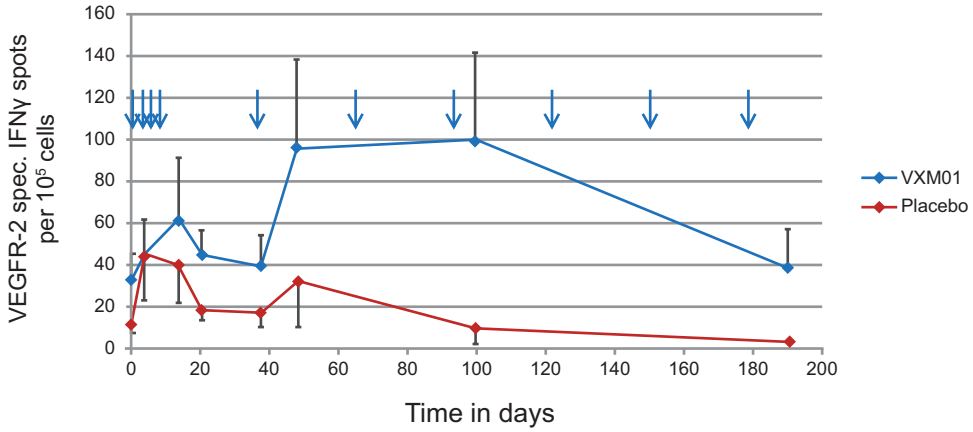
Part 1, T cell response over placebo: “Prime”



Activation was noted in both, subjects with and without pre-dosing existing immune response

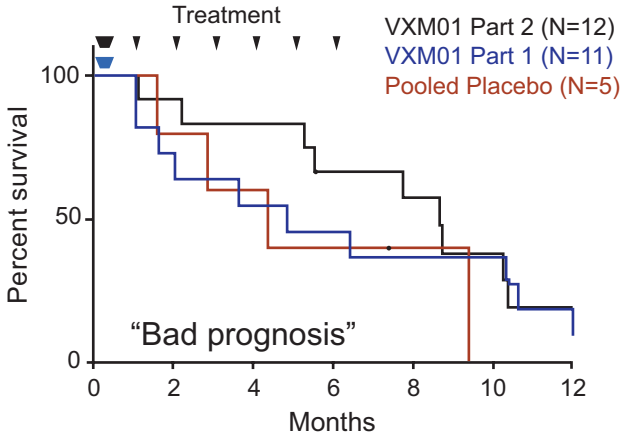
Boosting after 40 days sustained and increased the immune response:

“Boost”

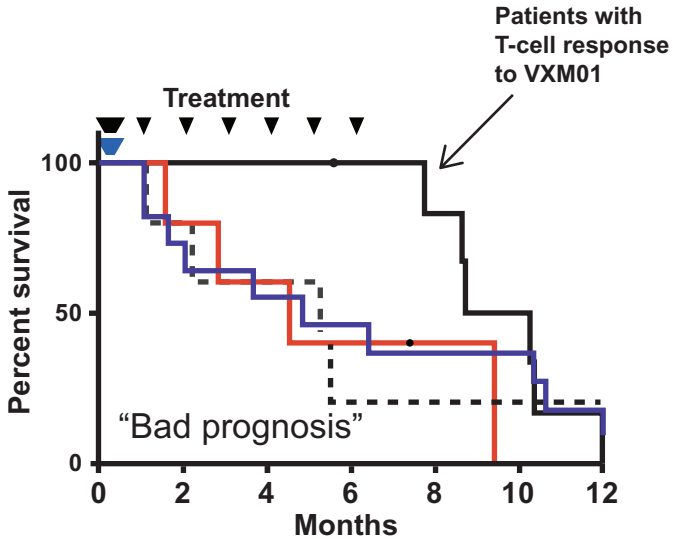


There was encouraging survival in subjects boosted in part 2 with bad prognosis based on CA-19-9, status, extend of disease.

Subgroup analysis “bad prognosis”:



The effect gets more pronounced when looking at patients with successful immune induction at prime:



Observed pharmacodynamic effects in VXM01 treatment group vs. placebo included

- a decrease in tumor perfusion,
- increase in serum collagen,
- mild elevation in blood pressure,
- mild drop in thrombo-cyte, leukocyte and lymphocyte counts.

All of which are indictive of successful vessel targeting and ratification. For example, increased blood pressure in patients treated with VXM01 over placebo indicates blood vessel rarefication.

Increase of VEGF-A and collagen IV (indicator of vessel destruction) after vaccination further supported the observed vaccination effects on tumor perfusion, particularly since we observed a significant inverse correlation between collagen IV serum levels and alterations of tumor perfusion after the vaccination.

DCE-MRI was employed to assess tumor perfusion. After 38 days, tumor perfusion as 18% reduced in the VXM01 subjects while unchanged in placebo treated patients

In conclusion, VXM01 elicits a productive, complex VEGFR-2-specific effector T-cell response in patients with pancreatic cancer that correlates with anti-angiogenic activity and has a favorable safety profile. Changes indicative of anti-angiogenic efficacy in tumor perfusion, serum biomarkers, and blood pressure in VXM01 treated patients but not in the control arm were recorded.

Importantly, no safety concerns were noted

Trial design end results are published in:

- Niethammer AG, Lubenau H, Mikus G, Knebel P, Hohmann N, Leowardi C, Beckhove P, Akhisaroglu M, Ge Y, Springer M, Grenacher L, Buchler MW, Koch M, Weitz J, Haefeli WE, Schmitz-Winnenthal FH. Double-blind, placebo-controlled first in human study to investigate an oral vaccine aimed to elicit an immune reaction against the VEGF-Receptor 2 in patients with stage IV and locally advanced pancreatic cancer. BMC Cancer. 2012 Aug 20;12:361.
- *Schmitz-Winnenthal FH, Hohmann N, Niethammer AG, Friedrich T, Lubenau H, Springer M, Breiner KM, Mikus G, Weitz J, Ulrich A, Buechler MW, Pianka F, Klaiber U, Diener M, Leowardi C, Schimmack S, Sisic L, Keller AV, Koc R, Springfeld C, Knebel P, Schmidt T, Ge Y, Bucur M, Stamova S, Podola L,*

Haefeli WE, Grenacher L, Beckhove P. Anti-angiogenic activity of VXM01, an oral T-cell vaccine against VEGF receptor 2, in patients with advanced pancreatic cancer: A randomized, placebo-controlled, phase 1 trial. Oncoimmunology. 2015 Mar 16;4(4):

2. A phase1 clinical trial of VXM01 in Glioblastoma was initiated in May 2016 (ClinicalTrials.gov ID: NCT02718443). The trial was conducted at the Neurology Clinic and National Center for Tumor Diseases in Heidelberg, Germany, and the principal investigator is Dr. Wolfgang Wick, MD, who is a professor at the Neurology Clinic and National Center for Tumor Diseases.

The phase I clinical trial was evaluated for 14 patients with recurrent glioblastoma who had progressed after standard treatment and were candidates for reoperation. The primary objective of the study was to examine the safety and tolerability of the investigational VEGFR2 DNA vaccine VXM01 after four vaccinations in glioblastoma patients. The secondary objective was to examine the immune and biomarker response to the vaccine. During the course of this clinical trial, 7 patients were alive and survived for more than 12 months after initiation of treatment. No adverse effects related to VXM01 were observed.

source: Wick, W et al. "P01.031 VXM01 phase I study in patients with progressive glioblastoma — final results." Neuro-Oncology vol. 20, Suppl 3 (2018): iii235. doi:10.1093/neuonc/noy139.073

As the Phase 1 trial progressed, VXM01 was granted orphan drug status by the FDA and EMA in 2017 for the treatment of glioma.

Authority	Orphan Designation	Designation date	Source
FDA	Treatment of Malignant glioma	08/31/2017	*https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=596117*
EMA	Treatment of glioma	23/08/2017	*https://ec.europa.eu/health/documents/community-register/html/o1909.htm*

As a next step, on November 21, 2018, a combination study of VXM01 and anti-PD-L1 checkpoint inhibitor avelumab in 28 patients with relapsed glioblastoma began (ClinicalTrials.gov ID NCT03750071). The trial included 25 patients with non-resectable tumors and 3 with resectable tumors. The main objective of the study is to evaluate the safety and tolerability of VXM01 vaccine treatment in combination with avelumab.

Dr. Wolfgang Wick, the principal investigator for the Phase I clinical trial and also a key opinion leader in the field of brain malignancies, also conducted this combination study. He will remain principal investigator for future trials.

This Phase I/II clinical trial was not sized or designed to yield advanced comparative statistical results. Larger patient cohorts and additional design features typical of Phase 2/PoC studies (including randomization, Blinding, control groups) are required to obtain data yielding advanced statistics and guide the design of registrational (Ph3) studies. Initiation of such trials is planned for 2026. That said, the data to date shows promising responses, including as single agent, having generated considerable interest in the field at the time.

VXM01 Phase 1/2 clinical trial — Patient selection criteria

Patients were selected by a third-party clinical trial provider, each of whom met the following criteria:

- **Diagnosis:** anaplastic astrocytoma (WHO Grade III) or glioblastoma (WHO Grade IV) located above the tentorium cerebelli in the brain.
- **Age:** 18 years or older.
- **Sex:** men or women who were post-menopausal for at least 2 years or surgically sterile.
- **Disease progression:** evidence of tumor growth after at least one treatment regimen containing radiation and temozolomide chemotherapy.
- **Resectable tumor:** eligible for a repeat surgery to remove the tumor, with the surgery able to be delayed for 30 days.

- **General health:** good bone marrow, liver, and kidney function (as determined by blood and urine tests); able to undergo MRI scans; no active infection at the time of vaccination; Karnofsky performance status greater than 70; and adequate blood counts.
- **No recent clinical trials:** no participation in another clinical trial within 30 days before screening.
- **No specific infections:** negative test results for Hepatitis B, Hepatitis C, and HIV.
- **No interfering conditions:** no other medical or social conditions that might interfere with the study or make it unsafe for the patient to participate.

The study included 14 white patients with a mean age of 56.8 years. The majority of participants (64.3%) were male.

VXM01 phase I clinical trial — Tumor response

The tumor response was assessed by objective response rate (ORR) according to immunotherapy Response Assessment for Neuro-Oncology (iRANO; 2015).

Overall, the tumor response to VXM01 was mixed, with some patients showing signs of stable disease or even tumor shrinkage, while others experienced disease progression. These findings highlight the variability in treatment response and the challenges of managing glioblastoma. The extension study results provide further insights into the potential for long-term disease control in some patients, but also underscore the need for further research to optimize treatment strategies and identify those most likely to benefit.

Best Overall Response	10^6 CFU (N=7) n (%)	10^7 CFU (N=6) n (%)	Total (N=13) n (%)
CR	1 (14.3)	—	1 (7.1)
PR	1 (14.3)	—	1 (7.1)
SD	5 (71.4)	5 (83.3)	10 (76.9)
PD	—	1 (16.7)	1 (7.1)
ORR (%) [95% CI]	28.6 [3.7 – 71.0]	0.0 [0.0 – 45.9]	15.4 [1.9 – 45.4]
DCRR (%) [95% CI]	100.0 [59.0 – 100.0]	83.3 [35.9 – 99.6]	92.3 [64.0 – 99.8]

Note: A hyphen (-) indicates no events were reported. n = number of patients with an event; N = number of patients; NR = non-resectable. Percentages are based on the number of patients. CR = complete response; PR = partial remission; SD = stable disease; PD = progressive disease; ORR = objective response rate (CR and PR); DCR = disease control rate (CR, PR, and SD).

In this study, we assessed clinical response using several measures, including progression-free survival (PFS) and overall survival (OS). PFS ranged from 9 to 366 days, with a median PFS of 0.8 months in the 10^7 CFU dose group and 2.6 months in the 10^6 CFU dose group. OS ranged from 67 to 416 days, with a median OS of greater than 14 months in the 10^6 CFU group and 7.6 months in the 10^7 CFU group.

For the 3 patients who entered the prolongation phase, PFS ranged between 30 and 960 days, and overall survival ranged between 776 and 1147 days. These findings suggest a potential advantage in terms of PFS and OS for the lower dose group, although they may be influenced by the slightly better baseline status of the patients in the 10^6 CFU dose group.

VXM01 phase 1/2 clinical trial — Immune response

The effect of VXM01 was explored by evaluating the VEGFR-2 specific T cell response and frequency of immune cells in peripheral blood, and by staining of immune- and biomarkers in tumor tissue obtained during resection.

Peripheral T-cell response:

All 9 tested patients showed a VEGFR2-specific T-cell and IFN-γ immune response, with a clear increase observed after the initial vaccination and further increases after the first booster dose. This indicates that VXM01 effectively stimulated an immune response against VEGFR2, a protein involved in tumor growth.

ELISpot assay was used to measure the number of these T cells that produced interferon gamma (IFN-γ) when stimulated with different fragments of the VEGFR-2 protein.

Mean difference count pool-all minus negative control	10^6 CFU; mean ± SD (N)	10^7 CFU; mean ± SD (N)	Total; mean ± SD (N)
Day 0	4.5 ± 6.22 (3)	18.1 ± 17.64 (5)	13.0 ± 15.46 (8)
Day 21	14.5 ± 10.35 (3)	10.4 ± 17.13 (4)	12.2 ± 13.68 (7)
Day 35	8.4 ± 7.06 (3)	13.4 ± 15.36 (5)	11.6 ± 12.48 (8)
Week 12 + 10 days	-17.5 (2)	30.6 ± 20.96 (5)	16.9 ± 30.39 (7)
Week 24 + 10 days	-2.0 (1)	-4.5 ± 9.57 (4)	-4.0 ± 8.36 (5)
Week 36 + 10 days	20.4 (1)	27.0 (2)	24.8 ± 4.45 (3)
Week 48 + 10 days	29.6 (1)	28.7 (1)	29.2 (2)

Brain Tumor Immunohistochemistry:

An analysis of tumor tissue from 8 re-operated patients showed a statistically significant increase in CD8 T-cells (immune cells that kill cancer cells) after vaccination with VXM01. Specifically, the mean number of CD8 T-cells increased from 159 cells/mm² in the primary tumor to 296 cells/mm² in the recurrent tumor, with a P-value of 0.0239 (paired t-test). Additionally, there was a decrease in regulatory T-cells (Treg), which are immune cells that suppress immune responses. The median number of Treg cells dropped from 32 cells/mm² in the primary tumor to 12 cells/mm² in the recurrent tumor. This resulted in a higher CD8:Treg ratio, which has been associated with better clinical outcomes in other studies.

VXM01 phase I clinical trial — Safety result

In this trial, there were no notable differences observed between the two dose groups (10^6 CFU and 10^7 CFU).

All patients experienced at least one treatment-emergent adverse event (TEAE), but most were mild or moderate in severity and considered unrelated to VXM01. The most common TEAEs were consistent with the underlying disease or progression of disease, and included aphasia, hemiparesis, fatigue, headache, and lymphopenia.

No treatment-limiting toxicities (TLTs) were observed. Four TEAEs (flatulence, dizziness, fatigue, and nausea) were considered related to VXM01, but all were mild and resolved without intervention. All serious adverse events (SAEs) and deaths were attributed to the underlying disease or disease progression.

Adverse after prime and boosting doses	10^6 CFU (N=7) n (%) E	10^7 CFU (N=6) n (%) E
Drug related TEAEs	1 (14.3) 2	2 (33.3) 2
Drug related SAEs	—	—
Drug related Treatment-Emergent SAEs	—	—
TLTs Related to VXM01	—	—
Treatment Discontinuations Due to AEs	—	—
Study Discontinuations Due to AEs	—	—

Note: A hyphen (-) indicates no events were reported. E = number of events; n = number of patients with an event; N = number of patients. Percentages are based on the number of patients. CFU: colony forming units.

VXM01 phase I/II clinical trial — Patient selection criteria

Patients were selected by a third party clinical trial provider, each of whom met the following criteria:

- **Diagnosis:** confirmed glioblastoma (WHO Grade IV) located above the tentorium cerebelli in the brain.
- **Disease progression:** evidence of tumor growth after receiving standard treatment with radiation and temozolomide chemotherapy.
- **Prior treatment:** completion of radiotherapy at least 3 months before entering the trial.

- **Resectable tumors (subset of patients):** eligible for a repeat surgery to remove the tumor, with the surgery able to be delayed for 30 days.
- **General health:** good bone marrow, liver, and kidney function; able to undergo MRI scans; no active serious infections; and a Karnofsky performance status of 70 or higher (meaning they could mostly care for themselves).
- **Tumor samples:** availability of tumor tissue for analysis.
- **Sex:** men were eligible. Women had to be post-menopausal or surgically sterile due to a lack of safety data on the vaccine's potential impact on reproduction.

With these criteria, the trial recruited 25 patients with non-resectable tumors and 3 with resectable tumors. Overall, the mean age of participants was 58 years, with the majority (78.6%) being male.

VXM01 phase I/II clinical trial — Tumor response

The tumor response was assessed by Objective Response Rate (ORR) and Duration of Response (DoR) according to immunotherapy Response Assessment for Neuro-Oncology (iRANO; 2015)

Overall, in the non-resectable patients the ORR was 12.0% (95% CI: 2.5 – 31.2), with 3 responders out of 25 patients (12.0%) who had a partial remission. Of the patients with a partial remission, 1 patient in the 10^6 CFU/mL group had a DoR of 5.6 months, while the patients in the 10^7 CFU/mL group had a DoR of 2.7 and 11.1 months. All patients who had stable disease (n=3) received 10^7 CFU/mL VXM01.

Best Overall Response	10^6 CFU/mL (N=3) n (%)	10^7 CFU/mL (N=25) n (%)	Total NR (N=25) n (%)
PR	1 (33.3)	2 (8.0)	3 (12.0)
SD	—	3 (12.0)	1 (4.0)
PD	2 (66.7)	20 (80.0)	21 (84.0)
ORR (%) [95% CI]	33.3 [0.8 – 90.6]	8.0 [1.0 – 26.0]	12.0 [2.5 – 31.2]
DCRR (%) [95% CI]	33.3 [0.8 – 90.6]	20.0 [6.8 – 40.7]	16.0 [4.5 – 36.1]

Note: A hyphen (-) indicates no events were reported. n = number of patients with an event; N = number of patients; NR = non-resectable. Percentages are based on the number of patients. CR = complete response; PR = partial remission; SD = stable disease; PD = progressive disease; ORR = objective response rate (CR and PR); DCR = disease control rate (CR, PR, and SD).

The clinical response was assessed by recurrence-free survival after re-operation (RFS) (in the 10^7 CFU/mL resectable group), time-to-progression (TTP), progression free survival (PFS), and overall survival (OS). In the patients who underwent tumor resection (10^7 CFU/mL resectable group), disease progression occurred only in Patient 01-17 with an RFS of 1.8. Patient 01-14 was censored with an RFS of 20.9 months. The results for TTP and PFS were identical, with an overall median of 2.7 months and range of 1.2 to 13.8 months in the non-resected patients (Total NR group). The median OS in the Total NR group was 11.1 months (95% CI: 8.5 – 15.1) with a range of 3.8 to 38.2 months. At the time of database lock, 1 patient in the 10^7 CFU/mL resectable group was alive and had stable disease without post-resection recurrence, while 3 patients in the 10^7 CFU/mL non-resectable group were alive with progressive disease in longterm follow-up.

VXM01 phase I/II clinical trial — Immune response

The effect of VXM01 plus avelumab was explored by evaluating the VEGFR-2 specific T cell response and frequency of immune cells in peripheral blood, and by staining of immune- and biomarkers in tumor tissue obtained during resection.

ELISpot assay was used to measure the number of these T cells that produced interferon gamma (IFN-γ) when stimulated with different fragments of the VEGFR-2 protein.

VEGFR-2 specific ELISpot counts were calculated as the ELISpot count per peptide pool minus the negative control. The VEGFR-2 specific T cell response was defined positive when the test peptide pool had at least two-fold higher spot counts compared to the negative control and the difference of the triplicates was significant in an *unpaired two-tailed student's t-test*.

Overall, 12 of 28 patients (42.9%, all in the 10^7 CFU/mL non-resectable group) had a VEGFR-2 specific T cell response classified as negative for all peptides at all time points tested. The VEGFR-2 specific T cell response was decreased on Day 21 compared with baseline in 6 patients, was increased in 4 patients (all 10^7 CFU/mL non-resectable group), and remained at the same level compared with baseline in 5 patients. At Week 16, the VEGFR-2 specific T cell response was increased compared with baseline in 7 patients (1 patient in 10^6 CFU/mL group, 6 patients in 10^7 CFU/mL group), decreased in 5 patients (all 10^7 CFU/mL group), and remained the same in 3 patients.

VXM01 phase I/II clinical trial — Safety result

The majority of reported events in this trial being mild to moderate severity in nature but would need to be assessed in a larger patient population. Notably, while SAEs were observed during the study period, all of them were target disease-related rather than treatment-related. The observed SAEs included brain edema, epilepsy, stroke, hyponatremia, gait disturbance, and pulmonary embolism, which are commonly reported symptoms in patients with brain tumors or severe illnesses as their disease progresses and were not attributable to VXM01 administration. A safety evaluation will be determined following review of all safety data by relevant regulatory agencies.

All patients (n=28; 100%) experienced multiple AEs, but no treatment-limiting toxicities (TLT) related to VXM01 or avelumab, or infusion-related adverse events (AEs) were recorded for any group. No treatment-related SAEs were recorded for the 10^6 CFU/mL and 10^7 CFU/mL resectable groups. No VXM01- or avelumab-related SAEs or treatment-emergent SAEs were recorded for any group. One patient discontinued study treatment due to rheumatoid arthritis which occurred after the first 5 weeks of treatment. This adverse event was assessed as unrelated to VXM01 administration and occurred independently of the patient's underlying condition, thus it was not reported as TLT. Four patients experienced a total of 5 (five) immune-related AEs (irAEs). These immune-related AEs included hypothyroidism, autoimmune thyroiditis, fatigue, and the aforementioned rheumatoid arthritis. As with other reported events, these immune-related AEs were assessed and determined to be unrelated to VXM01 administration.

Adverse Event Category	**10^6 CFU/mL (N=3) n (%) E**	**10^7 CFU/mL (N=25) n (%) E**
Drug related SAEs	—	—
Drug related Treatment-Emergent SAEs	—	—
TLT Related to VXM01	—	—
TLT Related to avelumab	—	—
Infusion-related Adverse Events	—	—
Immune-related Adverse Events	—	4 (16.0) 5
Treatment Discontinuations Due to AEs	—	1 (4.0) 1
Study Discontinuations Due to AEs	—	—

Note: A hyphen (-) indicates no events were reported. E = number of events; n = number of patients with an event; N = number of patients. Percentages are based on the number of patients.

Intellectual Property

Vaximm actively maintains 8 patent families relating to Vaximm's portfolio of assets, in the United States and in other major markets as described shown in the tables below of specific patents within each patent family that have been issued or are under examination. All patents within each of the active patent families have been issued or are currently under various stages of nationalization and are owned or in-licensed patent families by Vaximm and cover composition of matter, formulation and/or methods of use, are shown in the table below.

Manufacturing (1)
WO 2013/091898, Method for Producing High Yield Attenuated Salmonella Strains

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	21/12/2012	PCT/EP2012/005364			2013/091898	—	
AU	PCT	21/12/2012	2012359166	23/11/2017	2012359166	2012359166	21/12/2032	granted
CA	PCT	21/12/2012	2,853,656	29/12/2020	2,853,656	2,853,656	21/12/2032	granted
CN	PCT	21/12/2012	201280064144.2	19/04/2017	104066834	104066834	21/12/2032	granted
EP*	PCT	21/12/2012	12 808 264.1	30/08/2017	2 794 849	2 794 849	21/12/2032	granted
IN	PCT	21/12/2012	5386/DELNP/2014	10/06/2019	313960	IN05386DN2014	21/12/2032	granted
JP	PCT	21/12/2012	2014-547768	01/12/2017	6251179	2015-502162	21/12/2032	granted
KR	PCT	21/12/2012	10-2014-7020387	23/08/2019	10-2015932	10-2014-0105028	21/12/2032	granted
US	PCT	21/12/2012	14/366,186	15/11/2016	9,493,738	2014-0349274	21/12/2032	granted
ZA	PCT	21/12/2012	2014/04501	24/02/2016	2014/04501	2014/04501	21/12/2032	granted

VXM01 — dosing (2)
WO 2014/005683, DNA Vaccine for Use in Pancreatic Cancer Patients

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	26/06/2013	PCT/EP2013/001882			2014/005683	—	
AU	PCT	26/06/2013	2013286335	07/12/2017	2013286335	2013286335	26/06/2033	granted
AU	DIV	26/06/2013	2017258877	14/03/2019	201725887	2631924	26/06/2033	granted
CA	PCT	26/06/2013	2,877,938			2,877,938	26/06/2033	under examination
CN	PCT	26/06/2013	201380035905.6	30/10/2020	CN201380035905.6A	104519908	26/06/2033	granted
EP*	PCT	26/06/2013	13 732 833.2	25/09/2019	2 869 836	2 869 836	26/06/2033	granted
IN	PCT	26/06/2013	180/DELNP/2015			IN00180DN2015	26/06/2033	under examination
JP	PCT	26/06/2013	2015-518890	20/04/2018	6325534	2015-522263	26/06/2033	granted
KR	PCT	26/06/2013	10-2015-7002939	12/03/2020	10-2090612	10-2015-0036361	26/06/2033	granted
US	PCT	26/06/2013	14/409,434	16/08/2016	9,415,098	2015-0165011	26/06/2033	granted
US	CON2	31/05/2018	15/994,766	21/05/2019	10,293,037	2019-0008936	26/06/2033	granted
ZA	PCT	26/06/2013	2014/09156	27/07/2016	2014/09156	2014/09156	26/06/2033	granted

VXM06 — WT1 (3)
WO 2014/173542, Salmonella-based vectors for cancer immunotherapy targeting Wilms' tumor gene

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	24/04/2014	PCT/EP2014/001099			2014/173542	—	
EP*	PCT	24/04/2014	14 721 208.8	06/06/2018	2 988 762	2 988 762	24/04/2034	granted
JP	PCT	24/04/2014	2016-509326	12/10/2018	6416877	2016-518835	24/04/2034	granted
US	PCT	24/04/2014	14/786,652	20/03/2018	9,920,297	14/786,652	24/04/2034	granted
US	CON	24/04/2014	15/872,750	27/10/2020	10,815,455	2018/0163169	24/04/2034	granted

VXM04-MSLN (4)
WO 2015/090584, Novel MSLN targeting DNA vaccine for cancer immunotherapy

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	17/12/2014	PCT/EP2014/003403			2015/090584	—	
EP*	PCT	17/12/2014	14 821 508.0	28/08/2019	3 082 850	3 082 850	17/12/2034	granted
JP	PCT	17/12/2014	2016-559513	14/01/2020	6662787	2017-502692	17/12/2034	granted
US	CON	17/12/2014	15/785,743	15/10/2019	10,441,645	2018/0064794	17/12/2034	granted

VXM01 — combination (5)
WO 2016/202459, VEGFR-2 targeting DNA vaccine for combination therapy

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	16/06/2016	PCT/EP2016/001004			2016/202459	—	
AU	PCT	16/06/2016	2016278588	31/03/2022	AU2016278588A	2016278588	16/06/2036	granted
CA	PCT	16/06/2016	2989247	17/10/2023	CA2989247A	2989247	16/06/2036	granted
CN	PCT	16/06/2016	201680035593.2	13/07/2021	CN201680035593.2A	107995868	16/06/2036	granted
EP	PCT	16/06/2016	16736381.1	06/11/2019	3 310 379	3 310 379	16/06/2036	granted
EPHK	PCT		118111736.6	11/12/2020	HK1252435	HK1252435	16/06/2036	granted
EP(T1)	DIV		19205420.3			3626262	16/06/2036	under examination
IN	PCT	16/06/2016	201717043556	08.11.2023	467201	201717043556 A	16/06/2036	granted
JP	PCT	16/06/2016	2017-565248	21.09.2021	JP2017565248A	2018517419	16/06/2036	under examination
US	PCT	16/06/2016	15/737,659	02/02/2021	10,905,752	US 2018/0250345	16/06/2036	granted
US	CON	16/06/2016	17/107,203			US20210077605A1	16/06/2036	pending
ZA	PCT	16/06/2016	2017/08439	26/05/2021	2017/08439		16/06/2036	granted

VXM01 Tumor expression (7)
WO 2018/149982, Novel VEGFR-2 targeting immunotherapy approach

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	16/02/2018	PCT/EP2018/053918			WO 2018/149982	—	
AU	PCT	16/02/2018	2018222777	01/02/2024	2018222777B9	2018222777 A	16/02/2038	granted
CA	PCT	16/02/2018	305833			305833 A	16/02/2038	under examination
CN	PCT	16/02/2018	201880012318.8			110291187 A	16/02/2038	under examination
EP	PCT	16/02/2018	18 704 568.7			3 583 200 A	16/02/2038	under examination
IN	PCT	16/02/2018	201917030262			201917030262 a	16/02/2038	under examination
JP	PCT	16/02/2018	2019-544614				16/02/2038	under examination
US	PCT	16/02/2018	16/486,425	20/04/2021	10980868B2	2020038496 A	16/02/2038	granted

VXM10 — PD-L1 (8)
WO 2018/167290, Novel PD-L1 targeting DNA vaccine for cancer immunotherapy

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	16/02/2018	PCT/EP2018/056721			WO 2018/167290	—	
CN	PCT	16/02/2018	201880018761.6			110430893	16/02/2038	under examination
EP	PCT	16/02/2018	18710879			3 595 704	16/02/2038	under examination
JP	PCT	16/02/2018	2019-550795			2020-511139	16/02/2038	under examination

VXM01 in combination with an antibiotic (9)
WO 2021/144254, Salmonella-based DNA vaccines in combination with an antibiotic

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	12/01/2021	PCT/EP2021/050470			WO 2021/144254	—	
AU	PCT	12/01/2021	2021208400			2121208400	12/01/2041	under examination
CA	PCT	12/01/2021	3162994			3162994	12/01/2041	under examination
CN	PCT	12/01/2021	202180008543.6			114980871	12/01/2041	under examination
EP	PCT	12/01/2021	21700697			4090321	12/01/2041	under examination
IN	PCT	12/01/2021	202217033481			202217033481	12/01/2041	under examination
JP	PCT	12/01/2021	2022542046			2023510770	12/01/2041	under examination
KR	PCT	12/01/2021	1020227027291			1020220128638	12/01/2041	under examination
US	PCT	12/01/2021	17791282			20230121528	12/01/2041	under examination

Darnatein

Corporate Overview

Darnatein is developing design-augmented (DA) biologics for age-related and other degenerative diseases, such as osteoarthritis and spine and joint disorders. Darnatein's lead DA biologics are intended to be injected directly into pathological tissues to promote regeneration of target tissues such as bone or cartilage cells. Leveraging these innovative DA biologics to regenerate bone and cartilage has the potential to restore functionality and reduce pain across several degenerative conditions.

Darnatein has identified and advanced two therapeutic candidates, DRT-102, a clinical-stage asset for spinal fusion, and DRT-101, a pre-clinical stage asset for osteoarthritis. A small exploratory, clinical trial of 15 patients with DRT-102 indicated potential efficacy compared to a placebo, with no serious adverse events reported. Safety and efficacy evaluation will be determined following review of all safety data by relevant regulatory agencies. Larger clinical trials will be required to provide more extensive and accurate data on the safety and effectiveness of DRT102. A pre-clinical (non-human) trial of DRT-101 demonstrated cartilage regeneration and joint healing in animals, with no serious adverse events reported. Based on these preliminary results, Darnatein intends to continue the development and testing of DRT-101 and, when additional resources are available, DRT-102. Darnatein has not previously advanced any therapeutic candidates into late-stage clinical trials nor received regulatory and marketing approvals for any commercial sales of its products.

Opportunity

Age-related degeneration, such as osteoarthritis and spine disorders, is a naturally occurring process that may be accelerated due to chronic and cumulative impact over time. Limited therapeutic options exist and only offer limited and temporary symptomatic relief with no cure currently available.

Beyond therapeutic options, invasive surgical procedures may be available for spine and joint disorders but are not readily accessible and may not be a curative, pain-free, long-term solution. Additionally, neither symptomatic therapies nor invasive and costly surgical procedures address the underlying cause of chronic and age-related degenerative diseases. Darnatein's novel Design Augmented (DA) approach has the potential to overcome these limitations of spine and joint disorders and osteoarthritis with a regenerative therapy to overcome degeneration in bone and cartilage.

Design-Augmented Biologics Program

In recent years, scientists have studied the role of bone morphogenetic proteins (BMPs) in healing bone and cartilage. BMPs have been used clinically in orthopedic procedures but they are typically administered at high, supra-physiological concentrations that have been linked to undesirable local and systemic side effects. BMPs engineered to have enhanced therapeutic potency may circumvent this problem and provide the desired effects of healing bone and cartilage while minimizing the likelihood of adverse events.

DRT-101 for Cartilage and Joint Recovery

DRT-101 is a synthetic bio-signaling molecule that replaces BMPRII-binding segments of BMP-7, one of the bone-forming proteins, with high affinity ActRII binding segments of Activin A, a member of the transforming growth factor ß (TGF-ß). In nature, endogenous BMP7 promotes chondrogenesis in damaged cartilage tissue by signaling primarily via the type II receptor BMPRII and to a lesser extent via the activin type II receptor ActRII, which it binds with lower affinity. DRT-101 amplifies intracellular regeneration signaling capacity compared to natural BMP-7 and allows for regeneration and restoration of mechanically depleted cartilage cells to normal levels.

DRT-101 pre-clinical study in animals

DRT-101 was evaluated in Sprague Dawley rats by ChemOn Inc. in 2021 for toxicity measurement. This study was conducted to assess the approximate lethal dose (ALD) and the dose-range finding(DRF) of the test substance DRT-101, when administered intravenously.

The table below lists the type, species, purpose and results of our completed pre-clinical toxicology studies from 2021-2022. These studies were conducted with the assistance of Chemon Inc., a GLP-licensed third-party vendor.

Type of Study	Species	Purpose	Results	Period
Single Dose Intravenous Toxicity Test of DRT-101 in Sprague-Dawley Rats	Sprague Dawley Rats	Assess the toxicity of the test substance DRT-101 when administered intravenously to Sprague-Dawley Rats	The approximate lethal dose (ALD) was determined to exceed 10mg/kg for both males and females.	2021.03.05-2021.05.11
Single Dose Intravenous Toxicity Test of DRT-101 in Sprague-Dawley Rats	Sprague Dawley Rats	Investigate the toxicity and histopathological changes at the administration route	The approximate lethal dose exceeded 0.625 mg/kg for both males and females, and toxicologically adverse changes including dysplasia and hypertrophy of cartilage at the injection area were observed.	2021.04.29-2021.11.01

Type of Study	Species	Purpose	Results	Period
Two-Week Repeated Dose Intravenous Toxicity Test of DRT-101 in Sprague-Dawley Rats	Sprague Dawley Rats	Investigate the toxicity of DRT-101 when administered intravenously to Sprague-Dawley rats repeatedly for two weeks, with the aim of determining dosage for subsequent intravenous toxicity tests	DRT-101 was injected at dose of 0.069, 0.208, and 0.625 mg/kg/day. Swelling at the administration area (tail) was observed in male and female rats in dose groups above 0.208 mg/kg/day. Induration at the administration area was observed in all test substance groups of both sexes. The induration is speculated to be dysplasia and hypertrophy of cartilage in the tail. Accordingly, it is recommended to set 0.069 mg/kg/day as the high-dose group for the next repeated intravenous toxicity studies.	2021.12.07-2022.02.10

Currently, the toxicity test of DRT-101 is ongoing with BiotoxTech. The purpose of this study is to evaluate the potential toxicity and determine the dose levels for a repeated toxicity study of DRT-101, when given Intra-articular injection to rats and Beagles(non-rodents)

The table below outlines the type, species, purpose and results of the pre-clinical toxicology studies so far conducted with the assistance of BiotoxTech

Type of study	Species	Purpose	Results	Date of Completion
30-Day Repeated Intraarticular Injection (total 2 times) Dose Range Finding Study	Sprague-Dawley Rats	To evaluate the potential toxicity and determine the dose levels for a repeated toxicity study of DRT-101, when given Intra-articular injection to the Sprague-Dawley rats.	There were no DRT-101-related effects on body weight, food consumption, clinical pathology, or organ weight. In external and macroscopic evaluations, thickening in the injection site was observed in both sexes of the 3, 9 and 30 μg/animal groups in a dose-dependent manner. p-values < 0.05 (Anova&Dunnett)	2024.09.13
30-Day Repeated Intraarticular Injection (total 2 times) Dose Range Finding Study	Beagle dogs	To evaluate the potential toxicity of DRT-101 when administered via intra-articular injection to Beagle dogs 2 times with an interval of 4 weeks, and to determine the dose levels for a 6-week repeated toxicity study.	No deaths occurred during the course of the study. In clinical observations, all animals in DRT-101 dosing groups exhibited edemas at injection sites and abnormal gait after dosing. Edemas were exhibited in a broad area around the injection site, the right stifle joint, gradually recovering in 10 days for the 0.05 and 0.15 mg/animal dose groups, and in 24 days for the 0.5 mg/animal dose group.	2024.09.03

DRT-102 for Bone Regeneration

DRT-102 is an investigational product classified as a medical device product by the Ministry of Food and Drug Safety of the Republic of Korea ("MFDS"). DRT-102 is composed of freeze-dried AB204 protein, that promotes bone formation, and a synthetic bone graft in granular form.

The AB protein (AB204) is a synthetic protein, created by fusing Activin and BMP-2, both members of the BMP (Bone Morphogenetic Protein) family, growth factors by Darnatein's segmental reassembly technology. AB204 combines BMP's type II receptor binding with activin A's high-affinity type II receptor binding. It induces significantly greater and longer-lasting Smad 1/5/8 phosphorylation in osteoblastic cells compared to BMP2,

promoting mineral calcium nodule formation crucial for bone apatite formation. Unlike BMP2, AB204 is unaffected by noggin by design and also inhibits activin signaling, which further enhances its bone formation and is noteworthy since activin antagonism itself can promote bone formation. When used in conjunction with existing synthetic bone grafts, it facilitates the generation of new bone and can aid in fracture healing.

The synthetic bone graft uses approved products and is composed of hydroxyapatite and beta-tricalcium phosphate, with internal pores connected in a three-dimensional structure. By coating a highly bioactive and absorbable ß -TCP on an HA scaffold that can support structurally for a long period with excellent biocompatibility and slow biodegradation, it enables rapid initial bone bonding and long-term support dynamics.

DRT-102 pre-clinical study for toxicity measurement in animal models

The toxicity test of DRT-102 was conducted with multiple institutions including KTR (Korea Chemical Corporation), KIT (Korea Institute of Toxicology), and ChemOn. The purpose of this study is to evaluate the potential toxicity and determine the dose levels for a repeated toxicity study of DRT-102, when intravenously administered to rats and Beagles(non-rodents)

The table below outlines the type, species, purpose and results of the pre-clinical toxicology studies so far.

Type of study	Species	Purpose	Results	Date	Institution
Dose Range Finding Study: 2-Week Repeated Intravenous Injection	Sprague-Dawley Rats	To evaluate the potential toxicity and determine the dose levels for a repeated toxicity study of DRT-102, when intravenously injected to the Sprague-Dawley rats.	No deaths were observed. A slight dose-dependent increase in the absolute and relative weights of the spleen and liver was noted in female rats administered 0.25 and 0.5 mg/kg/day. Therefore, it was determined to set the high dose for the 4-week repeated intravenous toxicity study at 0.5 mg/kg/day	2013.11.11 ~ 2014.05.07	ChemOn
Single Intravenous Injection	Sprague-Dawley Rats	To evaluate the potential toxicity of DRT-102 when administered intravenously single time	The approximate lethal dose (ALD) of AB204 was determined to exceed 10 mg/kg (400 times the clinically intended dose) for both males and females.	2012.02.02 ~ 2012.04.09	ChemOn
4-Week Repeated Intravenous Injection with 2-Week Recovery Period for Rodents	Sprague-Dawley Rats	To evaluate the characteristics of DRT-102 when administered intravenously to Sprague-Dawley rats repeatedly for 4 weeks and to assess its recovery potential through a 2-week recovery period.	No deaths were observed, and no toxicologically adverse changes were detected. Under the conditions of this study, the No Observed Adverse Effect Level (NOAEL) of the test substance DRT-102 in rats was determined to be 0.32 mg/kg/day.	2014.01.02 ~ 2014.06.16	ChemOn
Dose Range Finding Study: 2-Week Repeated Intravenous Injection for Non-Rodents	Beagle dog	To evaluate the characteristics of DRT-102 when administered intravenously to Beagle dog repeatedly for 2 weeks.	No changes attributable to the test substance were observed. Therefore, in the upcoming 4-week repeated intravenous toxicity study, the high dose will be set at 0.5 mg/kg/day	2013.11.25 ~ 2014.02.13	ChemOn

Type of study	Species	Purpose	Results	Date	Institution
4-Week Repeated Intravenous Injection with 2-Week Recovery Period for Non-Rodents Following PK Sampling	Beagle dog	To examine the characteristics of DRT-102 when administered intravenously to Beagle dogs repeatedly for 4 weeks, and to assess its recovery potential through a 2-week recovery period	No toxicological changes were observed. Therefore, under the conditions of this study, the No Observed Adverse Effect Level (NOAEL) was determined to be 0.32 mg/kg/day for both males and females.	2014.02.11 ~ 2014.07.18	ChemOn
Safety Test — Cardiovascular System	Beagle Dog	To evaluate the effects of a single intravenous administration of DRT-102 to male Beagle dogs on cardiovascular function, including blood pressure, heart rate, and electrocardiogram (ECG), using a telemetry device for remote monitoring.	No adverse effect on cardiovascular function, including blood pressure, heart rate, and electrocardiogram (ECG) was observed.	2014.07.17 ~ 2014.08.07	KIT (Korea Institute of Toxicology)
Safety Test — Respiratory System	Sprague-Dawley Rats	To evaluate the effects of a single intravenous administration of the test substance AB204 on the respiratory system by measuring the respiratory rate and volume in Sprague-Dawley rats.	When DRT-102 is administered as a single intravenous dose of 0.8 mg/kg or lower, the test substance does not affect the respiratory system.	2014.07.17 ~ 2014.08.07	ChemOn
Safety Test — Central Nervous System	ICR Mouse	To evaluate the effects of a single intravenous administration of DRT-102 on the central nervous system by observing the animals' body temperature and systemic behaviors in ICR mice.	When DRT-102 was administered as a single intravenous dose of 0.8 mg/kg or lower to ICR mice, no changes in body temperature or systemic behaviors were observed.	2014.03.25 ~ 2014.04.29	ChemOn
Biological Safety Tests	—	Cytotoxicity test (Elution method)	Grade 2 (mildly cytotoxic)	2014.0924 ~ 2014.10.28	KTR (Korea Chemical Corporation)
	NZW rabbits	Intracutaneous reactivity	No signs of erythema or edema.		
	Dunkin Hartley guinea pigs	Skin Irritation test	No skin reactions after sensitization, indicating weak skin sensitization.		
	ICR mice	Acute toxicity test	No systemic toxicity changes observed within 72 hours after administration		
	NZW rabbits	Fever test	No body temperature increase of 0.5°C or higher.		
	—	Genotoxicity Test (Microbial Reversion Mutation)	Negative		
	—	Genotoxicity Test (Mammalian Chromosome)	Negative		

Pre-clinical study of DRT-102 for efficacy measurement in animal models

Efficacy test of DRT-102 was conducted with multiple institution including Joint Center for Bioscience, Inha University Hospital, Seoul Borame Medical Center, and Pharmalegacy (China). The purpose of this study is to evaluate the potential efficacy of DRT-102, when intravenously administered.

The table below outlines the type, species, purpose and results of the pre-clinical efficacy studies so far.

Type of study	Species	Purpose	Results	Date	Institution
Beagle dog spinal fusion	Beagle dog	To evaluate the efficacy of DRT-102 by tibial bone Fusion	– Test group implanted with DRT-102 showed a significantly higher fusion rate compared to the rhBMP-2 control group – Histological examination revealed that the AB204 group exhibited superior new bone formation and bone trabecular formation compared to both the rhBMP-2 and Osteon groups.	2013.07.01 ~ 2014.06.30	Seoul Boramae Medical Center
Rat spinal fusion	CD Rats	To evaluate the efficacy of DRT-102 by spinal bone Fusion	– 3 μg Implantation: In the group implanted with AB204, fusion rates were 50% at week 4 and 75% at week 8. In contrast, the rhBMP-2 group showed fusion rates of 25% at both week 4 and week 8. – 6 μg Implantation: In the AB204 group, fusion rates reached 100% at both week 4 and week 8. For the rhBMP-2 group, fusion rates were 25% at week 4 and 50% at week 8. – 10 μg Implantation: The AB204 group showed a 100% fusion rate at week 4, whereas the rhBMP-2 group showed only 75% fusion at week 4. – DRT-102 showed a concentration-dependent increase in new bone formation, with no pathological abnormalities observed.	2012.10.01 ~ 2014.03.31	Inha University Hospital
Rabbit tibial defect fusion	NZW Rabbit	To evaluate the efficacy of DRT-102 by tibial bone Fusion	– Histopathological evaluation of non-decalcified bone sections from the 8-week necropsy group, using Goldner's Trichrome staining, revealed that the bone area surrounding the test substance was greatest in the rhBMP-2 (positive control) group. The DRT-102 (100μg) group exhibited a slightly higher bone area around the test substance compared to the negative control group. Additionally, when measuring the length of osteoid relative to the area of new bone, the AB204 (100μg) group showed the highest ratio.	2014.06. 05 ~ 2014. 12.31	Korea Animal Medical Institute

Type of study	Species	Purpose	Results	Date	Institution
Mouse calvaria & Tibial defect fusion	C3H Rats	to evaluate the bone healing property of DRT-102 on Calvaria and Tibia osteotomy compared to rhBMP-2 in mouse.	– DRT-102 facilitates the healing of the CSD (critical-sized defect) in the tibia of rats. – CT scans and histological analyses showed that only DRT-102 was effective in healing the segment. – Bone generated by BMP2 did not integrate well with the existing bone, with visible boundaries, whereas bone newly formed by DRT-102 completely fused with the existing bone without visible differences. – The fidelity of the newly formed bone was particularly observed in Villanueva-stained tissue slides, which showed osteoblasts and mineralized bone.	2011.10. 01 ~ 2014. 9.31	JCB (joint center for biosciences)
In Vitro — Efficacy Test	MC3T3-E1 cell	To evaluate osteoinductivity of DRT-102 in MC3T3-E1 preosteblastic cells	– DRT-102 was not toxic to the cells. – DRT-102 promoted calcium nodule formation three times more than BMP2 – DRT-102 also increased ALP activity, another measure of osteogenic potential, by over 135% compared to BMP2	2011.10. 01 ~ 2014. 09.31	JCB (joint center for biosciences)
Monkey fibular defect fusion	Cynomolgus Monkey	To evaluate the efficacy of DRT-102 on primates' tibial bone defect	– When 5 mg of AB204/DBM was administered, it produced more than twice the amount of mineralized tissue compared to the 5 mg BMP-2/DBM treatment.	2014.06. 01 ~ 2014. 10.31	Pharmalegacy (China)
Mouse Calvaria Defect	C3H mouse	To evaluate the bone healing property of DRT-102 on Calvaria and Tibia osteotomy compared to rhBMP-2 in mouse.	– No animals died due to surgery – No individuals showed abnormal changes in body weight. – Bone remodeling was observed in X-ray images after 2 months post-surgery – The volume of new bone and the area of osteoid forming the new bone were more prominent than control group	2014.08 ~ 2014.10.15	JCB (joint center for biosciences)

Clinical trial of DRT-102

Darnatein is conducting a single-blind, active-controlled, randomized, multicenter confirmatory trial to evaluate the efficacy of DRT-102 for the treatment of Lumbar Spinal Fusion. The trial is being conducted at Boramae Medical Center of Seoul National University, Inha University Hospital, and Soonchunhyang University Seoul Hospital.

The clinical trial of DRT-102 includes both exploratory and confirmatory phases. The patient selection criteria for both studies are as follows:

Inclusion Criteria:

(1) Age between 30-80 years old.

(2) Patients requiring one-level posterior decompression and fusion between L1 and S1 due to severe spinal stenosis, spondylolisthesis, spondylosis, or retrolisthesis.

Exclusion Criteria:

(1) Average spine T-score< -2.5 on dual-energy X-ray absorptiometry (DEXA),

(2) History of cancer,

(3) Patient unable to discontinue anticoagulation therapy,

(4) Female patients of childbearing potential,

(5) Patients testing positive for DRT-102 antibody,

(6) Specific conditions, including psychological problems.

Patients were regularly followed up at 2, 12, 24 and 48 weeks postoperatively. Patients were divided into two groups: TLIF (Transforaminal Lumbar Interbody Fusion) performed with or without the use of DRT-102.

2 mg of DRT-102 was reconstituted using sterile water and the resulting solution was used to soak 6cc of Osteon II (Genoss, #OT7G2030600) were inserted into PEEK (polyetheretherketone) cages before placement into the prepared disc space. No autogenous grafts were used in the investigational group, while the control group received autograft in cages.

Exploratory clinical trial of DRT-102

DRT-102 was evaluated in a exploratory clinical trial with 4 patients (excluding two dropouts) conducted at Inha University Hospital managed by DT&R CRO in 2016 ~ 2019.

The primary objective of this study was to evaluate the bone fusion rate of DRT-102 for patients with severe spinal stenosis, spondylolisthesis, spondylosis, or retrolisthesis, all of whom required posterior decompression and fusion.

Source: Choi, Seung-hyun, et al. "Evaluation of Posterolateral Lumbar Fusion with Composite Bone Graft AB204-sp: A Preliminary Comparative Study and Therapeutic Exploratory Trial." Korea Health Industry Development Institute, Mar. 2019. National R&D Research Report, TRKO202000003168, scienceon.kisti.re.kr/srch/selectPORSrchReport.do?cn=TRKO202000003168. Accessed 21 Oct. 2024.

To assess the bone fusion rate, a CT scan was conducted for 6 months postoperatively to measure the fusion status.

The criteria for determining bone fusion were as follows:

a. Formation of continuous trabeculation between the adjacent vertebral body and the graft bone.

b. Evidence of remodeling between the adjacent vertebral body and the graft bone.

c. Absence of radiolucent areas between the adjacent vertebral body and the graft bone.

Fusion was determined successful if at least two of the criteria (a, b, or c) were met. In cases where only one criterion was met or none were satisfied, non-fusion was diagnosed.

The secondary evaluation parameters included the bone fusion rate observed on X-rays 6 months postoperatively, the rate of bone degeneration assessed on MRI 6 months postoperatively, the improvement in Visual Analog Scale (VAS) scores, and the improvement in the Oswestry Disability Index (ODI).

		SN003		SN004		SN005		SN006	
		Visit 1 (Screwening)	Visit 2 (6 month)	Visit 1 (Screening)	Visit 2 (6 month)	Visit 1 (Screening)	Visit 2 (6 month)	Visit 1 (Screening)	Visit 2 (6 month)
Procedure Site		L4 – L5		L4 – L5		L4 – L5		L4 – L5	
X-ray		Y	Y	Y	Y	Y	Y	Y	Y
CT-scan		—	Y a, c satisfied	—	Y a, c satisfied	—	Y 100% fusion on rt. side & 50% fusion on lt. side	—	Y a, c satisfied
MRI		—	Y	—	Y	—	Y	—	Y
VAS(mm)	Lumbar	100	45	95	94	32	17	93	74
	Lt. leg	100	41	94	9	0	18	91	74
	Rt. leg	0	0	64	68	0	16	40	50
ODI		44	17	34	26	12	13	19	15

NOTE: a: Formation of continuous trabeculation between the adjacent vertebral body and the graft bone, b: Evidence of remodeling between the adjacent vertebral body and the graft bone, c: Absence of radiolucent areas between the adjacent vertebral body and the graft bone.

This study has indicated that all patients exhibited strong spine fusion through X-ray, CT and MRI. Three patients (SN003, SN004, SN005) exhibited 100% spinal fusion at the procedure site. For patient SN005, 100% fusion was observed on the right side, while 50% fusion was observed on the left side.

Significant improvements were also observed in VAS and ODI scores. In the case of VAS, pain levels decreased from severe to worst pain levels to mild to moderate pain levels. For ODI, which measures discomfort in daily activities, scores improved from moderate to severe disability to minimal to moderate disability, indicating an enhancement in quality of life.

During the course of this clinical trial, no drug-related adverse effects or toxicity were observed.

Confirmatory clinical trial of DRT-102

DRT-102 was further evaluated in a confirmatory clinical trial from 2020 to 2022. This study involved 15 total patients and was conducted at Inha University, SNU Medical School Boramae Hospital, and SoonChunHyang Medical School Hospital. This trial was managed by DT&R CRO.

The primary objective of this study was to evaluate the bone fusion rate of DRT-102 in a larger patient population.

Primary efficacy endpoint was evaluated with bone fusion rate (%) as observed on CT scans at 24-weeks post-surgery.

Bone fusion is determined when at least two out of the following three criteria are satisfied:

a. Continuous trabeculation formation

b. Evidence of bone remodeling

c. Absence of radiolucent areas

[Bone Fusion Rate Based on CT Scans at 24 Weeks Post-Surgery]

Control	CT Scan		Test	CT Scan	
	Fufilled Critera	Bone Fusion		Fufilled Critera	Bone Fusion
1.	—	F	1	a, b, c	S
2.	—	F	2	b	F
3.	—	F	3	a, b, c	S
4.	—	F	4	a, b	S
5.	a, b	S	5	a, b, c	S
6.	a, b	S	6	a, b, c	S
7.	b	F	7	b	F
			8	a, b, c	S

	Success	Fail	Total
Control	2 (25%)	5 (71.4%)	7 (46.7%)
Test	6 (75%)	2 (28.6%)	8 (53.3%)

Note: S = Bone Fusion Success; F = Bone Fusion Failure; a = Continuous trabeculation formation; b = Evidence of bone remodeling; c = Absence of radiolucent areas

The bone fusion rate in the test group was 75%, while it was 28.57% in the control group, resulting in a difference of 46.43% between the two groups.

Secondary efficacy endpoints included Bone fusion rate (%) based on X-rays at 24 weeks post-surgery.

Bone fusion rate (%) based on X-rays at 24 weeks post-surgery

The number of successful and failed bone fusions was observed on X-rays post-surgery in the experimental and control groups, along with the bone fusion success rates. The difference in bone fusion rates between the two groups was evaluated using the chi-square test.

Evaluation Criteria

a. Formation of bridging callus

b. Absence of bone spurs connecting the two vertebrae at the surgical site.

Control Group	X-ray		Test Group	X-ray	
	Fulfilled Criteria	Bone Fusion		Fulfilled Criteria	Bone Fusion
1.		F	1	a, b	S
2.		F	2		F
3.		F	3	a, b	S
4.		F	4	a, b	S
5.	a, b	S	5	a, b	S
6.	a	S	6	a, b	S
7.		F	7		F
			8	a, b	S

	Success	Fail	Total
Control	2 (25%)	5 (71.4%)	7 (46.7%)
Test	6 (75%)	2 (28.6%)	8 (53.3%)
Total	8 (100%)	7 (100%)	5 (100%)

Note: S = Bone Fusion Success; F = Bone Fusion Failure; a = Continuous trabeculation formation; b = Evidence of bone remodeling; c = Absence of radiolucent areas

[Changes in p-value according to the number of subjects]

	Success	Fail	# of patients	p-value
Control	2	5	7	
Test	6	2	8	0.132
			15	

	Success	Fail	# of patients	p-value
Control	3	8	11	
Test	9	3	2	0.039
			23	

	Success	Fail	# of patients	p-value
Control	4	0	4	
Test	2	4	6	0.026
			30	

	Success	Fail	# of patients	p-value
Control	9	9	28	
Test	24	8	32	0.002
			60	

Note: S = Bone Fusion Success; F = Bone Fusion Failure; a = Continuous trabeculation formation; b = Evidence of bone remodeling; c = Absence of radiolucent areas

The clinical trial results indicate that the success rate in the test group was significantly higher at 75%, compared to only 25% in the control group. Additionally, the failure rate in the control group was 71.4%, which was markedly higher than the 28.6% observed in the test group. These findings demonstrate that the test group, which received DRT-102, exhibited a substantially better outcome in terms of bone fusion compared to the control group. Overall, the data strongly suggest that DRT-102 is more effective than the control treatment in promoting bone fusion.

The chi-square test of the study demonstrates how the p-value changes with varying sample sizes in the clinical trial, comparing the control and test groups. Initially, with a smaller sample size of 15 patients, the p-value is 0.132, indicating no statistically significant difference between the two groups. However, as the sample size increases to 23 patients, the p-value drops to 0.039, suggesting a statistically significant difference favoring the test group.

With a moderate sample size of 30 patients, the p-value further decreases to 0.026, indicating stronger statistical evidence of the difference in success rates between the control and test groups. Finally, in the largest sample size of 60 patients, the p-value reaches 0.002, demonstrating a statistically significant difference. Throughout the analysis, the test group outperformed the control group in success rates.

Development plans for DRT-101 and DRT-102

Based on preliminary tests of DRT-101 and DRT-102, Darnatein intends to expand the potential application of DRT-101 to other cartilage regeneration targets, including spinal cartilage in the treatment of lower back pain. Darnatein may, depending upon securing additional financial resources and other opportunities requiring investment, expand the potential application of DRT-102 to other bone regeneration targets, including non-fusion bone fracture in the treatment of deformed bone tissue. Darnatein's strategy generally involves the following key steps:

1. Identify novel drug candidate for cartilage- and bone-degenerative disorders: Darnatein will leverage its expert knowledge and experience in tissue regenerative medicine to identify new cartilage- and bone-degenerative disorders that can be targeted by Darnatein's DRT-101 and DRT-102 platforms.

2. Conduct preclinical studies with the FDA's good laboratory practice ("GLP") regulations: Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. Darnatein will first perform preclinical studies to evaluate the safety, immunogenicity, and efficacy of regenerating the new target tissue candidates.

3. File an Investigational New Drug (IND) application: Upon the successful completion of preclinical studies, Darnatein will submit an IND application to regulatory authorities such as the FDA. IND is a request for authorization from the FDA to ship an investigation product and then administer it to humans and must be allowed to proceed by the FDA before human clinical trials may begin. This submission includes all relevant data from preclinical studies and outlines the proposed clinical trial protocols. The IND review period typically takes 30 days, during which the regulatory agency evaluates the submission to ensure the safety of proceeding to human trials.

4. Initiate clinical trials: Based on the preclinical data, Darnatein will design and conduct additional Phase 1 clinical trials to assess the safety, tolerability, and preliminary efficacy of its regeneration of those new tissue candidates.

5. Conduct Phase 2 and Phase 3 clinical trials: Phase 2 trials are designed to determine if the new treatment has sufficiently promising efficacy to warrant further investigation in a large-scale randomized phase 3 trial, as well as to further assess safety. These studies usually involve a few hundred patients. Phase 2 trials also generate insights on adverse events and their management, the diseases in which the treatment is effective, and the best regimen for future use in a later phase, depending on the trial design.

   Phase 3 trials are large-scale, randomized, controlled studies designed to provide additional supporting evidence of the efficacy and safety of therapeutic candidates. These trials typically involve hundreds to thousands of patients and are typically conducted at multiple hospital sites worldwide.

   Darnatein will work closely with clinical investigators, regulatory authorities, and patient advocacy groups to design and execute initially Phase 2 and seek to continue with Phase 3 clinical trials based on evaluation of Phase 2 studies for its tissue targets.

6. Seek regulatory approval: Following the successful completion of Phase 3 clinical trials, the result of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, and proposed labeling, among other things, are submitted to authorities, such as the FDA or EMA. This stage is known as the New Drug Application (NDA) review.

Based on these steps and the timeline for regulatory approvals, Darnatein anticipates that its first therapeutic regimen to enter clinical trials within the next 2 – 3 years, with potential regulatory approval in the next 8 – 11 years.

For a description of the regulatory steps for the implementation of Darnatein's strategy described above, see *"Business of the Company and Certain Information About the Company — Vaximm — Regulatory Steps"*.

Intellectual Property

Darnatein owns exclusive intellectual property rights covered under 2 patent families relating to DRT-101, DRT-102 and other associated candidates filed in the United States and across major markets, including Europe, China, India, and Japan. This patent family covers composition of matter, with a priority date of 2019 and estimated expiry in 2039, not including potential patent term adjustments or patent term extensions.

Designer ligands of TGF-ß superfamily (Licensed Patent Rights) (0)
WO 2010/099219, Exclusive License Agreement between Joint Center for Biosciences and Darnatein

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	24/02/2010	PCT/US2010/025260			2010/099219		
EP	PCT	24/02/2010	10746779	10/02/2016	2401293B1	2401293	24/02/2030	granted
KR	PCT	24/02/2010	1020117021911	12/10/2015	1015586420000	1020110121642	24/02/2030	granted
CA	PCT	24/02/2010	2752647A1			2752647	24/02/2030	Under Examination
JP	PCT	24/02/2010	2011551315	20/11/2015	5841845	2012518420	24/02/2030	granted

DRT-101 (SAB-704) (1)
WO 2020/101366, Activin/bmp7 chimeras: super-active sab704 and sab715, and their respective noggin-sensitized variants, nab704 and nab715; and nab204

Country Code	Type	Filing date	Filing no.	Grant Date	Grant no.	Publ. No.	Expiry	Status
WO	PCT	13/11/2019	PCT/KR2019/015478			2020/101366	—	
US	PCT	13/11/2019	20210395322			20210395322	13/11/2039	granted
EP	PCT	13/11/2019	19885240			3880695	13/11/2039	Under Examination
KR	PCT	13/11/2019	1020217018273	30/10/2025	10-2725896	1020210077790	13/11/2039	granted
CN	PCT	13/11/2019	201980075594.3	14/7/2025	7795027	113039199	13/11/2039	granted

RMC

Corporate Overview

RMC is a Korea-based neurovascular intervention medical device and systems distribution company exclusively serving the Korea market currently. RMC distributes, but does not design or manufacture, commercial medical products, including cerebral surgical devices.

Opportunity

RMC distributes cerebrovascular surgery equipment in South Korea and seeks growth opportunities in South Korea for other medical device products and systems.

As a rapidly aging country, demand for medical equipment is expected to accompany the rise in cerebrovascular diseases such as strokes. RMC has established close relationships with leading university hospitals and general hospitals in Korea to supply cerebrovascular surgery equipment. These relationships provide opportunities for continued sales of products distributed by RMC as well as assisting RMC in identifying demand for other medical devices that RMC may add to enhance its product portfolio. This is expected to enhance RMC's competitiveness in South Korea.

RMC has established a nationwide sales network and logistics system, enabling it to swiftly and efficiently supply products to any region in the country. This serves as a significant strength compared to competitors and is expected to contribute to building long-term trust with medical institutions.

Products and Related Systems

The table below shows the products and related systems currently distributed by RMC.

Company	Product and System	Function of Product/System
Asahi Intecc	Chikai Guide Wire	This product is designed to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during endovascular therapy and is intended for use in the neurovascular field. It is used as a guidewire for stent delivery catheters, coil delivery microcatheters, carotid stent delivery catheters and balloon catheters used in cerebral aneurysm coil embolization.
	Fubuki Guide Catheter	This catheter is used to guide neurovascular interventional devices to sites for percutaneous endovascular procedures in neurovascular vessels; also used for contrast injection. This catheter is designed to guide therapeutic cerebrovascular catheters to lesions or sites for percutaneous endovascular procedures in the cerebral vasculature.

Company	Product and System	Function of Product/System
Microport Neurotech	Numen coil system	This product is a single-use device for endovascular embolization of intracranial aneurysms and other neurovascular malformations such as arteriovenous fistulas. It is used to dye blood vessels in the neurovascular system to permanently block blood flow to aneurysms or other vascular malformations, or for arterial and venous embolization in peripheral vessels.

Since 2015, RMC has also distributed neuro-intervention medical device equipment manufactured by Penumbra Inc. RMC's distribution agreement with Penumbra Inc. for the resale of its reperfusion catheter, neuron delivery catheter and related tubing and canister, expired on June 30, 2024. The parties' negotiations for a new (or extended) agreement terminated on November 20, 2024. RMC will not purchase additional Penumbra products. Certain issues, such as whether RMC may continue to sell its existing inventory of Penumbra products or whether Penumbra will repurchase RMC's inventory, have not as yet been resolved. To replace sales of Penumbra products, RMC intends to seek to become the sales representative of other neuro-intervention medical device equipment manufacturers, as well as expand sales of products offered by companies it currently represents.

Strategic Evolution into a Healthcare 4PL Platform

As described above, RMC has historically operated as a medical device importer and distributor in Korea with a primary focus on the neuro-intervention field. However, following a comprehensive strategic review, the management has determined to transform RMC into a fourth-party logistics ("4PL") platform for the Korean healthcare supply chain — a strategic evolution that we view as a significant new growth engine for the consolidated group and a material driver of revenue growth through 2030.

Industry Context and Market Opportunity

The Korean medical device import and distribution sector is under material structural stress, driven by two converging dynamics:

- Foreign exchange pressure: Import purchase obligations are predominantly USD-denominated, while distributor revenues are generated in KRW. Sustained KRW depreciation has materially increased the local currency cost of Minimum Purchase Guarantee ("MPG") commitments to global manufacturers, compressing margins and straining liquidity across the independent distributor base.
- Working capital mismatch: Large university hospitals — the dominant demand-side buyers — typically remit payment up to six months after device delivery, while receiving National Health Insurance Service ("NHIS") reimbursement within approximately two weeks of claim filing. Independent distributors are required to finance this five-to-six month A/R gap without adequate access to institutional capital.

These dynamics have produced a class of financially constrained distributors actively seeking to exit their Korea agency mandates, import licenses, and MPG obligations — a dislocation management believes presents RMC with a compelling and time-sensitive consolidation opportunity.

RMC's targeted 4PL product categories span eleven identified product lines with a combined total addressable market ("TAM") estimated at approximately **KRW 159.9 billion (~$110.7 million)**. Management notes that this estimate reflects a conservative, narrowly scoped assumption based on RMC's historical neurointervention focus, representing approximately 2.3% of total Korean medical device imports of ~USD 4.88 billion (Korean Medical Device Association, 2022). The Company intends to revisit and update this TAM as RMC establishes a presence in product categories beyond its current core market.

RMC 4PL Business Model

RMC's 4PL model addresses the structural pain points above by positioning the Company as a financially capable consolidator and central platform across the Korean medical device supply chain, built on three core capabilities:

- Mandate Acquisition: RMC assumes Korea agency mandates, import licenses, and MPG obligations from financially distressed independent distributors, consolidating a historically fragmented and undercapitalized segment of the supply chain.

- Working Capital Intermediation: Leveraging OSR Holdings' NASDAQ-listed parent credibility and financial resources, RMC bridges the structural A/R gap inherent in the distributor-to-hospital payment cycle — a capability most independent distributors cannot replicate.
- Scope Expansion and ICC Services: The 4PL platform aggregates mandates across medical device categories beyond neurointervention, enhancing scale economics and reducing concentration risk. In-Country Care ("ICC") services represent an additional, complementary revenue stream as the platform matures.

A number of Korean distributors have already approached RMC proactively, viewing its NASDAQ-listed parent as a credible and well-capitalized consolidator. Management believes RMC is positioned to execute its roll-up strategy promptly upon capital allocation by OSR Holdings.

4PL Product Pipeline

The table below sets forth the eleven identified 4PL product categories, each with estimated Korean market TAM, target MFDS approval year, and projected market share for 2027 – 2030 (KRW millions).

Product Category	TAM (KRW mil)	MFDS Target	2027E	2028E	2029E	2030E
Category A	12,600	2026	10%	15%	20%	20%
Category B	12,600	2026	5%	10%	10%	10%
Category C	10,410	2026	5%	20%	25%	25%
Category D	9,364	2026	20%	25%	30%	30%
Category E	1,314	2027	—	5%	5%	5%
Category F	66,647	2027	10%	15%	20%	25%
Category G	6,800	2026	15%	20%	30%	30%
Category H	6,726	2026	5%	5%	5%	5%
Category I	6,497	2027	20%	25%	25%	25%
Category J	9,311	2028	—	10%	20%	30%
Category K	17,634	2028	—	10%	20%	30%
Total TAM	**159,903 (~$110 mil)**					

Market share projections reflect management estimates based on identified pipeline opportunities and distributor consolidation targets. Actual results may differ materially.

Financial Projections

The table below summarizes RMC's projected revenue and profitability across its three segments for fiscal years 2026 – 2030 (KRW millions).

KRW mil	2026E	2027E	2028E	2029E	2030E
4PL Revenue	—	13,604	23,651	31,976	38,003
ICC Revenue	500	800	1,000	1,200	1,200
Current Business	3,600	4,400	4,600	5,000	5,600
Total Revenue	**4,100**	**18,804**	**29,251**	**38,176**	**44,803**
Net Income	615	1,880	2,340	3,054	3,584
Net Margin	15%	10%	8%	8%	8%

Forward-looking estimates prepared by management. Subject to risks and uncertainties. See "Forward-Looking Statements" and "Risk Factors" elsewhere in this Annual Report.

Key observations: (i) 4PL revenue is not projected to commence until 2027, reflecting the time required for mandate acquisition and MFDS approvals following 2026 capital deployment; (ii) total RMC revenue is projected to grow from KRW 4.1 billion in 2026 to KRW 44.8 billion in 2030 (~82% CAGR), driven primarily by the 4PL ramp; and (iii) net margin is expected to stabilize at approximately 8% from 2028, with the current business providing a stable organic base throughout.

Key Execution Considerations

Investors should be aware of the following principal risks specific to RMC's 4PL initiative:

- Capital Deployment: Execution pace is contingent upon OSR Holdings allocating sufficient capital; delays could materially impact the projected revenue ramp.
- Regulatory Timelines: MFDS oversight of import license and mandate transfers may defer revenue commencement beyond projected periods.
- Foreign Exchange: RMC will assume USD-denominated MPG obligations; continued KRW depreciation could increase local currency costs materially.
- Working Capital: Scaling the platform will require disciplined management of an expanding A/R base given the structural hospital payment cycle.
- Pipeline Conversion: No assurance exists that identified distributor candidates will transfer mandates on commercially acceptable terms or within projected timeframes.

Outlook

Management views RMC's 4PL transformation as one of the most significant value creation opportunities within the OSR Holdings portfolio. The Company will provide updates on mandate acquisitions, capital deployed, and MFDS milestones in its periodic filings and through other public disclosures as material developments warrant.

Intellectual Property

Except for trade secrets related to operating a medical product distribution business, there is no significant intellectual property owned or licensed by RMC.

Competition in our Industry

Competition for Product Candidates

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from pharmaceutical and biotechnology companies to public and private research institutions, among others.

If our current and/or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Our product candidates, if any are approved, may compete with these existing drug and other therapies.

The table below summarizes the main competitors we have identified for Vaximm's VXM01. Each of these identified competitors are developing therapies for glioblastoma and have active clinical trials ongoing assessing the safety and efficacy of their product candidates.

Drug Name	Company	Mechanism	Indication	Clinical Phase	NCT Number(s)
Depatuxizumab mafodotin (ABT-414)	AbbVie	Antibody-drug conjugate targeting EGFR	Newly diagnosed glioblastoma	Phase 2/3	NCT02573324
Durvalumab (MEDI4736)	AstraZeneca	PD-L1 checkpoint inhibitor	Newly diagnosed and recurrent glioblastoma	Phase 2	NCT02336165
Regorafenib	Bayer	Multi-kinase inhibitor	Recurrent glioblastoma	Phase 2	NCT02926222
Tasadenoturev (DNX-2401)	DNAtrix	Oncolytic adenovirus	Recurrent glioblastoma	Phase 2	NCT03178032
Ofranergene obadenovec (VB-111)	VBL Therapeutics	Dual-targeted gene therapy	Recurrent glioblastoma	Phase 3	NCT02511405
AV-GBM-1	Aivita Biomedical	Personalized dendritic cell vaccine	Newly diagnosed glioblastoma	Phase 2	NCT03400917
VAL-083	Kintara Therapeutics	DNA-targeting agent	Recurrent and newly diagnosed glioblastoma	Phase 2/3	NCT02717962, NCT03050736

With respect to Darnatein, competition takes two forms: pharmaceutical products (drugs) that address the underlying causes of osteoarthritis, and orthopedic solutions involving bone graft and other products. Several pharmaceutical companies and research institutions are actively working on developing Disease-Modifying Osteoarthritis Drugs (DMOADs) to address the underlying causes of osteoarthritis (current treatments primarily focus on symptom management). There are currently no approved DMOAD treatments for osteoarthritis but the table below identifies drugs under development:

The table below summarizes the main competitors we have identified for Darnatein's DRT-101. Each of these identified competitors are developing therapies for osteoarthritis and have active clinical trials ongoing assessing the safety and efficacy of their product candidates.

Drug Name	Company	Mechanism	Indication	Clinical Phase	NCT Number(s)
Invossa	Kolon TissueGene	Cell and gene therapy (TGF-ß1 expressing chondrocytes)	Osteoarthritis	Phase 3	NCT03383471
Lorecivivint	Biosplice Therapeutics	CLK/DYRK1A inhibitor	Osteoarthritis	Phase 3	NCT03928184
Sprifermin	Merck KGaA/EMD serono	Recombinant human fibroblast growth factor 18	Osteoarthritis	Phase 2	NCT01919164 NCT01033994

The table below summarizes the main competitors we have identified for Darnatein's DRT-102. Each of these identified competitors are commercialized orthopedic solutions.

Drug Name	Company	Mechanism	Indication
Infuse Bone Graft	Medtronic	rhBMP-2 and collagen sponge	Spinal fusion, long bone fractures, orthopedic surgery
Osteocel Plus	NuVasive	Demineralized bone matrix (DBM) and mesenchymal stem cells (MSC)	Spinal fusion, bone defects
Bio[4]	Stryker	A viable bone matrix containing endogenous bone forming cells	Bone repair and regeneration
i-Factor	Cerapedics	P-15 peptide and anorganic bone matrix	Spinal fusion, bone defects
Novabone IRM	Novabone	Composed of bioactive glass, chemically bonds with bone and promotes new bone formation	Bone defects, dental grafting

With aging populations comes a higher number of cerebrovascular disease patients. There are a number of potential treatments such as drug therapy and open surgery. Minimally invasive procedures, such as neurovascular intervention, have been growing. Various international medical device brands are competing for market share.

The table below summarizes the main competitors we have identified for RMC:

Device Name	Company	Mechanism	Indication
React catheter	Medtronic	Reperfusion catheter	Treatment of acute ischemic stroke
AXS infinity catheter	Stryker	Neurovascular Delivery catheter	Delivery of therapeutic devices in neurovascular procedures
AXS catalyst 7 distal access catheter	Stryker	Distal access support canister	Neurovascular access and support for device delivery
Synchro wire	Stryker	Neurovascular guide wire	Navigation through neurovascular anatomy
Traxcess wire	Microvention	Neurovascular guide wire	Navigation through neurovascular anatomy
Envoy guide catheter	Cerenovous	Neurovascular guide catheter	Support and delivery of neurointerventional devices
Guider soft tip guide catheter	Boston scientific	Soft tip neurovascular Guide catheter	Support and delivery of neurointerventional devices
Microplex coil system	Microvention	Detachable embolization coil system	Embolization of intracranial aneurysms
GDC coil system	Stryker	Detachable Coil system	Embolization of intracranial aneurysms
Axium prime coil system	Medtronic	Detachable Coil system	Embolization of intracranial aneurysms

Manufacturing

We do not have any manufacturing facilities or personnel at this time, except that Darnatein maintains and uses manufacturing facilities owned by Joint Center for Biosciences, Darnatein's affiliate and the Company's shareholder, for purposes of R&D and clinical and preclinical materials for its sole use. We currently rely on CMOs for the manufacture of our product candidates for preclinical and clinical testing in non-commercial quantities.

Our product candidates include small molecules, vaccines, and monoclonal and bispecific antibodies. Several contract manufacturing facilities exist that have expertise in each product type and we anticipate that our product candidates can be produced by them at scale and in a cost-effective manner. As needed, we also expect to rely on CMOs for the manufacturing of companion diagnostics, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Vaximm has a master service agreement with Richter-Helm BioLogics GmbH & Co. KG ("RHB"), a CMO located in Germany, for the manufacture of Vaximm's product candidates. RHB will provide cell line development, process development, manufacturing, and related services for Vaximm's product candidates. The agreement became effective April 10, 2012, and will remain in effect until terminated by either party. Vaximm pays RHB for services rendered based on agreed-upon rates specified in individual work orders. Vaximm retains ownership of all intellectual property related to its product candidates, while RHB owns IP related to manufacturing processes developed under the agreement.

Commercialization

We will objectively assess and choose each program's commercialization option that maximizes potential value for patients and for our stockholders. We anticipate optimizing commercial value through various options, including internal advancement, strategic partnerships, and spin-outs or public offerings. If we opt to commercialize a particular candidate ourselves, we anticipate assembling a commercialization team inclusive of sales and marketing operations to promote and sell our products. Our focus will be the community of relevant medical practitioners who are the key specialists in treating the patient populations for which our product candidates are being developed. We may also enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We currently do not have marketing and sales management operations for any of our pharmaceutical products and will rely, at least initially, on third parties for support. The responsibilities of marketing operations would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine. We will reevaluate the sales operations from time to time and may eventually build an in-house marketing and sales management organization.

Our Management Team

Members of our management team are not obligated to devote any specific number of hours to our matters, but they intend to devote as much of their time as they, in the exercise of their respective business judgment, deem necessary to our affairs until we have completed our initial business combination. The amount of time that any member of our management team will devote in any time period will vary based on whether a target business has been selected for our initial business combination and the current stage of the business combination process. We do not have an employment agreement with any member of our management team.

We believe our management team's operating and transaction experience and relationships with companies will provide us with a substantial number of potential business combination targets. Over the course of their careers, the members of our management team have developed a broad network of contacts and corporate relationships in the healthcare and biotechnology industry. This network has grown through the activities of our management team sourcing, acquiring and financing businesses, our management team's relationships with sellers, financing sources and target management teams and the experience of our management team in executing transactions under varying economic and financial market conditions. See "Item 10. Directors, Executive Officers and Corporate Governance" for a more complete description of our management team's experience.

Status as a Public Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced

disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the prices of our securities may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this extended transition period.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the aggregate worldwide market value of our common stock held by non-affiliates equaled or exceeded $250 million as of the prior June 30th and (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year or the aggregate worldwide market value of our common stock held by non-affiliates equaled or exceeded $700 million as of the prior June 30th.

Facilities

Our executive offices are located at 10900 NE 4th Street, Suite 2300, Bellevue, WA 98004 and Hoedong-gil, 37-36, 3F, Paju, Gyeonggi-do, 10881 Korea, and our telephone number is (425) 635-7700 and +82 31 948 9419, respectively. Our executive offices are provided to us by an affiliate of our Sponsor. Commencing on March 1, 2023, we agreed to pay an affiliate of our Sponsor a total of $7,500 per month for office space, utilities and secretarial and administrative support. We consider our current office space adequate for our current operations.

Website

We maintain a corporate website at *www.osr-holdings.com*. Our website and information contained on, or that can be accessed through, our website is not deemed to be incorporated by reference in, and is not considered part of, this report. You should not rely on any such information in making your decision whether to invest in our securities.

Employees

We currently have four officers. These individuals are not obligated to devote any specific number of hours to our matters, but they intend to devote as much of their time as they deem necessary, in the exercise of their respective business judgement, to our affairs until we have completed our initial business combination. The amount of time they will devote in any time period will vary based on whether a target business has been selected for our initial business combination and the stage of the initial business combination process we are in. We do not have an employment agreement with any member of our management team.

Periodic Reporting and Financial Information

We have registered our common stock and warrants under the Exchange Act and have reporting obligations, including the requirement that we file annual, quarterly and current reports with the SEC. In accordance with the requirements of the Exchange Act, our annual reports will contain financial statements audited and reported on by our independent registered public accountants. These filings are available to the public via the Internet at the SEC's website located at *http://www.sec.gov*. You may request a copy of our filings with the SEC (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

OSR Holdings, Inc.
10900 NE 4th Street, Suite 2300
Bellevue, WA 98004
Telephone: (425) 635-7700

We will provide stockholders with audited financial statements of the prospective target business as part of the tender offer materials or proxy solicitation materials sent to stockholders to assist them in assessing the target business. In all likelihood, these financial statements will need to be prepared in accordance with, or reconciled to, GAAP, or IFRS, depending on the circumstances, and the historical financial statements may be required to be audited in accordance with the standards of the PCAOB. These financial statement requirements may limit the pool of potential targets we may conduct an initial business combination with because some targets may be unable to provide such statements in time for us to disclose such statements in accordance with federal proxy rules and complete our initial business combination within the prescribed time frame. We cannot assure you that any particular target business identified by us as a potential business combination candidate will have financial statements prepared in accordance with GAAP or that the potential target business will be able to prepare its financial statements in accordance with the requirements outlined above. To the extent that these requirements cannot be met, we may not be able to acquire the proposed target business. While this may limit the pool of potential business combination candidates, we do not believe that this limitation will be material.

We will be required to evaluate our internal control procedures for the fiscal year ending December 31, 2025 as required by the Sarbanes-Oxley Act. Only in the event we are deemed to be a large accelerated filer or an accelerated filer will we be required to have our internal control procedures audited. A target company may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding adequacy of their internal controls.

The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such business combination. Prior to the date of our prospectus in connection with our IPO, we filed a registration statement on Form 8-A with the SEC to voluntarily register our securities under Section 12 of the Exchange Act. As a result, we are subject to the rules and regulations promulgated under the Exchange Act. We have no current intention of filing a Form 15 to suspend our reporting or other obligations under the Exchange Act prior or subsequent to the consummation of our initial business combination.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our shares of common stock that are held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the aggregate worldwide market value of our common stock held by non-affiliates equaled or exceeded $250 million as of the prior June 30th and (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year or the aggregate worldwide market value of our common stock held by non-affiliates equaled or exceeded $700 million as of the prior June 30th.

Item 1A. Risk Factors

In addition to the other information contained in (or incorporated by reference into) this Form 10-K Report including the matters addressed under the heading "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the following risk factors. The Company operates in a market environment that is difficult to predict and that involves significant risks, many of which will be beyond control. You should carefully consider the risks described below. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on the Company's business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of the Company securities could decline, and you could lose part or all of your investment. Unless otherwise indicated, references in this section and elsewhere in this Form 10-K Report to the Company's business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, the business, reputation, financial condition, results of operations, revenue and future prospects of the Company.

Conflicts of interest arising from related-party relationships could adversely affect the terms and economic outcomes of our licensing arrangements.

The Chief Executive Officer of OSR Holdings, Inc. ("OSRH" or the "Company") serves in senior leadership roles across affiliated entities, including as Chief Executive Officer of BCM Europe AG ("BCME") and as a board member of Vaximm AG, creating overlapping fiduciary obligations and potential conflicts of interest. In addition, Vaximm AG, our wholly owned subsidiary, has entered into a binding term sheet with BCME, our largest shareholder, for a proposed exclusive global license of the VXM01 oral cancer immunotherapy platform. Because Vaximm AG and BCM Europe AG are affiliated through common ownership and management, the negotiation and approval of this arrangement constitute a related-party transaction.

The structure of the transaction includes non-standard economic features, including a royalty pass-through mechanism under which BCME, acting as a financial intermediary, is entitled to use 100% of downstream royalty payments from any ultimate commercial partner to recover milestone payments made to Vaximm AG and a preferred return to its investment fund investors before any royalties are distributed to Vaximm AG. This recovery mechanism could significantly delay or reduce the timing of royalty revenues ultimately received by Vaximm AG and, indirectly, the Company.

Although the transaction is subject to an independent third-party fairness opinion, such safeguards may not eliminate all potential conflicts of interest. These relationships and structural features could influence the negotiation, approval, and ongoing operation of the arrangement in a manner that is not as favorable to the Company or its stockholders as terms that might have been obtained in an arm's-length transaction with an unaffiliated third party.

The Company's only significant asset is its ownership of OSR and such ownership may not be sufficient to pay its expenses or satisfy other financial obligations.

The Company is a holding company and will not directly own any operating assets other than its ownership of interests in OSR. The Company depends on OSR for distributions, loans and other payments to generate the funds necessary to meet its financial obligations, including its expenses as a publicly traded company. The earnings from, or other available assets of, the Company may not be sufficient to pay expenses or satisfy the Company's other financial obligations.

The Company's principal stockholders and management own a significant percentage of Company Common Stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their affiliates and our principal stockholders beneficially held, in the aggregate, approximately 48.5% of the outstanding shares of Company Common Stock as of December 31, 2025. As a result, these stockholders are able to exert significant influence over matters requiring stockholder approval, including the election of directors, amendments to our organizational documents and approval of mergers or other major corporate transactions. This concentration of ownership may discourage or delay a change in control that other stockholders may consider favorable.

Lack of Business Diversification

Our prospects for success depend largely on the future performance of a single business and a single industry — the health care sector. Unlike other entities that have the resources to operate multiple businesses across several industries, we may not have sufficient resources to significantly diversify our operations and mitigate the risks associated with operating in a single line of business. As a result, our lack of diversification may:

- subject us to negative economic, competitive and regulatory developments, any or all of which may have a substantial adverse impact on the particular industry in which we operate, and
- cause us to depend on the marketing and sale of a single product or limited number of products or services.

Ability of the Company's Management Team to Execute Its Business Strategy

The Company's future performance depends on the continued services and effectiveness of its management team. If members of management are unable to successfully execute the Company's business strategy, including advancing its clinical development programs and managing its operations as a public company, the Company's business, financial condition, and results of operations could be adversely affected.

In addition, the Company may need to recruit and retain additional qualified personnel to support its growth and operations. Competition for experienced executives, scientific personnel, and other key employees in the biotechnology industry is intense, and the Company may not be successful in attracting or retaining such individuals on acceptable terms, or at all. Any failure to build and maintain an effective management team could adversely affect the Company's ability to execute its strategic objectives.

The Company may be subject to tax liability if OSR fails to pay its local taxes.

Under the Framework Act on National Taxes, if OSR is unable to meet its national tax obligations with its assets, we will be subject to the secondary tax liability for any taxes accrued during the period we hold our shares in OSR. Under the Local Tax Act (of Korea), we may also be subject to the secondary tax liability if OSR fails to pay its local taxes. The secondary tax liability is equal to the amount of unpaid taxes multiplied by our shareholding ratio of OSR. There is no assurance that we will not be subject to such tax liabilities or that the Company will have sufficient cash flow to cover such potential tax liabilities.

In addition, as of December 31, 2025, OSR had deferred tax liabilities of approximately $27,021,305, resulting from the differences between book and tax basis for assets acquired or created during previous business combinations as a result of purchase price allocation for accounting purposes, which will be due if and only when certain taxable events occur in the future which will reverse or eliminate such basis difference (i.e., sales of subsidiaries).

Risks Related to Our Securities and Being a Public Company

The price of the Company's Common Stock and warrants may be volatile.

The price of the Company's Common Stock and warrants may fluctuate due to a variety of factors, including:

- actual or anticipated fluctuations in its quarterly and annual results and those of other public companies in the same or similar industry;
- mergers and strategic alliances in the industry in which it operates;
- market prices and conditions in the industry in which it operates;
- changes in government regulation;
- potential or actual military conflicts or acts of terrorism;
- the failure of securities analysts to publish research about the Company, or shortfalls in its operating results compared to levels forecasts by securities analysts;

- announcements concerning the Company or its competitors; and
- the general state of the securities markets.

These market and industry factors may materially reduce the market price of the Company's Common Stock, regardless of its operating performance. The market price of the Company's Common Stock has declined significantly in recent months, making the financing of continuing business operations more difficult and dilutive and increasing the risk of the Common Stock being delisted. These and other factors, including a potential loss of liquidity in the market for the Common Stock may limit the ability to sell the Company Common Stock.

We are no longer a "controlled company" under Nasdaq rules and we cannot rely on certain Nasdaq corporate governance requirement exemptions

The "controlled company" exception to the Nasdaq rules provides that a company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company, a "controlled company," need not comply with certain requirements of the Nasdaq corporate governance rules. Until December 31, 2025, Kuk Hyoun Hwang, directly and indirectly, owned a majority of the voting power of our outstanding common stock and was able to determine all matters requiring approval by our stockholders. As a "controlled company" within the meaning of the corporate governance rules of Nasdaq, during 2025, we were exempt from the Nasdaq's corporate governance rules requiring that listed companies have (i) a majority of the Board consist of "independent" directors under the listing standards of the Nasdaq rules, (ii) selection or recommendation for the Board's selection of director nominees made by (a) independent directors constituting a majority of the Board's independent directors in a vote in which only the independent directors participate or (b) a nominating and corporate governance committee composed entirely of independent directors (subject to exceptions under limited and exceptional circumstances) and a written nominating and corporate governance committee charter meeting the requirements of the Nasdaq rules and (iii) a compensation committee composed entirely of independent directors (subject to exceptions under limited and exceptional circumstances) and a written compensation committee charter meeting the requirements of the Nasdaq rules. As of the date of this Annual Report, Kuk Hyoun Hwang no longer owns a majority of the voting power of our outstanding common stock. As a result, we no longer qualify as a "controlled company" and have entered the applicable phase-in period for compliance with corporate governance requirements. We have also ceased relying on the exemption available to newly public companies regarding a majority independent board.

An active, liquid trading market for the Company Common Stock and warrants may not develop or persist, which may limit your ability to sell such common stock and warrants.

The Company's common stock and warrants are listed on the Nasdaq Stock Market under the ticker symbols "OSRH" and "OSRHW," respectively. However, a sufficiently liquid or active trading market for the Company Common Stock and warrants may not develop or may not be sustained. A public trading market having the desirable characteristics of depth, liquidity and orderliness depends upon the existence of willing buyers and sellers at any given time, such existence being dependent upon the individual decisions of buyers and sellers over which neither we nor any market maker has control. The failure of an active and liquid trading market to develop and continue would likely have a material adverse effect on the value of the Company Common Stock and warrants. An inactive market may also impair our ability to raise capital to continue to fund operations by issuing the Company's Common Stock and warrants.

In addition, the price of the Company securities can vary due to general economic conditions and forecasts, its general business condition and the release of its financial reports. Additionally, if its securities are not listed on, or becomes delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of its securities may be more limited than if it were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

The Company does not intend to pay dividends on its common stock so any returns will be limited to the value of our stock.

The Company currently anticipates that it will retain future earnings for the development, operation and expansion of the Company's business and does not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on the Company's Common Stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Future sales, or the perception of future sales, of the Company Common Stock by the Company or its stockholders in the public market could cause the market price for the Company Common Stock to decline.

The sale of shares of the Company Common Stock in the public market, or the perception that such sales could occur, by the Company or its stockholders or warrant holders, could harm the prevailing market price of shares of OSR Holdings Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for the Company to sell equity securities in the future at a time and at a price that it deems appropriate.

If the Company issues additional equity securities or debt securities, those securities offerings may adversely affect the market price of the Company Common Stock and warrants to purchase shares of the Company Common Stock and may be dilutive to existing stockholders.

In the future, the Company may issue additional shares of common stock or issue preferred stock or incur debt. Debt and preferred stock will generally have priority upon liquidation. Such securities also may be governed by an indenture or other instrument containing covenants restricting our operating flexibility. Additionally, any convertible or exchangeable securities that the Company issues in the future may have rights, preferences and privileges more favorable than those of the Company Common Stock. Because the decision to issue debt or equity in the future will depend on market conditions and other factors beyond the Company's control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of the Company Common Stock and warrants to purchase the Company Common Stock and be dilutive to existing stockholders.

The Company granted registration rights to certain stockholders and others, and the future exercise of such rights may adversely affect the market price of our common stock.

Pursuant to an agreement entered into in connection with the issuance and sale of the securities in the Company IPO, certain of the Company's stockholders and their permitted transferees can demand that the Company register the placement warrants, the placement rights, the shares of common stock issuable upon exercise of the placement warrants, the shares of common stock included in the placement units, and the shares of common stock underlying the placement rights. Additionally, holders of units that may be issued upon conversion of working capital loans can demand that the Company register the warrants and rights included in such units, the shares of common stock issuable upon exercise of such warrants, the shares of common stock included in such units, and the shares of common stock underlying such rights. The Company will bear the cost of registering these securities. The registration and availability of such a significant number of securities for trading in the public market may have an adverse effect on the market price of the Company's Common Stock.

The abovementioned risks are specifically relevant to the Company's Equity Line of Credit ("ELOC") Agreement

On February 25, 2025 we entered into an equity purchase agreement and registration rights agreement (taken together, the "*ELOC Agreement*") with White Lion GBM Innovation Fund, providing that the Company has the right, but not the obligation, to require White Lion to purchase, from time to time, up to the lesser of (i) $80,000,000 in aggregate gross purchase price of newly issued shares of the Company's common stock, par value $0.0001 per share, and (ii) the Exchange Cap, in each case, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement. A more detailed discussion of this agreement is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."

The ELOC Agreement is central to the Company's business strategy and financing needs, and therefore central to its risk profile. Depending upon how, when and at what level this facility is utilized by the Company, the ELOC Agreement could result in significant dilution for existing holders of Company Common Stock as well as having a potential negative impact upon the market price of such shares. The same and other factors create significant uncertainty as to the Company's ability to rely upon, and have access to funds from, the ELOC Agreement facility.

The Amended Bylaws require, to the fullest extent permitted by law, that derivative actions brought in our name, as applicable, against their respective directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders, as applicable.

The Amended Bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for (A) any derivative action or proceeding brought on our behalf, (B) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or employees to us or our stockholders, (C) any civil action to interpret, apply or enforce any provision of the DGCL, (D) any civil action to interpret, apply, enforce or determine the validity of the provisions of the Amended Charter or the Amended Bylaws or (E) any action asserting a claim governed by the internal affairs doctrine. In the event, however, that the Court of Chancery of the State of Delaware lacks jurisdiction over any of the foregoing actions, the Amended Bylaws provide that the sole and exclusive forum for such action shall be another state or federal court located in the State of Delaware, subject to such court having personal jurisdiction over the indispensable parties named as defendants. The Amended Bylaws expressly provide that the foregoing provisions do not apply to the resolution of any complaint asserting a cause of action under the Securities Act.

The Amended Bylaws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

The Amended Bylaws expressly provide that the foregoing provisions do not apply to any action asserting a claim arising under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The Delaware forum provision and the federal forum provision described above may impose additional litigation costs on stockholders who assert that such provision is not enforceable and may impose more general additional litigation costs in pursuing claims subject to such, particularly if the stockholders do not reside in or near the State of Delaware or the United States District Courts. In addition, these forum selection clauses in the Amended Bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. As noted above, the Amended Bylaws provides that the United States District Court will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce the federal forum provision in the Amended Bylaws. Investors also cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Anti-takeover provisions contained in the Company Charter and the Company Bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

The Amended Charter and the Amended Bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer, or by the directors entitled to cast a majority of the votes of the whole board of directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in the Company Charter and the Company Bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or delay or impede a merger, tender offer or proxy contest involving the Company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause the Company to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in the Company's board of directors could cause the market price of our common stock to decline.

In addition, because we are incorporated in Delaware and our certificate of incorporation has not opted out of the application of Section 203 of the DGCL, we are governed by the provisions of Section 203 of the DGCL.

In general, Section 203 of the DGCL prohibits a Delaware corporation that is listed on a national securities exchange or held of record by more than 2,000 stockholders from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time such stockholder becomes an interested stockholder, unless the business combination is approved in one of the manners described below. A "business combination" includes, among other things, certain mergers, asset or stock sales or other transactions together resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's outstanding voting stock. Under Section 203 of the DGCL, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became an interested stockholder, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon the consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding those shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or
- at or after the time the stockholder became an interested stockholder, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least 66⅔% of the outstanding voting stock which is not owned by the interested stockholder.

Under certain circumstances, Section 203 of the DGCL will make it more difficult for a person who would be an "interested stockholder" to effect various business combinations with the corporation for a three-year period. This provision may encourage persons interested in acquiring the Company to negotiate in advance with the board of directors of the Company. Section 203 of the DGCL also may have the effect of preventing changes in the Company's board of directors and may make it more difficult to accomplish transactions which stockholders may otherwise deem to be in their best interests.

If securities or industry analysts do not publish or cease publishing research or reports about the Company, its business, or its market, or if they change their recommendations regarding the Company securities adversely, then the price and trading volume of the Company securities could decline.

The trading market for the Company securities will be influenced by the research and reports that industry or securities analysts may publish about the Company, its business, its market, or its competitors. Securities and industry analysts may never publish research on the Company. If no securities or industry analysts commence coverage of the Company, the securities price and trading volume would likely be negatively impacted. If any of the analysts who may cover the Company change their recommendation regarding the Company's securities adversely, or provide more favorable relative recommendations about the Company's competitors, the price of the Company's securities would likely decline. If any analyst who may cover the Company were to cease coverage of the Company or fail to regularly publish reports on it, the Company could lose visibility in the financial markets, which could cause the Company's securities price or trading volume to decline.

There can be no assurance that the Company will be able to comply with the continued listing standards of Nasdaq. The Company's failure to meet the continued listing requirements of Nasdaq could result in a delisting of the Company's Common Stock and warrants.

The Company Common Stock and warrants were listed on Nasdaq under the symbols "OSRH" and "OSRHW," respectively. The Company's eligibility for listing on Nasdaq depends on its ability to comply with Nasdaq's continued listing standards, including requirements relating to the trading price and trading volume of its securities, and other corporate governance requirements. If the Company is not able to comply with the continued listing standards of Nasdaq, the Company and its stockholders could face significant material adverse consequences including, but not limited to:

- a limited availability of market quotations for its securities;
- reduced liquidity for the Company's securities;
- a determination that the Company Common Stock is a "penny stock," which will require brokers trading in the Company Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for the Company Common Stock;
- a limited amount of or no analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." As long as the Company's Common Stock and warrants are listed on Nasdaq, they will be considered covered securities. If the Company's securities were no longer listed on Nasdaq, the securities would not be covered securities and would therefore be subject to regulation in each state in which the Company offers its securities.

If the Company fails to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist the Company's securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, and no assurance can be provided that any action taken to restore compliance with listing requirements would allow the securities to become listed again, stabilize the market price or improve the liquidity of its securities, prevent its securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if the Company's securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on any of the markets offered by OTC Markets Group Inc., the liquidity and price of these securities may be more limited than if they were quoted or listed on Nasdaq or another national securities exchange. In such circumstances, Company securityholders may be unable to sell their securities unless a market can be established or sustained.

On February 15, 2024, the Company received a written notice (the "Notice") from the Nasdaq Listing Qualifications Department indicating that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(3), which requires the Company to have at least 300 public holders for continued listing on the Nasdaq Capital Market (the "Minimum

Public Holders Rule"). The Notice is only a notification of deficiency, not of imminent delisting, and has no current effect on the listing or trading of the Company's securities on the Nasdaq Capital Market. The Company submitted a plan to regain compliance with the Minimum Public Holders Rule to Nasdaq on April 1, 2024. On April 17, 2024, the Company received written notice from Nasdaq granting an extension to August 13, 2024, to regain compliance with the Minimum Public Holders Rule (the "Compliance Period"). On August 20, 2024, the Company received written notice (the "Second Notice") from Nasdaq stating that the Company had not regained compliance with the Minimum Public Holders Rule within the Compliance Period. In accordance with the Second Notice, BLAC timely requested a hearing before the Hearings Panel (the "Panel"), which automatically stayed any suspension or delisting action of the Company's securities and was held on October 1, 2024. On October 4, 2024, the Panel granted the Company's request for continued listing on the Nasdaq, subject to the requirement that on or before February 17, 2025, the Company shall demonstrate compliance with Listing Rule 5505, and that during the exception period, the Company shall provide prompt notification of any significant events that occur during this time that may affect the Company's compliance with Nasdaq requirements. On March 7, 2025, the Hearings Advisor from the Nasdaq Office of General Counsel sent a letter noting that on February 13, 2025, the Company had completed its Business Combination and finding that "[t]he post transaction entity demonstrated compliance with the requirements for initial listing under Listing Rule 5505 and the securities of OSRH began trading on the Nasdaq Capital Market February 18, 2025. ... [a]ccordingly, the Panel has determined to continue the listing of the Company's securities on The Nasdaq Stock Market LLC and is closing this matter." However, this is no guaranty that the Company will be able to maintain compliance with Nasdaq continued listing standards going forward.

On September 5, 2025, the Company received a written notice from the Nasdaq Listing Qualifications Department indicating that the Company was not in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) because the closing bid price of the Company's common stock had been below $1.00 per share for 30 consecutive business days. The notice had no immediate effect on the listing or trading of the Company's securities on the Nasdaq Capital Market. Nasdaq provided the Company with an initial compliance period of 180 calendar days, or until March 4, 2026, to regain compliance with the minimum bid price requirement. The Company did not regain compliance within that period and Nasdaq subsequently granted the Company an additional 180-day compliance period, extending the deadline to August 31, 2026, to regain compliance. If the Company does not regain compliance by that date, the Company's securities may become subject to delisting from Nasdaq. The Company intends to monitor the closing bid price of its common stock and may pursue available options to regain compliance, including a reverse stock split, although there can be no assurance that such actions would be successful or that the Company will be able to maintain compliance with Nasdaq's continued listing standards in the future.

We anticipate that the Company will qualify as an "emerging growth company" as well as a "smaller reporting company" within the meaning of the Securities Act, and if the Company takes advantage of certain exemptions from disclosure requirements available to emerging growth companies, this could make its securities less attractive to investors and may make it more difficult to compare its performance with other public companies.

We anticipate the Company will qualify as an "emerging growth company" within the meaning of Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, the Company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the Company stockholders may not have access to certain information they may deem important. the Company would remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of the Company Common Stock that is held by non-affiliates exceeds $700,000,000 as of the end of that year's second fiscal quarter, (ii) the last day of the fiscal year in which the Company has total annual gross revenue of $1,235,000,000 or more during such fiscal year (as indexed for inflation), (iii) the date on which the Company has issued more than $1,000,000,000 in non-convertible debt in the prior three-year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of the Company Common Stock, as defined by the JOBS Act. Investors may find the Company's securities less attractive because it may rely on these exemptions.

If some investors find the Company's securities less attractive as a result of its reliance on these exemptions, the trading prices of its securities may be lower than they otherwise would be, there may be a less active trading market for its securities and the trading prices of its securities may be more volatile.

Additionally, we anticipate the Company will qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K promulgated by the SEC. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. the Company will remain a smaller reporting company for so long as the market value of its common stock held by non-affiliates is less than $250,000,000 measured on the last business day of its second fiscal quarter, or its annual revenue is less than $100,000,000 during the most recently completed fiscal year and the market value of its common stock held by non-affiliates is less than $700,000,000 measured on the last business day of its second fiscal quarter. To the extent the Company takes advantage of such reduced disclosure obligations, it may also make comparison of its financial statements with other public companies difficult or impossible.

The Company may redeem unexpired public warrants after they become exercisable and prior to their exercise at a time that is disadvantageous to the holders, thereby making your public warrants worthless.

The Company has the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of the Company Common Stock equals or exceeds $16.50 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date the Company give notice of redemption. The Company will not redeem the warrants as described above unless a registration statement under the Securities Act covering the shares of the common stock issuable upon exercise of such warrants is effective and a current prospectus relating to shares of the common stock is available throughout the 30-day redemption period. If and when the public warrants become redeemable by the Company, it may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding public warrants could force the holders (i) to exercise their public warrants and pay the exercise price therefor at a time when it may be disadvantageous for them to do so, (ii) to sell their public warrants at then-current market price when you might otherwise wish to hold your public warrants or (iii) to accept the nominal redemption price which, at the time the outstanding public warrants are called for redemption, is likely to be substantially less than the market value of their public warrants. The value received upon exercise of the public warrants (1) may be less than the value the holders would have received if they had exercised their public warrants at a later time, where the underlying share price is higher and (2) may not compensate the holders for the value of the public warrants.

The private placement warrants are identical to the public warrants, except that the private placement warrants and the shares of common stock issuable upon the exercise of the private placement warrants were not transferable, assignable or salable prior to the completion of a Business Combination, subject to certain limited exceptions, and none of the private placement warrants are redeemable by the Company so long as they are held by their initial purchasers or their permitted transferees.

In the event the Company determines to redeem the warrants, holders of our redeemable warrants would be notified of such redemption as described in the Warrant Agreement. Specifically, in the event that the Company elects to redeem all of the redeemable warrants as described above, the Company will fix a date for the redemption (the "Redemption Date"). Notice of redemption will be mailed by first class mail, postage prepaid, by the Company not less than 30 days prior to the Redemption Date to the registered holders of the redeemable warrants to be redeemed at their last addresses as they appear on the registration books. Any notice mailed in the manner provided in the Warrant Agreement will be conclusively presumed to have been duly given whether or not the registered holder received such notice. Accordingly, if a holder fails to actually receive the notice of or otherwise fails to respond on a timely basis, it could lose the benefit of being a holder of a Company public warrant.

The closing price of the Company's common stock has not exceeded $16.50 per share for any of the 30 trading days prior to the date of this Annual Report on Form 10-K.

Risks Related to the Company Business and Operations

The following risk factors reference the risks and uncertainties relating to the business and operations of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

The Company's limited operating history, the early stage of its development programs and the inherent uncertainties and risks involved in pharmaceutical product development may make it difficult for it to execute on its business model.

We are a global drug development company with a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring our portfolio companies, establishing our intellectual property portfolio and performing research and development in support of our product candidates. We have no pharmaceutical product candidates approved for commercial sale and our product candidates have not generated any revenue. Our approach to the discovery and development of product candidates from early stage to drug launch is unproven, and we do not know whether we will be able to develop any products of commercial value. Except for a few clinical stage candidates in our portfolio, most of our other candidates are in the preclinical stages of development and will require additional preclinical studies and future clinical development as well as regulatory review and approval, which may not be granted. Since we are still in preclinical and clinical development, we would need to receive regulatory approvals, gain access to sufficient commercial manufacturing capacity and implement marketing efforts before we could begin generating revenue from product sales or arrange for a third party to do so on our behalf.

The Company will likely incur significant operating losses for the foreseeable future and may never achieve or maintain profitability.

We have never generated any operating profits and incurred operating losses of USD 11.7 million and USD 18.3 million for years ending 2024 and 2025, respectively. We have an accumulated deficit of USD 37.17 million as of December 31, 2025. We are likely to continue to incur operating losses in the future. While our RMC subsidiary generated revenues of USD 2.9 million for the year ended December 31, 2025, none of our other subsidiaries have generated any revenues from product sales because none of their current product candidates have received marketing or other required regulatory approvals anywhere in the world. We may never generate product revenue from the commercial sales of our pharmaceutical product candidates or achieve profitability.

Our business is dependent on the success of our product candidates that we advance into clinical trials and ultimately commercial distribution, which will require managing complex scientific, regulatory, management, sales, licensing and other issues.

Our ability to execute on our business model and generate revenues depends on a number of factors including our ability to:

- successfully develop new product candidates through our drug development strategy and advance those product candidates into pre-clinical studies and clinical trials;
- successfully complete ongoing pre-clinical studies and clinical trials and obtain regulatory approvals for our current and future product candidates;
- attract and retain experienced management and advisory teams;
- add operational, financial and management information systems and personnel, including personnel to support clinical, pre-clinical manufacturing and planned future commercialization efforts and operations;
- achieve market acceptance of product candidates in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

If we cannot successfully execute any one of the foregoing, our business may not succeed and the price of our common shares and warrants may be negatively impacted.

If one or more of our product candidates encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business could be significantly harmed. Before we can generate any revenue from sales of any of our product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

Drug development is a highly speculative business requiring substantial investments that may not ever generate operating cash flow.

Investment in drug development is highly speculative because it entails substantial upfront capital and operating expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage drug development companies in rapidly evolving fields.

Our product candidates will require substantial development time — including extensive clinical, and in many cases pre-clinical, research and development — and resources before we would be able to apply for or receive applicable regulatory approvals and begin generating revenue from product sales. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict precisely the timing or amount of increased expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever.

If we obtain regulatory approval for any of our product candidates, we still may never achieve profitability.

If we do successfully obtain regulatory approval to market product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the geographic areas for which we gain regulatory approval, the number of competitors in such markets, the accepted price for product candidates and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than expected, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved (especially for products receiving orphan drug designations). We cannot assure you that we will be profitable even if we successfully commercialize our product candidates.

Even if a product candidate we develop receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if a product candidate we own or develop receives regulatory approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the price we pay or any of our future collaborators charge for our products;

- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- the size and effectiveness of our sales, marketing and distribution support.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

Coverage and reimbursement may be limited or unavailable for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

Significant uncertainty exists as to the insurance coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

Additionally, our ability to obtain and maintain coverage for our products by certain government health care programs may depend on our participation in certain government pricing programs, such as the Medicaid Drug Rebate Program and the 340B program. These programs often include complex reporting and payment obligations, which are subject to frequent change. If we fail to provide timely and accurate information under these programs or comply with any rebate or discount pricing requirements, we may have reimbursement obligations or be subject to penalties or other sanctions.

Changes to currently applicable laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Because we have multiple programs and product candidates under development and are pursuing a variety of target indications and treatment modalities, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.

We have two subsidiaries and expect to have multiple subsidiaries with their own drug development plans, all of which will compete for financial resources to advance their development and commercialization. Due to our constrained financial and personnel resources, we will likely be unable to fund all of those opportunities. For example, under our current budget, our development plans focus on Darnatein's DRT 101 drug candidate but not DRT 102. As a result, we may need to postpone or cancel the pursuit of potential target conditions or product candidates that may later prove to have higher commercial potential compared to those we actually fund.

On July 24, 2025, the Company, together with OSR Holdings Co., Ltd., entered into a non-binding term sheet with Woori IO Co., Ltd. ("WORIO"), outlining the principal terms of a proposed share exchange transaction pursuant to which WORIO would become a wholly owned subsidiary of OSRK.

Pursuant to the term sheet, WORIO shareholders would receive newly issued shares of OSRK, which may be convertible into Company common stock within three years, subject to certain conditions. The parties also agreed to a six-month exclusivity period and to conduct mutual due diligence. The transaction is subject to the negotiation and execution of definitive agreements.

On January 26, 2026, the Company completed the acquisition of WORIO pursuant to definitive agreements entered into by the parties, and WORIO became a wholly owned subsidiary of OSRK.

A copy of the term sheet is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 16, 2025.

Our investments in ongoing and upcoming research and development programs might not yield any commercially viable candidates in the future. In addition, we may fail to accurately assess the commercial potential or target market for a particular product candidate leading us to relinquish valuable rights to that candidate through collaborations, licensing, or royalty arrangements, even when it would have been more advantageous for us to retain exclusive development and commercialization rights.

We plan to license or acquire early or development-stage technologies or programs, which introduces additional risks for our company. Identifying, selecting, and acquiring product candidates demands significant technical, financial, and human resources expertise. These efforts may not lead to the acquisition or licensing of a viable product candidate, potentially resulting in the diversion of our management's time and the expenditure of resources without any resulting tangible benefits. If we struggle to identify programs that eventually result in successful commercial products, we could spend substantial amounts of our capital and resources on evaluating, acquiring, and developing products that ultimately do not generate returns on our investments.

We may not be successful in our efforts to build a robust pipeline of product candidates with commercial value.

A key element of our strategy is to acquire companies, programs, product candidates, technologies or intellectual property that we believe are novel, employ differentiated mechanisms of action, are more advanced in development than competitors, or have a combination of these attributes. In addition, we plan to seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties. We face significant competition in these opportunities, and the negotiation process is time-consuming and complex. We may not be successful in our efforts in building a robust pipeline of product candidates through acquisitions, licensing or through internal development or in progressing these product candidates through clinical development.

Although we analyze whether we can replicate scientific results observed prior to our acquisition or investment in a product candidate, we may not be successful in doing so after our investment. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable

for clinical development or generate acceptable clinical data, including as a result of unacceptable toxicity or other characteristics that indicate that they are unlikely to receive approval from the U.S. Food and Drug Administration ("FDA") or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

The market opportunities for our product candidates may vary widely as we intend to develop product candidates to address unmet diseases, with some product candidates having smaller target markets, and our estimates of the prevalence of our target patient populations may be inaccurate.

We have acquired, and seek to create or acquire, companies or select intellectual property with the potential as breakthrough designations for unmet diseases, including rare or orphan diseases. While we believe our efforts can result in commercial success, if our estimates of the target patient populations are too optimistic, if the target patient population is relatively small, or if our drug candidates do not address the entire target patient population of a rare disease for example, such drug candidates may not generate significant product revenue and could adversely affect our financial position and our stock price.

Our subsidiaries may become a party to certain agreements that provide our licensors, collaborators or other stockholders in our subsidiaries with rights that could delay or impact the potential sale of our subsidiaries or could impact the ability of our subsidiaries to sell assets, or enter into strategic alliances, collaborations or licensing arrangements with other third parties.

Our subsidiaries may directly or indirectly license intellectual property from third parties and may be partially or majority owned by third party investors. These third parties may have certain rights that could delay collaboration, licensing or other arrangements with another third party, and the existence of these rights may adversely impact the ability to attract an acquirer or partner.

We may form additional subsidiaries and enter into similar agreements with future partners or investors, or our subsidiaries may enter into further agreements, that in each case may contain similar provisions or other terms that are not favorable to us.

Although we currently own 100% of our subsidiaries (i.e., there are no third-party, minority investors), we may, in the future, acquire companies that have minority shareholders or we may make investments where we are a minority shareholder. Where we are the majority shareholder, we will have certain duties to minority shareholders, which may limit our ability to integrate operations with our other subsidiaries. If we make an investment as a minority investor, we are unlikely to exert much, if any, control over the business and we may be limited in our ability to realize value from those investments.

We currently own wholly-owned subsidiaries, and plan to be the majority owner of future subsidiaries. In the event that we acquire a majority ownership interest or make an investment in another company, or if any of our subsidiaries require additional capital and such additional capital is obtained from third party investors rather than from us, we may be (or may become) a minority shareholder and unable to control the business and operations of those companies.

If the companies in which we are a minority shareholder conduct their business in a manner detrimental to our interests, business, or reputation, our returns may be adversely affected. Companies in which we are a minority shareholder may not consult us on business decisions and could take actions without our consent, which could have an adverse impact on our returns.

If we acquire less than all of the ownership interests in a subsidiary or if we reduce our interest in a wholly-owned subsidiary, our resulting majority ownership will create additional risks because we must be sure that any contracts between such subsidiaries and our company or any of our other subsidiaries are conducted on an "arms-length" basis. As a result, we will be unable to manage majority-owned subsidiaries in the same fashion as our wholly-owned subsidiaries (where contracts with affiliates need not be on an arms-length basis). These constraints may require management to incur time and resources to determine "arms-length" provisions of contracts with majority-owned subsidiaries. Minority shareholders of majority-owned subsidiaries may, after the fact, claim

breach of fiduciary duties with respect to contracts that they assert are not "arms-length" or not fair to the minority shareholders. These types of claims may result in judgments or settlements that require us or our subsidiaries to pay damages to the minority shareholders.

A single or limited number of portfolio companies may comprise a large proportion of our value.

A large proportion of our value may, at any time, reside in one or two of our subsidiaries, including intellectual property rights and the value ascribed to the product candidate or program that it is developing. Our consolidated financial condition and prospects may be materially diminished if the clinical development or potential commercialization prospects of a subsidiary's product candidate or program or one or more of the intellectual property rights held by a specific subsidiary becomes impaired. Furthermore, a large proportion of our consolidated revenue may at any time be derived from one, or a small number of, licensed technologies, and termination or expiration of licenses to these technologies would likely have a material adverse effect on our consolidated revenue. Any material adverse impact on the value of a particular subsidiary, including its intellectual property rights or the clinical development of its product candidate or program, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects.

The business of our subsidiary that is a distributor of medical products is subject to other risks, including risks related to its customer concentration, its holding inventory that may decline in value, foreign exchange rate fluctuations, its dependency on sales agency agreements and the risks relating to economic conditions and government regulation of the healthcare industry in Korea.

Our Korean subsidiary, RMC, is a distributor of medical products currently serving only the Korean market. Three main customers of RMC have in recent years represented approximately 95% of RMC's total sales. This customer concentration creates risks for RMC (and OSR) in the event that one or more of those customers terminates its distribution agreement with RMC, one of which occurred on November 20, 2024, when Penumbra Inc. and RMC terminated negotiations for a new (or extended) distribution agreement.

RMC is required under some of its sales agency agreements to make annual minimum purchases of products, which if not sold may decline in value and require RMC to write-down the value under accounting standards. In addition, failure to meet sales goals may result in termination of RMC's contracts with medical product manufacturers. RMC's sales are currently exclusively to hospitals, hospital networks and physicians across Korea, so that its business is highly dependent upon economic conditions and government regulation of the healthcare industry in Korea.

Our principal assets are our interests in our various subsidiaries, and accordingly, we will depend on distributions and dividends from our subsidiaries to make additional cash investments, pay taxes and cover our corporate and other overhead expenses.

We are a holding company and have no material assets other than our ownership interests in our subsidiaries. We are dependent on our subsidiaries for generating revenue or cash flow and have no other means of generating revenue or operating cash flow. In the future, we may be limited, however, in our ability to cause our subsidiaries to make dividend payments or other distributions to us due to restrictions contained in any credit agreement to which our subsidiaries are bound. To the extent that we need funds and our subsidiaries are restricted from making dividend payments or other distributions under applicable law or regulation or under the terms of their financing arrangements or are otherwise unable to provide such funds, our liquidity and financial condition could be adversely affected.

The Company has previously identified material weaknesses in its internal control over financial reporting, which could adversely affect its ability to report its financial condition and results of operations accurately and on a timely basis.

The Company has identified material weaknesses in its internal control over financial reporting, which could adversely affect its ability to report its financial condition and results of operations accurately and on a timely basis.

Management previously concluded that its internal control over financial reporting was not effective as of December 31, 2024. Although management implemented remediation measures during 2025 and concluded that such material weaknesses had been remediated as of June 30, 2025, additional deficiencies were identified in

connection with the year-end evaluation as of December 31, 2025, including deficiencies related to the completeness and accuracy of liabilities and the sufficiency of personnel within the accounting and financial reporting function. As a result, management concluded that material weaknesses existed as of December 31, 2025.

These material weaknesses could result in material misstatements not being prevented or detected on a timely basis. For additional information, see "Item 9A. Controls and Procedures."

Risks Related to the Company's Strategy to Grow the Business

The following risk factors reference the risks and uncertainties relating to the business and operations of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

We may not be successful in our efforts to acquire, in-license or discover and develop new product candidates.

The success of our business is highly dependent on our ability to successfully identify new product candidates, whether through acquisitions or in-licensing transactions, or through our internal capabilities. Our acquisition and in-licensing efforts focus on identifying assets in development by third parties across a diverse range of therapeutic areas. Our strategy often entails designing optimal, efficient studies that result in quick "go/no-go" decisions when deciding whether or how to proceed with future development for a given asset. We may decide to proceed with the development of a drug candidate on this basis and later determine that the more costly and time-intensive trials do not support the initial value the product was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of initial investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

We currently have no marketing and sales organization for pharmaceutical products and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our pharmaceutical products, we may not be able to generate pharmaceutical product revenue.

We have no internal sales, marketing or distribution capabilities for pharmaceutical products (one subsidiary markets and sells medical products and devices), nor have we commercialized a product. If any of our pharmaceutical product candidates ultimately receive regulatory approval, we expect to establish either an internal or external pharmaceutical marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in applicable major markets, which will be expensive and, to the extent we establish such an organization in-house, time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in establishing or managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal or external pharmaceutical sales, marketing and distribution capabilities would adversely impact the commercialization of these products. If we choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we may not be able to enter into collaborations or hire consultants or external service providers to assist us in pharmaceutical product sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our pharmaceutical product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any pharmaceutical products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our pharmaceutical products effectively. If we are not successful in commercializing our pharmaceutical products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future pharmaceutical product revenue and we would incur significant additional losses.

Our investment strategy and future growth rely on a number of assumptions, some or all of which may not be realized.

Our strategy for investment and plans for future expansion are founded upon a range of assumptions. These assumptions, particularly for our pharmaceutical product candidates, include considerations related to the adoption of a specific therapy, the price at which the product candidate might be sold (or reimbursed by third-party payors), the occurrence of a particular medical condition, the preference for our product candidate over competing therapies, and the size of patient populations. Some or all of these assumptions might prove to be inaccurate because our ability to predict whether our product candidates will attain significant market acceptance or if a market for our product candidates will indeed materialize as anticipated, is inherently uncertain. If any of these assumptions turn out to be incorrect or overly optimistic, it could have a substantial and adverse impact on our results and future prospects.

Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel.

We heavily depend on the expertise of our executive officers, directors, and scientific teams for their expertise in areas such as management, research and development, drug development, finance, and business development, both for the Company and our subsidiaries and investments. Their departure could adversely impact our research, development, and our licensing pursuits, and impede the execution of our business strategy. We do not carry "key person" insurance for our executives or staff so that replacing them might be challenging due to our inability to pay premium salaries or signing bonuses, together with the scarcity of individuals with the required breadth of skills and experience in our industry. We might struggle to attract, train, retain, or motivate them, given the numerous competing pharmaceutical and biotechnology companies.

Our reliance on a central team consisting of a limited number of employees who provide various administrative, research and development and other services to all our subsidiaries presents operational challenges that may adversely affect our business.

As of December 31, 2025, we had 22 full-time employees whom we rely on for drug development planning, employee relations, financing, accounting matters and other support services for our company and all of its subsidiaries. These individuals may not have sufficient time and bandwidth to perform their responsibilities effectively, potentially hindering the achievement of our goals and jeopardizing the execution of our business strategy. While our current structure helps us minimize certain overhead expenses, the relatively small size of our central team limits our ability to allocate enough personnel, time, and resources to effectively manage our subsidiaries and investments creation of effective drug development plans, employee recruitment and retention, and overseeing financial and accounting matters. Members of our central team may lack sufficient information about various aspects of our subsidiaries' business and operations to adequately address these responsibilities.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We anticipate expanding our roster of full-time employees, which will require significant management time and attention to hire qualified employees, which will divert a disproportionate amount of attention away from our daily operations and dedicate significant time to overseeing these growth initiatives. We will face challenges in effectively managing the expansion of our operations, which could lead to operational errors, missed business prospects, employee attrition, and decreased productivity among those who remain. Anticipated growth could necessitate substantial capital investments and potentially divert financial resources from other projects, including the advancement of additional product candidates. If our management team struggles to manage our growth effectively, it could lead to higher-than-expected expenses, curtailed revenue generation and growth capabilities, and potential obstacles in executing our business strategy. The success of our future financial performance and our ability to effectively bring product candidates to market and maintain competitiveness will hinge, in part, on our capacity to adeptly manage any forthcoming expansion.

Risks Related to the Company's Requirements for Additional Capital

The following risk factors reference the risks and uncertainties relating to additional capital requirements of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts and/or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years. The Company's operations, through its subsidiaries, have consumed substantial amounts of cash since inception. We currently do not have sufficient committed sources of additional capital to fund our current development plans. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our preclinical and clinical development programs, seek regulatory approvals for our product candidates, and launch and commercialize any products for which we receive regulatory approval. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to implement our current development plans or expand them. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

Based on our current operating plan, and in part due to the cancellation of our previously anticipated PIPE Investment, following the closing of our Business Combination, there still remains some doubt as to our ability to fund our operating expenses and capital expenditure going forward, and, as noted by our auditor, our ability to survive as a going concern. A more detailed discussion of this agreement is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources." Despite the fact that we appear to have obtained alternative financing under our ELOC Agreement, our actual capital requirements may also vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and necessary activities associated with the development of our product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates, including whether and when to advance our diverse portfolio of product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to finish the clinical trials;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, European Medicines Agency and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the extent to which we enter into additional collaboration agreements with regard to product discovery or acquire or in-license products or technologies;
- the effect of competing technological and market developments;

- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. This additional funding may not be sufficient for us to fund any of our products through regulatory approval.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility and unforeseen events, such as the COVID-19 pandemic and the conflict between Russia and Ukraine or in the Middle East, could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We may be unable to obtain additional financing to adequately capitalize the Company or to fund the operations and growth of the Company and its subsidiaries, which could adversely affect the future prospects of the Company.

We did not receive substantial proceeds from the Company's IPO to provide capital to the Company and fund its growth following the completion of the Business Combination. We will be required to seek additional financing to provide such operating capital. We cannot assure you that such financing will be available on acceptable terms, if at all. We may require such financing to fund the operations or growth of the Company. The failure to secure additional financing could have a material adverse effect on the continued development or growth of the Company. None of the Company's Sponsor, officers, directors or their affiliates are obligated to provide any financing to the Company in connection with or following the Business Combination. If they elect to do so, their additional contributions of capital to the Company may require them to first sell a portion of their founders shares or other Company common stock holdings in qualified insider transactions, which may impact the market price levels of Company common stock.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our pharmaceutical product candidates. We are unable to estimate the actual funds we will require to execute on our strategy because the length of time and activities associated with successful development of our pharmaceutical product candidates is highly uncertain, and due to the inherent challenges and uncertainties associated with the development of novel healthcare technologies.

The additional capital that we need to fund our operations may not be available at all, or on terms that allow us to continue operations or provide any hope of generating future profits.

We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of any product candidate, delay the launch or expansion of

a given product or potentially discontinue our operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our business. Because of the numerous risks and uncertainties associated with our business, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current product development programs and technology products.

Our future cash flows from operations are unlikely to satisfy our capital needs, so we will continue to need to obtain financing through other means that may involve dilution of our stockholders, limits on our financing activities or reductions of our interest in our subsidiaries and investments.

Until such time, if ever, that we can generate substantial operating revenues, we expect to continue to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities at the parent or subsidiary level, our existing stockholders' ownership, or our ownership in our subsidiaries, may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could harm the rights of our stockholders. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. The foregoing restrictions associated with potential sources of additional capital may make it more difficult for us to raise additional capital or to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, if and when we require it, our ability to grow or support our business and to respond to business challenges could be significantly limited.

If we enter into acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring new product candidates, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our or our subsidiaries' equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates, intellectual property, and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

There is substantial doubt about the Company's ability to continue as a going concern, which could prevent the Company from executing its business plan and adversely affect its financial condition and stock price.

The Company has incurred recurring operating losses and negative cash flows since its inception and expects to continue to do so for the foreseeable future. The Company will need to raise additional capital through equity or debt financings, collaborations, or other sources, and there is no assurance that such capital will be available on favorable terms or at all. Failure to raise sufficient capital as and when needed would significantly impair the Company's ability to operate its business and could result in a reduction of workforce, suspension or termination of programs, or even bankruptcy. As a result, substantial doubt exists about the Company's ability to continue as a going concern.

Risks Related to the Company's Management of the Business and Operations

The following risk factors reference the risks and uncertainties relating to the management of the business and operations of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

We incur increased costs as a result of operating as a public company, and our management will devote substantial time to compliance with its public company responsibilities and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that OSR did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act.

We are subject to the reporting requirements of the Exchange Act which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. EGCs are permitted to implement many of these requirements over a longer period. Stockholder activism, government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income, if any, and/or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Company's management team has limited experience managing and operating a U.S. public company.

Members of the Company's management team have limited experience managing and operating a U.S. publicly traded company, interacting with U.S. public company investors, and complying with the increasingly complex laws pertaining to U.S. public companies. As a U.S. public company, the Company is subject to significant regulatory oversight and reporting obligations under the U.S. federal securities laws and the continuous scrutiny of securities analysts and investors. These obligations and constituents require significant attention from its senior management and could divert their attention away from the day-to-day management of its business. The Company may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of U.S. public companies. The development and implementation of the standards and controls necessary for the Company to achieve the level of accounting standards required of a public company may require costs greater than expected. To support its operations as a U.S. public company, the Company may recruit additional qualified employees or external consultants with relevant experience, which will increase its operating costs in future periods.

Our ability to successfully operate the business depends largely upon the efforts of certain key personnel, including the key personnel of the Company and its subsidiaries. The loss of such key personnel could adversely affect the operations and profitability of the Company's business.

Our ability to recognize certain benefits of the Business Combination and successfully operate the Company's business following the Business Combination depends upon the efforts of its key personnel. Although many of such key personnel have continued with the Company following the Business Combination, the unexpected loss of key personnel may adversely affect its operations and profitability. In addition, the Company's future success depends in part on its ability to identify and retain key personnel to succeed senior management. Furthermore, while we have closely scrutinized the skills, abilities and qualifications of the key Company or its subsidiaries' personnel employed by the Company, our assessment may not prove to be correct. If such personnel do not possess the skills, qualifications or abilities expected or those necessary to manage a public company, the operations and profitability of the Company's business may be negatively impacted.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

The Amended Bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, the Amended Bylaws and the indemnification agreements that we will enter into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at its request, to the fullest extent permitted by Delaware law. Delaware law generally provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that, if required by the DGCL, such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to the Amended Bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; and
- the rights conferred in the Amended Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

The outbreak of new, novel diseases, similar to the world's recent experience with COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. The virus spread globally and government measures taken in response had a significant impact, both direct and indirect, on businesses and commerce, resulting in worker shortages, disruption of supply chains, and closure of offices, laboratories, and production facilities. Demand for certain goods and services, such as medical services and supplies, spiked, while demand for other goods and services, such as travel, fell dramatically. If a new disease began to spread, we may experience disruptions that could severely impact our business, including:

- interruptions in preclinical studies due to restricted or limited operations at our laboratory facilities or at facilities of our collaborators;
- interruption of, or delays in receiving, supplies for preclinical studies and/or clinical trials from our Contract Research Organizations ("CROs"), Contract Manufacturing Organizations ("CMOs") or other collaborators due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to outsourced research and discovery and clinical activities;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in commencing enrollment of patients in our clinical trials, enrolling and retaining patients in our clinical trials in adequate numbers and difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial participant visits and study procedures that are deemed nonessential, which may impact the integrity of participant data and clinical trial endpoints; and
- interruption or delays in the operations of the FDA, European Medicines Agency or other regulatory authorities, which may impact review and approval timelines.

The extent to which an outbreak impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of any disease, the duration of any pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Shareholder litigation and regulatory inquiries and investigations are expensive and could harm the Company's business, financial condition and operating results and could divert management attention.

Since securities class action litigation and/or stockholder derivative litigation and inquiries or investigations by regulatory authorities often follow significant business transactions, such as the sale of a company or announcement of any other strategic transaction, we may become subject to those types of lawsuits or investigations. Shareholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Any stockholder litigation, stockholder activism, including potential proxy contests, and/or regulatory investigations against the Company, whether or not resolved in the Company's favor, could result in substantial costs and divert the Company's management's attention from other business concerns, which could adversely affect the Company's business and cash resources and the ultimate value the Company's shareholders receive from their investment in the Company.

We may be the target of securities class action and derivative lawsuits which could result in substantial costs.

Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. We may be the target of this type of litigation in the future. Even if the lawsuits are without merit, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. We cannot predict whether any such lawsuits will be filed.

The outcome of any future claims and litigation could have a material adverse impact on our business, financial condition and results of operations.

We may, from time to time, be subject to claims and may become party to litigation in the normal course of business, including class action lawsuits. Such claims and litigation proceedings may be brought by third parties, including our customers, competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. The final outcome of these claims and litigation, including any settlements, may be significant and may differ substantially from our expectations. We may not be able to determine the amount of any potential

losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In March and May of 2025, Company Management became aware of a civil action filed against the Company by Benjamin Securities, Inc. in Supreme Court, New York County, seeking $500,000.00 in brokerage fees and costs the plaintiff alleges are due and owing. On September 2, 2025, Chardan Capital Markets, LLC commenced an action in federal court in the United States District Court for the Southern District of New York seeking $2,070,000 in damages.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite having security measures in place, both our internal computer systems and those of our future CROs, contractors, collaborators and consultants could be susceptible to potential damage, disruption or failure as a result of hardware malfunctions, power outages, natural disasters, computer viruses, cyber-attacks, employee theft or misuse and other unauthorized access. While we don't believe we have experienced any significant system failures or security breaches to date, the occurrence of such an event could lead to substantial disruptions in our development programs and overall business operations and subject us to governmental sanctions and private causes of action. For instance, the loss of clinical trial data, whether from completed, ongoing, or future trials, could lead to delays in our efforts to gain regulatory approval and result in substantial costs to recover or reproduce the lost data.

We could be held liable for monetary damages resulting from security breaches of our internal computer systems, and our insurance policies may be insufficient to cover potential losses.

We may also incur liability for unauthorized disclosure of sensitive information, especially personal identifying information or personal health data. Specific data breaches may necessitate reporting to affected individuals, governmental bodies, and, in some instances, the media, under regulations like the Health Insurance Portability and Accountability Act ("HIPAA") and other U.S. federal and state laws, as well as requirements from non-U.S. jurisdictions. Our existing insurance policies might not be sufficient to cover potential losses stemming from breaches, system failures, catastrophic events, or other forms of disruption to our infrastructure. Additionally, there's a possibility that such insurance may not be available to us in the future on economically viable terms, or at all. Furthermore, our insurance might not cover all claims brought against us, and the process of defending a lawsuit, regardless of its merit, could be both expensive and divert management's focus.

We or the third parties upon whom we depend on may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our operating subsidiaries are located in South Korea and Switzerland. South Korea is subject to various natural disaster risks, including flooding, storms and typhoons, primarily during the summer season, and to a more infrequent extent, earthquakes. Switzerland, due to its topography, is particularly vulnerable to natural disasters such as flooding. Natural disasters could cause significant disruptions to the operations of our subsidiaries, which could seriously impact our business, financial condition, results of operations, and future prospects. Our ability to sustain our business operations might be challenging, and in some cases, impossible for a considerable duration. Our current disaster recovery and business continuity plans have limitations and might not be sufficient to address a severe disaster or similar occurrence effectively. We might incur substantial expenses due to the inherent limitations of our disaster recovery and business continuity plans. The combination of these limitations along with our lack of earthquake insurance could lead to a significant adverse impact on our business.

Tensions with North Korea could have an adverse effect on our business, financial condition, and results of operations, and the price per share of our common stock.

Relations between South Korea and North Korea have fluctuated over the years. Tension between South Korea and North Korea may increase or change abruptly as a result of current and future events. In particular, there have been heightened security concerns in recent years stemming from North Korea's nuclear weapon and ballistic missile programs as well as its hostile military actions against South Korea.

North Korea's economy also faces severe challenges, which may further aggravate social and political pressures within North Korea and affect South Korea. Beginning in 2018, North Korea held a series of bilateral summit meetings with South Korea and the United States to discuss peace and denuclearization of the Korean peninsula. However, those discussions have ended and North Korea has since resumed its missile testing and bellicose statements, heightening tensions, and increasing uncertainty.

Further tensions in North Korean relations could develop due to a leadership crisis, breakdown in high-level inter-Korea contacts or military hostilities. Alternatively, tensions may be resolved through reconciliatory efforts, which may include peace talks, alleviation of sanctions or reunification. We cannot assure that future negotiations will even occur and, if they do, result in any lasting resolution of key issues, such as North Korea's nuclear program, or that the level of tensions between South Korea and North Korea will not escalate. Any increase in the level of tension between South Korea and North Korea, an outbreak in military hostilities or other actions or occurrences, could adversely affect our business, prospects, financial condition, and results of operations and could lead to a decline in the price per share of our common stock.

Except with respect to RMC, our Korean subsidiary engaged in the sale and distribution of medical products in Korea, we do not expect to carry any business interruption insurance or any other insurance (except for director and officer liability insurance). As a result, we may incur uninsured losses, increasing the possibility that you would lose your entire investment in the Company.

Our pharmaceutical products may expose us to product liability or other product claim risks. We currently do not have product liability or other insurance for such claims and may not be able to obtain such insurance on acceptable terms or that any insurance we do obtain will be sufficient to protect us against potential claims or that insurance will be available in the future in amounts sufficient to protect us. A product liability claim or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

The contracts and other arrangements that pharmaceutical manufacturers have with third-party payors, health care providers and customers create risk that the pharmaceutical manufacturers may violate broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute ("AKS") and the federal False Claims Act ("FCA"). Those laws and regulations may constrain the business or financial arrangements and relationships through which pharmaceutical manufactures sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. If we do not strictly comply with these laws and regulations, we may be found to be criminally or civilly liable for violations under those laws and regulations, including a false or fraudulent claim, which could subject us (and, potentially, our employees) from significant fines and penalties, including prison.

The scope and enforcement of each of these laws may be uncertain and subject to rapid change in the current environment of healthcare reform. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

If we are not successful in defending ourselves or asserting our rights, governmental or other actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation

of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities, all of which will require us to incur significant costs and expenses. In addition, we will be subject to continued compliance with the Current Good Manufacturing Practices ("cGMP") and Good Clinical Practices ("GCP") requirements for any clinical trials that we conduct post-approval.

If we do not comply with regulatory requirements and applicable standards or if problems occur after a product reaches the market, the FDA or European Medicines Agency may impose consent decrees or withdraw approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the requirement of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a Risk Evaluation and Mitigation Strategy ("REMS"), which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's, European Medicines Agency's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA, European Medicines Agency and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, European Medicines Agency and other regulatory agencies strictly regulate the post-approval marketing, labeling, advertising, and promotion of products that are placed on the market. The FDA, European Medicines Agency and other regulatory agencies impose stringent restrictions on sponsors' communications regarding

off-label use. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA, European Medicines Agency and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the FCA, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The Affordable Care Act and the Inflation Reduction Act, as well as other ongoing healthcare legislative and regulatory reform measures, may have a material adverse effect on our business and results of operations.

Congress and regulatory agencies in the United States (and to a lesser extent, state legislatures) have in recent years proposed and sometimes adopted substantial changes in laws and regulations that affect the healthcare and pharmaceutical industry. These laws, including what is known as the Affordable Care Act (the "ACA"), and the IRA, have substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry, including permitting the Centers for Medicare and Medicaid Services (the "CMS"), for the first time, to negotiate prices with pharmaceutical companies for selected drugs.

Many legislative and regulatory proposals have sought to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. These legislature and regulatory changes may significantly adversely impact our business and profitability.

The IRA was passed on August 16, 2022 and, among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by up to 15 Part D drugs in 2027, up to 15 Part B or Part D drugs in 2028, and up to 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of the IRA on our business and the healthcare industry in general is not yet known. We cannot predict how CMS will interpret the IRA or how the provisions of the law will affect our business once fully implemented.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, requirements for substitution of generic products, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

These laws, and future state and federal healthcare reform measures that may be adopted in the future, could adversely affect the prices we may obtain for any of our product candidates or the frequency with which any such product candidate is prescribed or used. We expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes, all of which may adversely affect our business and future profits.

If the Company's officers and directors serve as directors or officers of majority-owned subsidiaries, those individuals will have fiduciary and other duties to those subsidiaries and their minority stockholders, potentially causing conflicts of interest between their duties to the Company and their duties to those subsidiaries.

Certain of our directors or officers, including Mr. Hwang, are also directors and/or officers of one or more of our subsidiaries and, if those subsidiaries become majority-owned subsidiaries (as a result of third-party financing or investments), our officers would have fiduciary or other duties both to us and any majority-owned subsidiaries (including future subsidiaries). The conflicts of interest that arise from such duties could interfere with the management of those subsidiaries and their programs and product candidates, or result in disagreements with our majority-owned subsidiaries' other stockholders. For example, an individual who is both our director and a director of one of our subsidiaries, owes fiduciary duties to the subsidiary and to us, and such individual may encounter circumstances in which his or her decision or action may benefit the subsidiary while having a detrimental impact on us, or vice versa, or on another subsidiary. Further, our officers and directors who are also officers and directors of any majority-owned subsidiaries will need to allocate his or her time to responsibilities owed to us and each of the subsidiaries for which he or she serves as an officer or director, and will make decisions on behalf of one entity that may negatively impact others. In addition, disputes could arise between us and our subsidiaries' other directors, officers and stockholders regarding a conflict of interest. Those stockholders also may disagree with the amount and quality of resources that we devote to the subsidiary in which they are invested. Any such disputes or disagreements could lead to claims, and potential damages, of breach of fiduciary duties, and distract our management, interfere with our relations with those stockholders, and take significant time to resolve. Those issues could disrupt the development of our product candidates, delay our potential commercialization efforts, result in increased costs or make it less likely that other third parties will choose to partner with us in the future.

Our employees, independent contractors, consultants, and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We face the potential risk of encountering fraudulent activities, misconduct, or other unlawful behaviors involving our employees, independent contractors, consultants, commercial partners, and vendors. This misconduct could encompass intentional, reckless, or negligent actions that result in failure to: adhere to the regulations of the FDA or similar foreign regulatory bodies; provide accurate and complete information to the FDA and equivalent foreign regulatory authorities; adhere to the manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar fraudulent misconduct laws in other countries; adhere to applicable privacy and data security laws in the United States and in other countries; or accurately report financial information or disclose unauthorized activities.

Risks Related to International Operations of the Company's Business

The following risk factors reference the risks and uncertainties relating to the international operations of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

If political and economic conditions in South Korea deteriorate, our current business and future growth could be materially and adversely affected.

The Company's significant operations and assets are located in Korea. There is currently a high level of political unrest occurring in Korea. As a result, we are subject to political, economic, legal and regulatory risks specific to Korea, and our performance and successful fulfilment of our operational strategies are dependent in part on the overall Korean economy. The economic indicators in Korea in recent years have shown mixed signs of growth and uncertainty, and the current political environment in Korea is expected to continue to result in an erosion of the currency exchange rate between the Korean Won and the U.S. dollar. As a result, future growth of the Korean economy is subject to many factors beyond our control, including developments in the global economy.

The Korean economy is closely tied to, and is affected by developments in, the global economy. In recent years, adverse conditions and volatility in the worldwide financial markets, fluctuations in oil and commodity prices, and the COVID-19 pandemic, have contributed to the uncertainty of global economic prospects in general and have adversely affected, and may continue to adversely affect, the Korean economy. Due to liquidity and credit concerns and volatility in the global financial markets, the value of the Korean Won relative to the U.S. dollar and other

foreign currencies and the stock prices of Korean companies have fluctuated significantly in recent years. Further declines in the Korea Composite Stock Price Index, and large amounts of sales of Korean securities by foreign investors and subsequent repatriation of the proceeds of such sales may adversely affect the value of the Korean Won, the foreign currency reserves held by financial institutions in Korea, and the ability of Korean companies to raise capital. Any future deterioration of the Korean economy or the global economy could adversely affect our business, financial condition, and results of operations.

Fluctuations in exchange rates could result in foreign currency exchange losses to us.

The value of the Korean Won and other currencies against the U.S. dollar has fluctuated, and may continue to fluctuate and is affected by, among other things, changes in political and economic conditions. Since late 2024, there has been an increased level of political unrest in Korea, including the impeachment and arrest of the Korean President and the exchange rate between the Korean Won and the U. S. dollar has been adversely affected. It is difficult to predict how market forces or Korean or U.S. government policy, including interest rate changes by the U.S. Federal Reserve, may impact the exchange rate between the Korean Won and the U.S. dollar in the future.

A substantial percentage of our revenue and costs are denominated in Korean Won, and a significant portion of our financial assets are also denominated in Korean Won, while we anticipate that a substantial portion of any debt incurred will be denominated in U.S. dollars. We are a holding company and we may receive dividends, loans and other distributions on equity paid by our operating subsidiaries in Korea. Any significant fluctuations in the value of the Korean Won may materially and adversely affect our liquidity and cash flows. For example, the depreciation of the Korean Won and other foreign currencies against the U.S. dollar typically results in a material increase in the cost of hosting services and equipment purchased from outside of Korea and the cost of servicing debt denominated in currencies other than the Korean Won. As a result, any significant depreciation of the Korean Won or other major foreign currencies against the U.S. dollar may have a material adverse effect on our results of operations. If we decide to convert our Korean Won into U.S. dollars for the purpose of repaying principal or interest expense on any future U.S. dollar-denominated debt, making payments for dividends on our common stock, or other business purposes, depreciation of the Korean Won or other foreign currencies against the U.S. dollar would have a negative effect on the U.S. dollar amount we would receive. Conversely, to the extent that we need to convert U.S. dollars into Korean Won for our operations, appreciation of the Korean Won against the U.S. dollar would have an adverse effect on the Korean Won amount we would receive.

There are special risks involved with investing in Korean companies, including the possibility of restrictions being imposed by the Korean government in emergency circumstances, accounting and corporate disclosure standards that differ from those in other jurisdictions, and the risk of direct or vicarious criminal liability for executive officers of our Korean affiliates.

OSR is a Korean company and operates in a business and cultural environment that is different from that of other countries. For example, under the Foreign Exchange Transaction Act of Korea, if the Korean government determines that in certain emergency circumstances, including sudden fluctuations in interest rates or exchange rates, extreme difficulty in stabilizing the balance of payments or substantial disturbance in the Korean financial and capital markets are likely to occur, it may impose any necessary restriction such as requiring Korean or foreign investors to obtain prior approval from the Minister of Economy and Finance of Korea prior to entering into a capital markets transaction, repatriating interest, dividends or sales proceeds arising from Korean securities or from the disposition of such securities or other transactions involving foreign exchange. Although investors will hold shares of the Company Common Stock, its majority owned subsidiary, OSR, may experience adverse risks and in turn could adversely impact the Company's business, prospects, financial condition, and results of operations and could lead to a decline in the price per share of its common stock.

In addition, under Korean law, there are circumstances in which certain executive officers of a company may be investigated or held criminally liable either directly or vicariously for the actions of the company and its executives and employees. For example, complaints alleging infringement of intellectual property rights, breaches of certain Korean laws (*e.g.*, labor standards laws and fair trade laws), and product-related claims may be investigated and prosecuted as criminal offenses with both the company and the company's executive officers being named as defendants in such proceedings.

As a result of these current and changing risks, OSR's executive officers may be named in the future in criminal investigations or proceedings stemming from its operations. In Korea, company executive officers being named in such investigations or proceedings are a common occurrence, even though in practice many such cases result in no liability to the individual. If OSR's executive officers were to be named in such criminal proceedings or held either directly or vicariously criminally liable for the actions of OSR and its executives and employees, the Company's business, financial condition, and results of operations may be harmed.

OSR is subject to certain requirements and restrictions under Korean law that may, in certain circumstances, require it to act in a manner that may not be in the Company's or its stockholders' best interest.

Under applicable Korean law, directors of a Korean company, such as OSR, owe a fiduciary duty to the company itself rather than to its stockholders. This fiduciary duty obligates directors of a Korean company to perform their duties faithfully for the good of the company as a whole. In addition, while the facts and circumstances of each case will differ, the duty of care required of a director under Korean law may not be the same as the fiduciary duty of a director of a U.S. corporation. Although the "business judgment rule" concept exists in Korea, there is insufficient case law or precedent to provide guidance to the management and stockholders as to how it should be applied or interpreted. As a result, if circumstances arise in which the best interests of OSR conflict with the best interests of the Company or its stockholders, OSR may not be permitted under applicable Korean law to act in a manner that is in the best interest of the Company or its stockholders.

Approval by the board of directors of a Korean company is required for, among other things, all transactions between a director or major stockholder (including a 10% or more stockholder) and the company for the director's or the major stockholder's account. As a result, intercompany transactions between the Company and OSR (or any other Korean subsidiary we may own, from time to time), could arise in the future in which the directors of the Korean subsidiary are not able to act in the Company or its stockholders' best interest as a result of competing interests of the subsidiary. Since substantially all of our operations are conducted by OSR, any such occurrence with respect to OSR could adversely affect our business, financial condition, and results of operations.

OSR's transactions with related parties are subject to close scrutiny by the Korean tax authorities, which may result in adverse tax consequences.

Under Korean tax law, there is an inherent risk that OSR's transactions with its subsidiaries, affiliates or any other person or company that is related to us may be challenged by the Korean tax authorities if such transactions are viewed as having been made on terms that were not on an arm's-length basis. If the Korean tax authorities determine that any of its transactions with related parties were on other than arm's-length terms, it may not be permitted to deduct as expenses, or may be required to include as taxable income, any amount which is found to be undue financial support between related parties in such transaction, which may have adverse tax consequences for us and, in turn, may adversely affect our business, financial condition, and results of operations.

If we are deemed to have a "place of effective management" in Korea, we will be treated as a Korean company for the purpose of Korean corporate income tax with regards to our worldwide income.

Under Korean law, a corporation having a "place of effective management" in Korea will be subject to Korean corporate income tax. The "place of effective management" is determined on a case-by-case basis, taking into account factors such as the place where meetings of the board of directors are usually held, the place where the key executives usually perform their duties, the place where the day-to-day management of senior managers is carried out, and the place where accounting documents are routinely recorded and kept, etc.

Because many of our directors and executive officers are located in Korea, it is possible that the Company will have a "place of effective management" in Korea. Additionally, the Company and certain of its subsidiaries will have physical business offices in Korea, where several of our key executive officers will conduct business. Further, our board of directors includes several Korean citizens who will make significant decisions regarding our business, including decisions regarding capital raising and acquisitions.

Additional reasons the Korean tax authorities may conclude that we have a "place of effective management" in Korea include that (i) Mr. Kuk Hyoun Hwang, OSR's Chairman of the Board of Directors, is a Korean national, and Mr. Hwang spends most of the year working in Korea and will continue to do so after the Closing; (ii) most of

the members of the board of directors of our largest subsidiary, OSR, are Korean; and (iii) important documents, including the accounting documents of our domestic business, may be maintained and controlled in Korea. If we are deemed to have a "place of effective management" in Korea, we will be required to file annual corporate income tax returns with the Korean tax authorities and be subject to Korean corporate income tax. Currently, the applicable rates are 11% (inclusive of local corporate taxes) for taxable income up to 200 million Korean Won, 22% (inclusive of local corporate taxes) for taxable income exceeding 200 million Korean Won and less than 20 billion Korean Won, 24.2% (inclusive of local corporate taxes) for taxable income greater than 20 billion won and less than 300 billion Korean Won, and 27.5% (inclusive of local corporate tax) for taxable income greater than 300 billion Korean Won. Taxable income would include any worldwide income, such as dividends we receive from our Korean operating company and any interest income earned outside of Korea. If we are required to pay Korean corporate income tax, it may reduce our cash flow and negatively impact the returns to investors.

If we are deemed to have a "permanent establishment" in Korea, we will be subject to Korean corporate income tax with regards to any Korean source income attributable to or effectively connected with such permanent establishment.

Under Korean law, where a foreign corporation has a fixed place for the operation of all or part of its domestic business, the foreign corporation shall be deemed to have a "permanent establishment" in Korea. In addition, even if a foreign corporation does not have a physical fixed place of business in Korea, it is deemed to have a "permanent establishment" in Korea if it operates the business in Korea through persons (the "Dependent Agent(s)") who are authorized to conclude business contracts under the name of the foreign corporation.

According to the Supreme Court of Korea, in order for a foreign corporation to be considered to have a physical "permanent establishment" in Korea, the foreign corporation must have a fixed place of business, such as a building or facility in Korea that the foreign corporation has the right to dispose of or use, and the employees or persons under its direction must carry out essential and important business activities, rather than preliminary or auxiliary business activities. In addition, in order for a foreign corporation to be deemed to have a "permanent establishment" in Korea through a Dependent Agent, the agent must exercise the right to enter into contracts in the name of the foreign corporation on a regular basis in Korea, and the authority must be essential and important to the business activities, rather than preliminary or auxiliary.

We do not expect that we are likely to be deemed as having a "permanent establishment" in Korea, because we do not have a principal office, branch office or any other form of business office in Korea, nor do we have any physical fixed place of business in Korea that we have the right to dispose of or use. Further, our essential and important business activities, including the acquisition of companies, are made in the United States through the decisions of our board and we have not authorized any person or entity to make decisions regarding whether or not to enter into a business acquisition agreement in Korea.

However, we cannot rule out, on a conservative basis, the possibility that we may be deemed to have a "permanent establishment" in Korea after the Closing given that (i) Mr. Hwang, our Chairman of the Board of OSR, is a Korean national and will continue to perform his duties primarily in Korea and (ii) most of the members of the board of directors of OSR who will be performing substantial functions in connection with our business after the Closing are Korean. If we are deemed to have a "permanent establishment" as defined under Korean tax law, we would be required to file annual corporate income tax returns with the Korean tax office and be subject to Korean corporate income tax. The applicable rates are 11% (inclusive of local corporate taxes) for taxable income up to 200 million Korean Won, 22% (inclusive of local corporate taxes) for taxable income exceeding 200 million Korean Won and less than 20 billion Korean Won, 24.2% (inclusive of local corporate taxes) for taxable income greater than 20 billion won and less than 300 billion Korean Won, and 27.5% (inclusive of local corporate tax) for taxable income greater than 300 billion Korean Won. Taxable income includes any Korean source income attributable to or effectively connected with such permanent establishment, such as dividends we receive from our Korean operating company. If we are required to pay Korean corporate income tax, it may reduce our cash flow and negatively impact the returns to investors.

New or higher taxes resulting from changes in tax regulations or the interpretation thereof in South Korea could adversely affect our results of operations and financial condition in the future.

New tax laws and regulations, and uncertainties with respect to future tax policies pose risks to us. Changes in tax-related laws and regulations, and interpretations thereof, can create additional tax burdens on us and our businesses by increasing tax rates and fees, creating new taxes, limiting tax deductions, and/or eliminating tax-based incentives and non-taxed income. In addition, tax authorities and competent courts may interpret tax regulations differently than us, which could result in tax litigation and associated costs and penalties in part due to the novelty and complexity of new regulation.

A focus on regulating copyright and patent infringement by the Korean government subjects OSR to extra scrutiny in its operations and could subject OSR to sanctions, fines, or other penalties, which could adversely affect the Company's business and operations in Korea.

The Korean government has recently focused on addressing copyright and patent infringement in Korea. Despite measures we have taken to address copyright and patent infringement, the Korean government may subject us to sanctions, fines, or other penalties, which could adversely affect our business and operations in Korea.

We are a global organization with business operations in the United States, Korea, Switzerland, and in other European Union countries, which makes us subject to a variety of additional risks that may negatively impact our operations, many of which have already manifested and are likely to increase, given recent executive action in the United States.

We and currently all of our subsidiaries and investments conduct operations outside of the United States, so that we are subject to the special considerations or risks associated with companies operating in the United States and in an international setting, including any of the following:

- higher costs and difficulties inherent in managing cross-border business operations and complying with different commercial and legal requirements of overseas markets;
- rules and regulations regarding currency exchange;
- complex corporate withholding taxes on individuals;
- laws governing the manner in which future business combinations may be effected;
- tariffs and trade barriers;
- regulations related to customs and import/export matters;
- longer payment cycles and challenges in collecting accounts receivable;
- tax issues, including but not limited to tax law changes and variations in tax;
- currency fluctuations and exchange controls;
- rates of inflation;
- cultural and language differences;
- employment regulations;
- trade restrictions including limitations on imports or exports of components or assembled products, unilaterally or bilaterally;
- trade sanctions and related regulatory enforcement actions and other proceedings;
- potential trade wars;

- increased scrutiny by the media and other third parties of labor practices within our industry (including but not limited to working conditions) which may result in allegations of violations, more stringent and burdensome labor laws and regulations and inconsistency in the enforcement and interpretation of such laws and regulations, higher labor costs, and/or loss of revenues if our customers become dissatisfied with our labor practices and diminish or terminate their relationship with us;
- imposition of restrictions on currency conversion or the transfer of funds;
- expropriation of private entities;
- ineffective legal protection of our intellectual property rights in certain countries;
- crime, strikes, riots, civil disturbances, terrorist attacks, natural disasters and wars;
- deterioration of political relations with the United States; and
- government appropriations of assets.

We may not be able to adequately address these additional risks. If we were unable to do so, our operations might suffer, which may adversely impact our results of operations and financial condition. *Many of the foregoing risks have already manifested, and are likely to increase in scope and impact in light of the recent public posture and executive action of the new presidential administration in the United States*.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions, where we will become subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

The EU and other companies have adopted legislation or regulations that, much like the U.S. AKS, restricts the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products. Violations of these laws could result in substantial fines and imprisonment. Failure to comply with these requirements could also result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers (including information relating to their representatives) in connection with clinical trials. Processing of personal data, including health related information, is increasingly subject to legislation and regulations in numerous jurisdictions around the world, including General Data Protection Regulation ("GDPR") and each of the California Consumer Privacy Act of 2018 and HIPAA in the United States, among many others. The application and enforcement of data protection laws and regulations may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others, including potential significant penalties. We expect the data protection laws will increase our compliance costs and potential liability.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Apart from the FCPA, we are subject to various other anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and broadly prohibit companies, their employees and third-party intermediaries to authorize, offer or provide, directly or indirectly, improper payments or benefits to recipients in the public or private sector. As we increase our international sales and business, we may engage with business partners and third-party intermediaries to market our products and to obtain necessary permits, licenses, and other regulatory approvals. In addition, we or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or -affiliated entities. We could be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to the Development of the Company's Product Candidates

The following risk factors reference the risks and uncertainties relating to the development of product candidates by the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

Our business includes subsidiaries that are developing oral immunotherapies for the treatment of cancer and design-augmented biologics. These companies have a limited operating history, and their programs are in early stages of development. This may make it difficult to evaluate our prospects and likelihood of success.

Our business includes subsidiaries that are developing oral immunotherapies for the treatment of cancer, design-augmented biologics for age-related and other degenerative diseases, and, following the recent acquisition of Woori IO Co., Ltd., non-invasive biosensing technologies for glucose monitoring and related health parameters. Each of these subsidiaries is an early-stage company with a limited operating history, has no pharmaceutical products approved for commercial sale and has not generated any revenue from sales of its products. Our approach to the discovery and development of any therapeutic product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. These product candidates will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We do not yet have substantial experience progressing therapeutic product candidates through clinical trials. We may be unable to demonstrate safety and efficacy in clinical trials, obtain regulatory approval, manufacture at a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization of any of our product candidates.

We have not yet demonstrated the ability to progress any therapeutic product candidate through clinical trials to regulatory approval. Our oral immunotherapy candidates and design-augmented biologics are still in early-stage development and may not be able to obtain regulatory approval. Neither OSR nor any of its subsidiaries have (1) manufactured any product on a commercial scale, (2) contracted with a third party to produce any product on a commercial scale (we have contracted with a third party for limited quantities of our products necessary for testing and clinical trials), or (3) conducted sales and marketing activities for approved therapeutic products (RMC does conduct sales and marketing activities for medical devices designed and manufactured by third parties).

Investment in drug development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors and risks frequently experienced by early-stage companies in rapidly evolving fields. Consequently, we have no meaningful history of drug development operations experience upon which to evaluate our drug development business, and predictions about its future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing therapeutic products.

Our product candidates will, of necessity, be subjected to pre-clinical and clinical trials prior to commercialization. Delays in those trials, or if the results of the trials raise regulatory issues, may adversely impact our results of operations and financial condition.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- timely completion of our preclinical studies and clinical trials;
- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- the prevalence, duration and severity of potential product-related side effects experienced by participants receiving our product candidates in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting Investigational New Drug ("IND") or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling participants in clinical trials;
- high drop-out rates of participants from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact of recessions, man-made and/or natural disasters, pandemics, and/or any other such events;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of any of our product candidates, which may adversely impact our results of operations and financial condition.

We may experience delays in initiating or completing clinical trials. Clinical trials can be delayed or terminated for a variety of reasons, including:

- regulators or institutional review boards ("IRB") or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- The number of participants required for clinical trials of any product candidates may be larger than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from a clinical trial protocol or drop out of a trial, which may require that we add new clinical trial sites or investigators;
- we may need to address any safety concerns that arise during the course of a clinical trial;
- we may experience delays and interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- logistical issues relating to any future clinical trials we may conduct;
- we may elect to, or regulators, IRBs, Data and Safety Monitoring Boards, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Our product development costs will increase if we experience additional delays in preclinical or clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Clinical trials and pre-clinical studies are very expensive, time-consuming, and difficult to design and implement and involve uncertain outcomes. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials or pre-clinical studies on the expected timelines, if at all.

Clinical trials and pre-clinical studies are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The FDA, an IRB or other regulatory authorities may not agree with the proposed analysis plans or trial design for the clinical trials of our product candidates, and during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of a New Drug Application ("NDA"), a Biologic License Application ("BLA") or similar application. The FDA may also find that the benefits of any product candidate in any applicable indication do not outweigh its risks in a manner sufficient to grant regulatory approval or may find that our proposed development program is not sufficient to support a marketing authorization application, or that the proposed indication is considered to be too broad. Moreover, the FDA or other regulatory authorities may also refuse or impose certain restrictions on our reliance on data supporting our marketing authorization application should such data originate from studies outside of the relevant jurisdiction. In each case, this could delay the clinical development timeline for a given product candidate.

Our principal investigators for our clinical trials may also serve as scientific advisors or consultants to our subsidiaries and investments, which may raise regulatory issues with the FDA or other regulatory authorities.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of any of our product candidates.

Negative results or safety signals in our clinical trials may make it difficult or impossible to recruit and retain patients in our clinical trials.

Any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one

or more of our trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

The results of our clinical trials may not support our proposed claims for our product candidates, or regulatory approvals on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical and initial clinical trials. In addition, results from clinical trials or pre-clinical studies may require further evaluation, delaying the next stage of development or submission of an NDA/BLA or similar application. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon our product candidates. Any delay in, or termination of, our clinical trials will delay the submission of an NDA/BLA or other similar applications to the FDA or other relevant comparable non-U.S. regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenues. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidates. The FDA has substantial discretion in the review and approval process and may disagree that our data support the differentiated claims we propose. In addition, only a small percentage of product candidates under development result in the submission of an NDA/BLA or other similar application to the FDA and other comparable non-U.S. regulatory authorities and even fewer are approved for commercialization.

Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary and top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line data we previously published. As a result, preliminary and top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects.

We may not be able to file INDs or IND amendments or comparable applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA or other regulatory authorities may not permit us to proceed.

We may not be able to file Investigational New Drug ("IND") applications or other comparable applications for our product candidates on the timelines we expect. For example, we or our third party collaborators may experience manufacturing delays or other delays with IND-enabling studies or FDA or other regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we cannot be sure that submission of an IND or other comparable application will result in the FDA or other regulatory authorities allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by institutional review boards or independent ethics committees, or by the FDA or other regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if FDA or other regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or comparable application, we cannot guarantee that they will not change their requirements or expectations in the future. These considerations also apply to new clinical trials

we may submit as amendments to existing INDs or to a new IND or other comparable application. Any failure to file INDs or other comparable applications on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We may in the future seek orphan drug designation for our product candidates, but we may be unable to obtain orphan drug designation and, even if we obtain such designation, we may not be able to realize or maintain the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate products intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug or biologic product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a marketing application. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes the same drug treating the same indication for a period of seven (7) years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

We may seek orphan drug designation for some of our future product candidates in which there is a medically plausible basis for the use of these products. We may be unable to obtain and maintain orphan drug designation and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, venture capital firms, hedge funds, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products, or already have products in the market, for the diseases in oncology and immunology. Although we believe that our approaches are or will be unique, there is no assurance that they will demonstrate advantages or even parity against competitive products from other companies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments as well, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to out-license our product candidates.

Although we intend to maintain product liability insurance, including coverage for clinical trials that we sponsor, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs increase in size. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to the Company's Reliance on Third Parties

The following risk factors reference the risks and uncertainties relating to the reliance on third parties by the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

We currently outsource, and intend to continue to outsource, much of our discovery, clinical development, and manufacturing functions to third-party providers or consultants. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business, results of operations, and financial condition.

Our business model relies upon the use of third parties, such as vendors and consultants, to conduct our drug discovery, preclinical testing, clinical trials, manufacturing, and all other aspects of clinical development. While our reliance on third parties allows us to purposely employ a small number of full-time employees, we may not be able to effectively manage and oversee the third parties that our business depends upon and we have less control over our

operations due to our reliance on third parties. While we believe our business model significantly reduces overhead cost, we may not realize the efficiencies of this arrangement if we are unable to effectively manage third parties or if our employees are unable to manage the operations of each of our subsidiaries, including the development of their programs and product candidates. The failure to successfully and efficiently outsource operational functions or appropriately manage the operations of our subsidiaries could materially adversely affect our business, results of operations, and financial condition.

We rely on third parties to conduct important aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend upon third parties to conduct important aspects of our preclinical studies and clinical trials, under agreements with CROs, CMOs, strategic collaborators and others. We expect to continue to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely heavily on third parties over the course of our preclinical studies and clinical trials, and, as a result, we control only certain aspects of their activities. When working with third parties, we have less direct control over the conduct, timing and completion of our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we relied entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP and cGMP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP and cGMP requirements through periodic inspections of trial sponsors, clinical investigators, manufacturers and trial sites. If we or any of these third parties fail to comply with applicable GCP or cGMP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials or determine that our clinical trials do not comply with the GCP or cGMP requirements. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions.

Any third parties conducting aspects of our preclinical studies, clinical trials or manufacturing process will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs, CMOs or others terminate, we may not be able to enter into arrangements with alternative CROs, CMOs or other third parties in a timely manner or to do so on commercially reasonable terms. Switching or adding additional CROs or CMOs involves additional cost and requires extensive time and focus of our management. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines which may have a material adverse impact on our business, financial condition and prospects.

Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any commercial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. For example, the COVID-19 pandemic would have significantly impacted our ability to procure sufficient supplies for the development of our product candidates. Any future pandemic or similar public health crisis may create delays or gaps in supply of materials driven by the response to any pandemic or similar public health crisis. In particular, any replacement of a contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials become limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability or bridging study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

To the extent that we enter into future manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are optimized along the way in an effort to improve yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, if we advance a biological candidate into IND-enabling studies, the manufacturing processes for biological products is more complex and expensive than with small molecule products and additional manufacturing suppliers may be needed to manufacture clinical supplies for these programs. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture of drug products, and particularly biologics, is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our current product candidates or any future product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, particularly biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our current product candidates or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to the Company's Intellectual Property

The following risk factors reference the risks and uncertainties relating to the intellectual property of the Company. References in this section to "we," "us," and "our" refer to OSR Holdings, Inc.

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and any future product candidates. We also seek to protect our proprietary position by in-licensing or acquiring intellectual property and filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, there is always a risk that our licensed or owned issued patents and any pending and future patent applications may not protect our product candidates, in whole or in part, and may not effectively prevent others from commercializing competitive product candidates, or that an alteration to product candidates or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of their research and development output, such as employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, while we will have pre-publication review procedures in effect, premature or inadvertent publication of potentially patentable subject matter could preclude our ability to obtain patent protection.

We may choose not to seek patent protection for certain innovations or product candidates and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable and, in any event, any patent protection we obtain may be limited. As a result, product candidates may not be protected by patents in all jurisdictions. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell product candidates and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell product candidates and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. The patent applications that we own or in-license may fail to result in issued patents with claims that cover product candidates in the United States or in other countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable.

The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or any future product candidate in the United States or in other countries. Our pending PCT patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications have been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate an issued patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may ultimately obtain. Even if patents do successfully issue and even if such patents cover our product candidates

or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowly construed, invalidated, or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar product candidates or limit the length of terms of patent protection we may have for our product candidates and technologies. Other companies may also design around technologies we have patented, licensed or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing product candidates or practicing our own patented technology or impose a substantial royalty burden to do so. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidates or other technologies, competitors and other third parties could market product candidates and use processes that are substantially similar to, or superior to, ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The standards that the U.S. Patent and Trademark Office (the "USPTO") and its counterparts in other countries use to grant patents are not always applied predictably or uniformly. In addition, the laws of countries other than the United States may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in such jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Other parties have developed technologies that may be related or competitive to our own technologies and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own or licensed patent applications or issued patents. Furthermore, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made significant changes to U.S. patent law, including the way patent applications are prosecuted, redefined prior art and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad.

Any patents that we have or may be issued provide us some protections but the patent issuance may be challenged on multiple grounds. We may in the future be subject to third-party pre-issuance submissions of prior art to the USPTO or its equivalents and we or our licensors have in the past, and may in the future, become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings in the U.S. or in other jurisdictions challenging our patent rights or the patent rights of others. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights or result in our breach of agreements pursuant to which we license such rights to our collaborators or licensees. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that falls outside the scope of our patent protection. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, it may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to our own and, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms and their scope may be inadequate to protect our competitive position on current and future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In certain instances, the patent term may be adjusted to add additional days to compensate for delays incurred by the USPTO in issuing the patent. Also, the patent term may be extended for a period of time to compensate for at least a portion of the time a product candidate was undergoing FDA regulatory review. However, the life of a patent, and the protection it affords, is limited. Even if patents covering product candidates are obtained, once the patent life has expired, we may be open to competition from competitive product candidates, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We do not currently and may not in the future own or license any issued composition of matter patents covering certain of our product candidates, and we cannot be certain that any of our other issued patents will provide adequate protection for such product candidates.

Composition-of-matter patents on the active pharmaceutical ingredient ("API") in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. While we generally seek composition of matter patents for our product candidates, such patents may not be available for all of our product candidates.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

Our owned and licensed patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own or license with respect to our product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidate begins to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of product candidates, one or more of our U.S. patents may be eligible for a limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data to obtain approval of competing product candidates following our patent expiration and launch their product earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated as a result of non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of the patent. The USPTO and various national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction(s). Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent applications, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or any future product candidate, our competitors might be able to enter the market earlier than anticipated, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement, misappropriation or other violations of third-party patents or other proprietary rights or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of our product candidates and any future product candidate.

Our commercial success depends in part on our avoidance of infringement, misappropriation and other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review, and post-grant review before the USPTO, as well as oppositions and similar processes in other jurisdictions. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

Additionally, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe that we are not aware of. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent

expires. In either case, such a license may not be available on commercially reasonable terms or at all. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could be time-consuming and divert the attention of senior management.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business, as well as potentially be liable for substantial, or even treble, damages.

Persons may seek injunctive or other equitable relief, which may prevent us from continuing to develop and commercialize our product candidates. The defense costs to such actions are substantial and require management and other knowledge employees to divert their attention from existing operations to defending such claims. In the event of a successful infringement or other intellectual property claim against it, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because the competitors have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our product candidates, services, and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our common shares.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might harm our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's

prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect and we may incorrectly conclude that a third-party patent is invalid or unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file and prosecute legal claims against one or more third parties, which can be expensive and time-consuming, even if ultimately successful. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which it and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. Additionally, any adverse outcome could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Because many of the patents we own are owned by our subsidiaries and investments, and in certain cases by subsidiaries or investments that are not or will not be directly commercializing products, we may not be in a position to obtain a permanent injunction against a third party that is found to infringe our patents.

Many patents that we own are assigned to our subsidiaries or investment companies. If a third party is found to be infringing such patents, we and our direct subsidiaries may not be able to permanently enjoin the third party from making, using, offering for sale or selling the infringing product or activity for the remaining life of such patent in the United States or other jurisdictions when the patent is assigned to a subsidiary, which is not the entity that is or would be commercializing a potentially competitive product or service. In such a circumstance, such third party may be able to compete with us or our subsidiaries or investment companies, which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, the Company's success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings, including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect the Company's competitive position.

In addition, The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken the Company's ability to obtain new patents or to enforce patents that it might obtain in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European

patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and non-U.S. legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates or patents that cover our biologic product candidates can be challenged by third parties.

If one of our product candidates is approved by the FDA and if a third party files an application under Section 505(b)(2) or an abbreviated new drug application ("ANDA") under Section 505(j) for a generic product containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic product. A certification under 21 CFR § 314.94(a)(12)(i)(A)(4) that the new product will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products before an ANDA or 505(b)(2) NDA is filed we will be unable to obtain a 30-month stay of FDA approval of a 505(b)(2) or ANDA.

For biologics, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological product candidates. Due to the large size and complexity of biological product candidates, as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA does not require reference product sponsors to list patents in the FDA's Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims, it could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or result in a finding of non-infringement.

If we are unsuccessful in enforcing our patents against generics or biosimilars, our products could face competition prior to the expiration of the patents which cover such products, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, any such litigation or other

proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing product candidates made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and may also export infringing product candidates to territories where we have patent protection, but enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in all countries in which a market may exist. Moreover, in jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in other countries product candidates and services that are the same as or similar to our product candidates and services, and our competitive position would be harmed.

Many companies have encountered significant problems in protecting and defending intellectual property rights in other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology product candidates, which could make it difficult for us to stop the infringement of our patents or marketing of competing product candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of any trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for any product candidates, we may rely on trade secrets, including know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect this information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants.

Because we rely and expect to continue to rely on third parties to manufacture our product candidates and future product candidates, and we collaborate and expect to continue to collaborate with third parties on the development of current and future product candidates, we must, at times, share trade secrets with them. If we conduct joint research and development programs, we may be required to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in the market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors and other third parties may discover our trade secrets, including our proprietary software, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's or other third party's discovery of our trade secrets, including our proprietary software, would impair our competitive position and have an adverse impact on our business.

We cannot guarantee that we have entered into non-disclosure, confidentiality agreements, material transfer agreements or consulting agreements with each party that may have or have had access to our trade secrets or proprietary software, technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and proprietary software, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets, including our proprietary software, were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, including our proprietary software, were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We rely on a combination of internally developed and in-licensed intellectual property rights and we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or other third parties who are involved in developing product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents,

trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, contractors and other third parties who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our invention assignment agreements may not be self-executing or may be breached, and we may not have adequate remedies for any such breach. Additionally, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish product candidates that are approved for marketing from the product candidates of our competitors. Our current and future trademark applications in the United States and in other jurisdictions may not be allowed or may subsequently be opposed, challenged, infringed, circumvented, declared generic or determined to be infringing other marks. Additionally, once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties have in the past opposed, are currently opposing and may in the future oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage.

Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to product candidates, but that are not covered by the claims of the patents that we own;
- others may be able to make product candidates that are similar to product candidates that we intend to commercialize that are not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensor or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, they could significantly harm our business and results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

As an early stage developing company, we depend on the digital technologies of third parties. Accordingly, the Company and third parties may be subject to attacks on or security breaches in our or their systems. Because of our reliance on the technologies of third parties, we also depend upon the personnel and the processes of third parties to protect against cybersecurity threats, and we have no personnel or processes of our own for this purpose. The Audit Committee of the Company Board, on the Board's behalf, will periodically review all enterprise risk management issues, including cyber risk. In the event of a cybersecurity incident impacting us, the management team will report to the Board and provide updates on the management team's incident response plan for addressing and mitigating any risks associated with such an incident.

As an early-stage company without significant investments in data security protection, we may not be sufficiently protected against such occurrences. We also lack sufficient resources to adequately protect against, or to investigate and remediate any vulnerability to, cyber incidents. It is possible that any of these occurrences, or a combination of them, could have material adverse consequences on our business and lead to financial loss. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the section titled "Risk Factors" in Part I, Item 1A of this Annual Report.

Item 2. Properties

We do not own any real estate or other physical properties materially important to our operations. Our executive offices are located at 10900 NE 4th Street, Suite 2300, Bellevue, WA 98004 and Hoedong-gil, 37-36, 3F, Paju, Gyeonggi-do, 10881 Korea, and our telephone numbers are (425) 635-7700 and +82 31 948 9419, respectively. Under an administrative services agreement we entered into with BCM effective on February 9, 2023, we have agreed to pay BCM, an affiliate of our Sponsor, a total of $7,500 per month for office space, utilities and secretarial and administrative support through and after our initial business combination to the extent that our corporate administrative needs are served through the facilities and assets of our Sponsor. We consider our current office space, combined with the other office space otherwise available to our executive officers, adequate for our current operations.

Item 3. Legal Proceedings

We may from time to time become subject to a range of actual or potential claims, lawsuits and other legal and administrative proceedings (including those described below) that may arise in the ordinary course of business. Some of these claims, lawsuits and other proceedings may range in complexity and result in substantial uncertainty; it is possible that they may result in damages, fines, penalties, non-monetary sanctions, or relief.

In March and May of 2025, Company Management became aware of a civil action filed against the Company by Benjamin Securities, Inc., in Supreme Court, New York County, seeking $425,000.00 in brokerage fees and costs that the plaintiff alleges are due and owing. As of September 30, 2025, the matter remains pending.

On September 2, 2025, Chardan Capital Markets, LLC filed a complaint (the "Complaint") in the United States District Court for the Southern District of New York against the Company and Kuk Hyoun Hwang (*Chardan Capital Markets, LLC v. OSR Holdings, Inc. et al.*, No. 1:25-cv-07285-SHS). The Complaint asserts claims for breach of contract and related causes of action. The case has been assigned to Judge Sidney H. Stein, with Magistrate Judge Robert W. Lehrburger designated to handle matters that may be referred in this action.

Service of process was waived on September 5, 2025, and an answer to the Complaint was filed on November 4, 2025. On October 6, 2025, the Court entered a Civil Case Management Plan and Scheduling Order setting discovery deadlines. The parties are currently engaged in settlement discussions while discovery proceeds.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Our common stock and warrants are traded on the Nasdaq Capital Market under the symbols "OSRH" and "OSRHW," respectively. The combined Company's common stock and warrants commenced public trading on Nasdaq on February 18, 2025 (shortly after the Business Combination).

Post closing of the consummation of the Business Combination, the common stock and warrants of Company were listed on Nasdaq under the symbols "OSRH" and "OSRHW" respectively. The closing prices of OSRH's securities on December 31, 2025, the last trading day during the fiscal year covered by this Form 10-K were $0.56. for OSRH common stock, $0.05 for OSRH warrants.

Holders

As of December 31, 2025, the Company had 26,597,769 shares of Common Stock issued and outstanding held of record by 75 holders, no shares of preferred stock outstanding and 7,330,000 warrants outstanding held of record by 8 holders. Such amounts do not include DTC participants or beneficial owners holding shares through nominee names.

Dividends

We have not paid any cash dividends on our common stock to date. It is the present intention of the Company Board to retain all earnings, if any, for use in the Company's business operations and, accordingly, the Board does not anticipate declaring any dividends in the foreseeable future. The payment of cash dividends in the future will be dependent upon the Company's revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends is within the discretion of the Board. Further, the ability of the Company to declare dividends may be limited by the terms of financing or other agreements, and other agreements entered into by the Company or its subsidiaries from time to time.

Securities Authorized for Issuance Under Equity Compensation Plans

As previously reported by the Company's Current Report on Form 8-K dated February 14, 2025, the Company held a special meeting of its stockholders on February 13, 2025 (the "February 13, 2025 Special Meeting"). At the February 13, 2025, Special Meeting, the Company's stockholders approved the Company's 2025 Omnibus Incentive Plan ("Omnibus Plan"). A description of the material terms of the Omnibus Plan is set forth below. This summary is qualified in its entirety by reference to the complete text of the Omnibus Plan, a copy of which is attached as Exhibit 10.22 to this Annual Report on Form 10-K.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	0	n/a	6,300,000
Equity compensation plans not approved by security holders	0	n/a	0
Total	**0**	**n/a**	**6,300,000**

Awards Granted Prior to Filing Date	No stock-based compensation awards were granted prior to the filing date.
Shares Available	As of the filing date, a total of 6,300,000 shares remained available for issuance under the Omnibus Plan.
Future Considerations	The Company may consider issuing equity-based awards in future periods as part of its strategy to attract and retain key personnel.

The Omnibus Plan is intended to (i) provide eligible individuals with an incentive to contribute to the Company's success and to operate and manage the Company's business in a manner that provides for long-term growth and profitability and that benefits stockholders and other important stakeholders, including Company employees and customers, and (ii) provide a means of recruiting, rewarding, and retaining key personnel.

Equity awards may be granted under the Omnibus Plan to officers, directors, including non-employee directors, other employees, advisors, consultants or other service providers of the Company or the Company's subsidiaries or other affiliates, and to any other individuals who are approved by the Committee (as defined below) as eligible to participate in the Omnibus Plan. As of December 31, 2025, approximately 30 individuals, including employees, directors and certain service providers are eligible to participate in the Omnibus Plan. Only the Company's employees or employees of the Company's corporate subsidiaries are eligible to receive incentive stock options.

The Omnibus Plan became effective on January 29, 2025, the date it was adopted by the Company Board (the "Effective Date"). The Omnibus Plan will terminate automatically at 11:59PM ET on the day before the tenth (10^{th}) anniversary of the Effective Date unless earlier terminated by the Board or in accordance with the terms of the Omnibus Plan.

Recent Sales of Unregistered Securities

Simultaneously with the closing of our IPO, our sponsor, Bellevue Global Life Sciences Investors, LLC ("*Sponsor*"), purchased an aggregate of 430,000 units at a price of $10.00 per unit, for an aggregate purchase price of $4,300,000 pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act ("*Private Placement Units*").

In connection with our IPO, the underwriters were granted a 45-day option from the date of our prospectus issued in connection with our IPO (the "*Over-Allotment Option*") to purchase up to 900,000 additional units to cover over-allotments (the "*Over-Allotment Units*"), if any. On February 21, 2023, the underwriters purchased 900,000 Over-Allotment Units fully exercising the Over-Allotment Option. The Over-Allotment Units were sold at an offering price of $10.00 per Over-Allotment Unit, generating additional gross proceeds of $9,000,000 to the Company.

On October 16, 2024, the Company issued an unsecured promissory note to Duksung Co., LTD. ("*Duksung*") in the principal amount of $800,000 (the "*Duksung Promissory Note*"). In the event of, and simultaneously with the closing of a Qualified PIPE Financing (as defined in the Duksung Promissory Note), the Duksung Promissory Note automatically converts into Company common stock. Subsequently, on October 16, 2025, the Company entered into an amendment to the Duksung Promissory Note pursuant to which the maturity date was extended to October 16, 2026 and the conversion feature was modified to permit conversion at any time at a fixed conversion price of $8.10 per share. The outstanding balance of the Duksung Promissory Note as of December 31, 2025 is $650,000, which is convertible to 80,246 shares of the Company's Common Stock.

As previously disclosed on the Company's Current Report on Form 8-K filed on February 28, 2025, on February 25, 2025 the Company entered into a common stock purchase agreement (the "Common Stock Purchase Agreement") and a related registration rights agreement (the "White Lion RRA") with White Lion GBM Innovation Fund ("White Lion"), which agreements were subsequently amended, as disclosed in the Company's Current Report on Form 8-K filed on May 12, 2025. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Common Stock Purchase Agreement, as amended.

Pursuant to the Common Stock Purchase Agreement, as amended, Company has the right, but not the obligation, to require White Lion to purchase, from time to time, up to the lesser of (i) $80,000,000 in aggregate gross purchase price of newly issued shares of the Company's common stock, par value $0.0001 per share (the "Common Stock"), and (ii) the Exchange Cap, in each case, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement. The Company intends to use the net proceeds from any such sales for general corporate purposes, including working capital, research and development, and other operating expenses.

In connection with the foregoing, the Company issued a warrant to White Lion to purchase shares of its common stock with an aggregate value of up to approximately $4.0 million and convertible promissory notes with an aggregate funding amount of approximately $1.0 million. Shares of the Company's common stock issuable under the Common Stock Purchase Agreement, upon exercise of the warrant, and upon conversion of the convertible promissory notes have been registered for resale pursuant to the Company's registration statement on Form S-1, initially filed on May 28, 2025 and subsequently amended by Form S-1/A filed on June 10, 2025. .

To the extent the warrant is exercised for cash, the Company expects to receive additional proceeds for general corporate purposes. A portion of the convertible promissory notes has been converted into shares of the Company's common stock, and the Company received cash proceeds from such conversions.

A more detailed discussion of this agreement is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."

Use of Proceeds from Registered Offerings

In connection with the closing of the Company's business combination in February 2025, approximately $1.2 million remained in the trust account following shareholder redemptions. As of the date of this report, such funds have not yet been released and therefore have not been available for use by the Company. See "Item 3. Legal Proceedings" for additional information regarding certain ongoing matters involving the Company.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and the notes related thereto contained elsewhere in this report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Cautionary Note Regarding Forward-Looking Statements," "Item 1A. Risk Factors" and elsewhere in this report.

Overview

OSR Holdings, Inc. (the "Company") is a holding company focused on the development of innovative therapeutic and medical technologies through its subsidiaries, including businesses developing oral immunotherapies for cancer, design-augmented biologics for age-related and other degenerative diseases, and, following the acquisition of Woori IO Co., Ltd. in January 2026, non-invasive biosensing technologies for glucose monitoring and related health parameters. On February 14, 2025, the Company completed its initial business combination, transitioning from a blank check company to an operating company. Since then, the Company has focused on advancing its subsidiaries' product candidates and expanding its portfolio through strategic transactions. The Company has not generated revenue from product sales and continues to incur significant research and development and operating expenses. Its future performance will depend on the successful development and commercialization of its product candidates, the ability to obtain regulatory approvals, access to additional financing, and the effective management and integration of its subsidiaries.

Recent Developments

Amended and Restated Certificate of Incorporation

As previously reported by the Company on Form 8-K dated February 13, 2025, on that date the Company filed an Amended and Restated Certificate of Incorporation with the Secretary of the State of Delaware. The terms of the Amended and Restated Certificate of Incorporation are described in the proxy statement (the "Proxy Statement") for the special meeting of stockholders held by the Company on February 13, 2025 (the "Special Meeting"). A copy of the Company's Amended and Restated Certificate of Incorporation is attached to the Company's Form 8-K dated February 13, 2025, as Exhibit 3.1 and is incorporated herein by reference.

Special Meeting of Stockholders

On February 13, 2025, the Company held the Special Meeting of stockholders. There were 2,319,752 shares of Company common stock, par value $0.0001 per share ("Company Common Stock"), outstanding as of the January 27, 2025, record date for the Special Meeting, and a quorum was present.

At the Special Meeting, stockholders approved, among other matters, the Business Combination, the Amended and Restated Certificate of Incorporation, certain governance proposals, the adoption of an incentive plan, the election of directors, and the issuance of shares in connection with the Business Combination. A description of the proposals considered at the Special Meeting is set forth in the Company's Proxy Statement for the Special Meeting, filed with the Securities and Exchange Commission on January 31, 2025, which is incorporated herein by reference.

The final voting results for the proposals considered at the Special Meeting are set forth in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 13, 2025, which is incorporated herein by reference.

Joinder Agreement for Share Exchange with Non-Participating Shareholders

Pursuant to the Business Combination Agreement, the Company entered into a Joinder Agreement with Non-Participating Shareholders, first executed on February 10, 2025. The Joinder contemplates the transfer to OSRH, on or after January 1, 2026 (the "Trigger Date"), of up to 411,857 shares of common stock of OSR Holdings Co., Ltd., a corporation organized under the laws of the Republic of Korea ("OSRK," and such shares, the "OSRK Shares") held by the Joined Parties in exchange for up to 5,338,712 shares of the common stock of OSRH (the "OSRH Shares").

As a subsequent event following the end of the period covered by this Form 10-K, certain Non-Participating Shareholders exercised their put options, and an aggregate of 410,721 OSRK Shares were transferred in exchange for 5,323,986 OSRH Shares. The effective date of such exchange was January 30, 2026.

Global License Agreement for VXM01

On November 21, 2025, Vaximm AG ("Vaximm"), a wholly owned subsidiary of the Company, entered into a global license agreement term sheet (the "License Agreement") with BCM Europe AG ("BCME"), the Company's largest shareholder.

Pursuant to the License Agreement, Vaximm granted BCME an exclusive, worldwide, sublicensable license to develop, manufacture, and commercialize the VXM01 oral cancer immunotherapy platform for all indications. BCME is responsible for advancing development and pursuing a potential out-license of VXM01 to a global pharmaceutical partner.

In consideration for the license, BCME agreed to pay Vaximm an upfront payment of $20.0 million and up to an additional $815.0 million in clinical, regulatory, and commercial milestone payments. In addition, BCME will pass through to Vaximm any downstream royalties received from an ultimate licensee, subject to a recovery mechanism pursuant to which BCME is entitled to recover certain development and milestone costs prior to such pass-through.

As a subsequent event following the end of the period covered by this Form 10-K, on January 13, 2026, Vaximm and BCME entered into a binding term sheet (the "Binding Term Sheet"), which supersedes and replaces the previously executed non-binding term sheet in its entirety. Under the Binding Term Sheet, the upfront payment was increased

to $30.0 million, consisting of $15.0 million in cash and $15.0 million in digital assets, while the aggregate milestone payments of up to $815.0 million remain unchanged. The Binding Term Sheet also maintains the royalty pass-through structure, subject to a recovery mechanism whereby BCME is entitled to recover certain development costs and a preferred return prior to such pass-through.

The foregoing descriptions are summaries and are qualified in their entirety by reference to (i) the License Agreement, which is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 25, 2025, and (ii) the Binding Term Sheet, which is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 14, 2026, each of which is incorporated herein by reference.

Acquisition of Woori IO Co., Ltd.

On January 26, 2026, OSR Holdings Co., Ltd. ("OSRK"), a subsidiary of the Company, completed the acquisition of Woori IO Co., Ltd. ("WORIO"), a South Korea-based medical device company developing non-invasive biosensing technology for glucose monitoring and related health parameters.

The acquisition was effected pursuant to a Share Exchange Agreement, dated October 13, 2025, under which OSRK acquired all of the issued and outstanding shares of WORIO through a comprehensive share exchange, and WORIO became a wholly owned subsidiary of OSRK and an indirect subsidiary of the Company. In connection with the transaction, OSRK issued an aggregate of 84,338 shares to the former shareholders of WORIO in exchange for all outstanding shares of WORIO. No shares of the Company's common stock were issued in connection with the transaction.

The foregoing description is a summary and is qualified in its entirety by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 27, 2026, which is incorporated herein by reference.

Compliance with Continued Exchange Listing Requirements

As previously disclosed in the Company's Current Report on Form 8-K filed on February 21, 2024, on February 15, 2024 the Company received a letter (the "Notice") from the Listing Qualifications Department of Nasdaq notifying the Company that the Company no longer met the minimum 300 public holders requirement for The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(3) (the "Minimum Public Holders Requirement"). On April 1, 2024, the Company submitted to Nasdaq a plan to regain compliance with the Minimum Public Holders Requirement and, on April 17, 2024, the staff of Nasdaq approved the plan and granted the Company an extension until August 13, 2024 to demonstrate compliance with the Minimum Public Holders Requirement (the "Compliance Period").

As previously reported by the Company on Form 8-K dated August 20, 2024, on that date the Company received written notice (the "Second Notice") from Nasdaq stating that the Company has not regained compliance with the Minimum Public Holders Requirement within the Compliance Period. According to the Second Notice, unless the Company timely requested a hearing before a Hearings Panel (the "Panel"), the Company's securities would be subject to suspension or delisted from Nasdaq.

As previously reported by the Company on Form 8-K dated October 4, 2024, in accordance with the Second Notice, the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"), which automatically stayed any suspension or delisting action of the Company's securities, and the hearing was held on October 1, 2024. On October 4, 2024, the Panel granted the Company's request for continued listing on the Nasdaq, subject to the requirement that on or before February 17, 2025, the Company shall demonstrate compliance with Listing Rule 5505, and that during the exception period, the Company shall provide prompt notification of any significant events that occur during this time that may affect the Company's compliance with Nasdaq requirements.

On March 7, 2025, the Hearings Advisor from the Nasdaq Office of General Counsel sent a letter to Donohoe Advisory Associates LLC, who have advised the Company on SEC compliance matters, noting that on February 13, 2025, the Company had completed its business combination with the Company Co., Ltd. and finding that "[t]he post transaction entity demonstrated compliance with the requirements for initial listing under Listing Rule 5505 and the

securities of OSRH began trading on the Nasdaq Capital Market February 18, 2025. ... [a]ccordingly, the Panel has determined to continue the listing of the Company's securities on The Nasdaq Stock Market LLC and is closing this matter."

On September 5, 2025, the Company received a notification from The Nasdaq Stock Market LLC ("Nasdaq") stating that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2) after the closing bid price fell below USD 1.00 per share for 30 consecutive business days. The Company has been provided a grace period until March 4, 2026, to regain compliance by maintaining a closing bid price of at least USD 1.00 for ten consecutive business days.

The Company did not regain compliance within that period and Nasdaq subsequently granted the Company an additional 180-day compliance period, extending the deadline to August 31, 2026, to regain compliance. If the Company does not regain compliance by that date, the Company's securities may become subject to delisting from Nasdaq. The Company intends to monitor the closing bid price of its common stock and may pursue available options to regain compliance, including a reverse stock split, although there can be no assurance that such actions would be successful or that the Company will be able to maintain compliance with Nasdaq's continued listing standards in the future.

Status of ELOC Agreement

The ELOC Agreement, inclusive of its associated Warrants and Convertible Note, remains in place under the terms referenced in the Company's Current Report on Form 8-K filed on February 28, 2025, as amended by the amendment to the ELOC Agreement reported on Form 8-K filed on May 12, 2025. From January 1, 2026 to March 20, 2026, the Company has drawn under the ELOC facility to sell an aggregate of 1,373,000 shares of the Company's common stock to White Lion, and White Lion did not exercise any warrants to purchase shares of the Company's common stock during the same period.

Results of Operations

Comparison of the Year Ended December 31, 2024 and 2025

The following tables present OSR Holdings' statements of operations for the year ended December 31, 2024 and 2025, and percentage change between the two periods:

	Year Ended December 31,			
	2024	**2025**	**Change $**	**Change %**
Net Sales:	3,530,303	2,905,805	-626,498	-18%
Cost of Sales	2,719,067	2,312,900	-406,167	-15%
Gross Profit	811,236	592,905	-218,331	-27%
Expenses:				
Selling, general and administrative expenses	12,503,433	18,928,908	6,425,475	51%
Operating income (loss)	(11,692,197)	(18,336,004)	-6,643,807	57%
Other income (expense)	(200,481)	(10,552,358)	-10,351,877	5,164%
Profit (loss) before income taxes	(11,892,678)	(28,888,361)	-16,995,683	143%

Net Sales, Cost of Sales, Gross Profit

OSR Holdings' net sales, cost of sales, and gross profit are primarily derived from RMC, its subsidiary engaged in the distribution of medical devices.

RMC's net sales for the year ended December 31, 2025 decreased by $626,498, or 18%, compared to the prior year. Cost of sales also decreased by $406,167, or 15%, resulting in a decline in gross profit of $218,331, or 27%.

The primary driver of these changes was a modification in contractual arrangements with two of RMC's suppliers.

With one supplier, RMC transitioned from a traditional purchase-and-resale model to a consignment-based arrangement under which only commission revenue is recognized. As a result, reported net sales decreased accordingly.

With another supplier, the supplier elected to internalize distribution activities in Korea. In connection with this transition, RMC sold its previously held inventory back to the supplier at cost, which materially impacted the gross margin for the period.

In addition, the cost of products purchased from certain key customers increased by approximately 5%, which also negatively affected the gross profit margin.

Selling, General and Administrative Expenses

For the year ended December 31, 2025, OSR Holdings' selling, general and administrative (SG&A) expenses increased by $6,425,475, or 51%, compared to the prior year.

This increase was primarily attributable to a significant rise in professional service fees, including legal, accounting, and disclosure-related expenses incurred in connection with the business combination completed on February 14, 2025. In addition, costs increased as the Company incurred expenses necessary to fulfill its obligations as a public company.

The increase was also driven by higher personnel-related expenses, including salaries, severance payments, employee benefits, bonuses, and travel costs.

Additional SG&A expenses included amortization of intangible assets, research and development expenses, non-income taxes, insurance premiums, and employee recruiting and training expenses.

Research and Development (R&D) Expenses

OSR Holdings' research and development (R&D) expenses consist primarily of development costs associated with product candidates in pre-clinical and clinical trials, as well as related salaries and contractor costs.

R&D costs are expensed as incurred.

For the year ended December 31, 2025, OSR Holdings incurred $318,446 in R&D expenses, representing an increase of $157,290, or 98%, compared to $161,155 in the prior year. These expenses were primarily related to maintenance of the cGMP facility of Darnatein, one of the Company's subsidiaries.

Beginning in the second half of 2026, OSR Holdings expects to incur and report R&D-related expenses primarily through its subsidiaries actively engaged in research and development at an estimated $2.5 million to $3.0 million per quarter, which could potentially increase to $5.0 million to $6.0 million per quarter.

Operating Loss

For the year ended December 31, 2025, OSR Holdings' operating loss increased by $6,643,807, or 57%, compared to the prior year.

As discussed in the section titled "Selling, General and Administrative Expenses," this increase was primarily attributable to higher professional service fees and personnel-related expenses incurred in connection with the Business Combination completed on February 14, 2025.

Other Income (Expense)

OSR Holdings' other income (expense) consists of interest income, interest expense, foreign exchange-related gains and losses, and other non-operating items.

For the year ended December 31, 2025, net other expenses increased by $10,351,877, from $200,481 in the prior year to $10,552,358. This substantial increase was primarily attributable to approximately $8.5 million of merger-related expenses incurred in connection with the business combination completed on February 14, 2025. These merger-related expenses were one-time in nature and did not involve cash outflows.

Loss Before Income Taxes

For the year ended December 31, 2025, OSR Holdings' loss before income taxes increased by $16,995,683, or 143%, compared to the prior year.

As discussed in the section on Selling, General and Administrative Expenses, this increase was primarily attributable to higher SG&A expenses incurred in connection with the business combination completed on February 14, 2025, as well as the recognition of approximately $8.5 million in one-time, non-cash merger-related expenses.

In addition, the increase in loss before income taxes was further impacted by expenses of approximately $4.8 million related to the warrants and convertible notes issued in connection with the Company's agreement with White Lion Capital, LLC on May 6, 2025. These expenses primarily consisted of 1) non-cash losses from net changes in the fair value of derivative liabilities, 2) interest expense related to the convertible notes and 3) issuance costs, including commission fees.

The warrants and convertible notes were accounted for as a single financial transaction, and the proceeds were allocated between the instruments based on their relative fair values. As of December 31, 2025, the convertible notes had an outstanding principal balance of $265,000; however, such convertible notes were fully repaid on January 12, 2026, and no balance remains as of the date of this report. In addition, the loss recognized from the remeasurement of warrant liabilities may reverse in future periods upon settlement, expiration, or other extinguishment of the warrants, at which point the related liability would be derecognized, and upon exercise, reclassified to equity.

For additional information regarding the terms of the warrants and convertible notes, see "Liquidity and Capital Resources."

Liquidity and Capital Resources

Since its inception through December 31, 2025, OSR Holdings has incurred significant operating losses and negative cash flows from operating activities. The Company recorded an operating loss of approximately $18.34 million for the year ended December 31, 2025, compared to an operating loss of approximately $11.69 million for the same period in 2024. As of December 31, 2025, OSR Holdings had an accumulated deficit of approximately $37.17 million.

To date, OSR Holdings has funded its operations primarily through the issuance of common stock and convertible bonds, bank borrowings, loans from affiliates, and, to a lesser extent, product revenue generated by its subsidiary, RMC. As of December 31, 2025, the Company had cash and cash equivalents of approximately $1.7 million, consisting primarily of bank deposits.

The Company incurred significant expenses in connection with the business combination and the filing of its Form S-4 registration statement, which, together with other general operating expenses, reduced the funds available for operations and created an urgent need for additional capital. In response, in February 2025, OSR Holdings entered into an equity line of credit ("ELOC") agreement with an investor, providing for up to $80 million in potential capital. As of December 31, 2025, the Company had issued a total of 1,692,500 shares under the ELOC, raising gross proceeds of $1,259,753. In addition, the Company has executed or is exploring various financing initiatives through the issuance of warrants and notes.

OSR Holdings expects to continue utilizing the ELOC until the end of the Commitment Period (December 31, 2026) as set forth by the ELOC Agreement with White Lion, however we intend to exercise a higher level of prudence and control in the execution of ELOC in order to minimize the dilution and price impact it might have on our equity's market. Also, we plan to institute new equity facilities which are generally considered as less dilutive and more controllable than ELOC, such as At-the-Market (ATM) offering following our submission of this Form 10-K.

Duksung Promissory Note

As previously reported by the Company on Form 8-K dated October 22, 2024, on October 16, 2024, the Company issued an unsecured promissory note to Duksung Co., LTD. ("Duksung") in the principal amount of $800,000 (the "Duksung Promissory Note"). The Duksung Promissory Note originally bore interest at a simple rate of 5% per annum and, unless earlier converted or prepaid, was scheduled to mature on October 15, 2025. Under the original

terms, in the event of a Qualified PIPE Financing (as defined in the Duksung Promissory Note), the note would automatically convert into shares of the Company's common stock at a conversion price of $8.10 per share. As of the Business Combination on February 14, 2025, a Qualified PIPE Financing had not occurred.

On October 16, 2025, the Company and Duksung entered into an addendum to the Duksung Promissory Note pursuant to which (i) the outstanding principal amount was reduced to $650,000 reflecting a partial repayment of $150,000, (ii) the maturity date was extended to October 15, 2026, (iii) the interest rate was set at 7% per annum for the remaining term, and (iv) certain terms of the note were amended, including the removal of conditions previously required for conversion, such that the note is convertible in accordance with its amended terms. The outstanding principal balance of $650,000 is convertible into 80,246 shares of the Company's common stock.

The foregoing description of the Duksung Promissory Note is qualified in its entirety by reference to the full text of the Promissory Note, a copy of which is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 22, 2024 and incorporated herein by reference. The foregoing description of the addendum to the Duksung Promissory Note is qualified in its entirety by reference to the full text of such addendum, a copy of which is filed as Exhibit 10.39 to this Annual Report on Form 10-K and incorporated herein by reference.

ELOC Agreement

As previously disclosed on the Company's Current Report on Form 8-K filed on February 28, 2025, on February 25, 2025 the Company entered into a common stock purchase agreement (the "Common Stock Purchase Agreement") and a related registration rights agreement with White Lion GBM Innovation Fund ("White Lion"), which agreements were subsequently amended, as disclosed in the Company's Current Report on Form 8-K filed on May 12, 2025. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Common Stock Purchase Agreement, as amended.

Pursuant to the Common Stock Purchase Agreement, as amended, the Company has the right, but not the obligation, to require White Lion to purchase, from time to time, shares of its common stock for aggregate gross proceeds of up to approximately $80,000,000, subject to certain limitations and conditions set forth therein.

In connection with the foregoing, the Company agreed to issue commitment shares and a warrant to White Lion as part of the commitment fee, including a warrant to purchase up to approximately $4,000,000 of shares of the Company's common stock. The amendment also updated the Company's registration obligations to require the filing of a resale registration statement covering all shares issuable under the arrangement, including shares issued pursuant to purchase notices, commitment shares, and shares issuable upon exercise of the warrant.

The foregoing description of the Common Stock Purchase Agreement, as amended, is qualified in its entirety by reference to the full text of such agreement and the related amendment, copies of which are filed as exhibits to the Company's Current Reports on Form 8-K filed on February 28, 2025 and May 12, 2025, respectively, and are incorporated herein by reference.

Off-Balance Sheet Arrangements

We have no obligations, assets or liabilities which would be considered off-balance sheet arrangements as of December 31, 2025. We do not participate in transactions that create relationships with unconsolidated entities or financial partnerships, often referred to as variable interest entities, which would have been established for the purpose of facilitating off-balance sheet arrangements. We have not entered into any off-balance sheet financing arrangements, established any special purpose entities, guaranteed any debt or commitments of other entities, or purchased any non-financial assets.

Contractual Obligations

We do not have any long-term debt, capital lease obligations, operating lease obligations, purchase obligations or long-term liabilities, other than an agreement to pay an affiliate of our Sponsor a monthly fee of $7,500, for office space, utilities and secretarial and administrative support. We began incurring these fees on March 1, 2023 and will continue to incur these fees monthly through and after our initial business combination to the extent that our corporate administrative needs are served through the facilities and assets of our Sponsor.

Chardan is entitled to a deferred underwriting commission of $2,070,000. Also, we have incurred deferred legal fees payable upon consummation of our initial business combination of approximately $1.25 million.

The holders of the founder shares, equity participation shares, placement units, and units that may be issued upon conversion of working capital loans (and in each case holders of their component securities, as applicable) are entitled to registration rights pursuant to the registration rights agreement. These holders are entitled to make up to two demands, excluding short form registration demands, that we register such securities for sale under the Securities Act. In addition, these holders will have "piggyback" registration rights to include their securities in other registration statements filed by us. We will bear the expenses incurred in connection with the filing of any such registration statements. Chardan may not exercise its demand and "piggyback" registration rights after five and seven years, respectively, after the date of our prospectus issued in connection with our IPO and may not exercise its demand rights on more than one occasion.

Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and income and expenses during the periods reported. Actual results could materially differ from those estimates. We have not identified any critical accounting estimates.

Recent Accounting Standards

Accounting Pronouncements Adopted

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides an exception to fair value measurement for contract assets and contract liabilities related to revenue contracts acquired in a business combination. The ASU requires an entity (acquirer) to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with Topic 606 as if it had originated the contracts. The ASU is effective for the Company for annual and interim periods in fiscal years beginning after December 15, 2023. The ASU is applied to business combinations occurring on or after the effective date. The Company adopted this ASU as of January 1, 2024 and there is no impact on the Company's consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires enhanced disclosure of significant segment expenses on an annual and interim basis. This ASU will be effective for the annual periods beginning the year ended December 31, 2024, and for interim periods beginning January 1, 2025. Early adoption is permitted. Upon adoption, this ASU should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted this ASU as of January 1, 2025 and there is not impact on the Company's consolidated financial statements.

Accounting Pronouncements Issued but Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements — Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The ASU modifies the disclosure or presentation requirements of a variety of Topics in the Codification to align with the SEC's regulations. The ASU also makes those requirements applicable to entities that were not previously subject to the SEC's requirements. The ASU is effective for the Company two years after the effective date to remove the related disclosure from Regulation S-X or S-K. As of the date these financial statements have been made available for issuance, the SEC has not yet removed any related disclosure. The Company does not expect the adoption of ASU 2023-06 to have a material effect on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures.

This ASU will be effective for the annual periods beginning the year ended December 31, 2026. Early adoption is permitted. Upon adoption, this ASU can be applied prospectively or retrospectively. The Company is currently evaluating the impact this ASU will have on the Company's consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data

This information appears following Item 16 of this Annual Report on Form 10-K and is included herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure controls and procedures are controls and other procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2025.

Management previously concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2024 due to the identification of material weaknesses in internal control over financial reporting.

During 2025, management implemented remediation measures designed to address these previously identified material weaknesses. In the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, management concluded that the previously identified material weaknesses had been remediated.

However, during the Company's year-end evaluation of internal control over financial reporting as of December 31, 2025, management identified additional deficiencies in internal control over financial reporting, including deficiencies relating to the completeness and accuracy of liabilities and the sufficiency of personnel within the accounting and financial reporting function. As a result of these deficiencies, management concluded that material weaknesses in internal control over financial reporting existed as of December 31, 2025.

Accordingly, management concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2025.

However, a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system will be met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, within a company have been detected.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our

financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on criteria specified in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Management previously identified material weaknesses in internal control over financial reporting as of December 31, 2024, including:

1. In November 2023, the Company withdrew $561,957 of interest income earned in the Trust Account for payment of the Company's franchise tax and income tax liabilities as permitted by the terms of the Trust Agreement governing the Trust Account. The Company deposited the funds in the Company's unrestricted general account and they were used for the payment of general operating expenses. On April 16, 2024, the Company paid $461,957 in income taxes. On April 17, 2024, the Company withdraw of $100,000 of interest income earned in the Trust Account for payment of the Company's state franchise tax and income tax liabilities as permitted by the terms of the Trust Agreement governing the Trust Account. On May 20, 2024, the Company paid $193,183 in franchise taxes. On May 23, 2024, the Company withdrew $218,857 of interest income earned in the Trust Account for payment of the Company's franchise tax and income tax liabilities as permitted by the terms of the Trust Agreement governing the Trust Account. The Company deposited the funds in the Company's unrestricted general account and they were used for payment of general operating expenses. On October 29, 2024, the Company paid $127,200 in franchise taxes. On November 25, 2024, the Company withdrew $136,805 of interest income earned in the Trust Account for payment of the Company's franchise tax and income tax liabilities as permitted by the terms of the Trust Agreement governing the Trust Account. As of December 31, 2024, the Company withdrew $1,017,619 of interest income earned in the Trust Account for payment of the Company's franchise tax and income tax liabilities as permitted by the terms of the Trust Agreement governing the Trust Account and paid $798,589 in franchise and incomes taxes resulting in $219,030 having been withdrawn from the Trust Account and not used to pay franchise and income taxes. As of December 31, 2024, the Company's obligations for franchise taxes has been paid in full. As of December 31, 2024, the Company has outstanding income tax obligations of $358,333 and has recorded prepaid franchise taxes of $78,383 related to future periods.

2. The Company failed to maintain effective internal control over the timely recognition and payment of excise tax obligations, which resulted in the incurrence of penalties and interest totaling $121,186. As of December 31, 2024, the Company had recorded total excise tax payable of $843,464.

3. The Company did not maintain effective internal control over the completeness and accuracy of its liabilities.

4. The Company did not have sufficient personnel in its accounting and financial reporting group which could result in errors in reporting in the future.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

During 2025, management implemented remediation measures designed to address these material weaknesses. In the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, management concluded that the previously identified material weaknesses had been remediated.

However, as part of management's year-end evaluation of internal control over financial reporting as of December 31, 2025, management identified additional deficiencies in internal control over financial reporting, including deficiencies relating to the completeness and accuracy of liabilities and the sufficiency of personnel within the accounting and financial reporting function.

As a result, management concluded that the Company's internal control over financial reporting was not effective as of December 31, 2025.

Management is continuing to implement measures intended to remediate these material weaknesses, including strengthening internal review procedures, enhancing processes relating to the identification and recording of liabilities, and evaluating additional resources within the accounting and financial reporting function.

Remediation Process

Management is committed to maintaining a strong internal control environment and has initiated measures designed to remediate the material weaknesses identified in internal control over financial reporting.

During 2025, the Company began taking steps intended to strengthen its internal control environment, including enhancing internal review procedures and evaluating processes related to the identification and recording of liabilities. The Company also assessed the adequacy of its accounting and financial reporting resources.

However, as of December 31, 2025, these remediation efforts had not yet been fully implemented or operated for a sufficient period of time for management to conclude that the material weaknesses had been fully remediated.

Management continues to develop and implement additional remediation measures, including:

- enhancing internal review and approval procedures over financial reporting processes;
- strengthening processes related to the identification, recording and review of liabilities;
- improving documentation and review controls over significant accounting estimates and financial statement preparation; and
- evaluating additional accounting and financial reporting resources to support the Company's financial reporting requirements.

The Company will continue to monitor the effectiveness of these remediation efforts and will not be able to conclude that the material weaknesses have been fully remediated until the redesigned controls have been implemented and have operated effectively for a sufficient period of time.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) as of December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

As of the date of this report, our current directors and executive officers are as follows:

Name	Age	Position
Kuk Hyoun Hwang	50	Chief Executive Officer and Director
Jun Chul Whang	61	Chief Legal Officer and Director
Constance Höfer	57	Chief Scientific Officer
Gihyoun Bang	49	Chief Financial Officer
Seng Chin Mah	66	Independent Director
Hyuk Joo Jee	59	Independent Director
Joong Myung Cho	77	Independent Director
Alcide Barberis	68	Independent Director
Reto Fierz	57	Independent Director

Kuk Hyoun Hwang has been the Chief Executive Officer and a director of OSR since March 2020. Mr. Hwang is also the President and Chief Executive Officer of the Company as of the Closing of the Business Combination. Mr. Hwang is the Managing Partner of BCM, which he founded in August 2012. Since then, he has led BCM's and its subsidiaries' growth and expansion as a cross-border healthcare investment group in three countries: the U.S., South Korea and Switzerland. He is also the Chief Executive Officer of BCME, a position he has held since March 2020, and the Chairman of the Board of Vaximm AG since November 2022. Since July 2019 until April 2021 and December 2022 to August 2024, Mr. Hwang has also served as Chief Executive Officer of OSR, a global drug development company and a subsidiary of BCM, where he has also served as chairman since July 2019. Prior to founding BCM in 2012, Mr. Hwang served with financial services firms in Korea and the U.S., including North Head Capital Partners LLC from 2011-2012, Kim Eng Research Korea and Kim Eng Securities USA from 2006-2008, and Shinhan Investment Corp from 2002-2004 and 2006. Mr. Hwang received a BA in sociology from Korea University in 1998. Mr. Hwang is well qualified as Chief Executive Officer and director of the Company because of his significant investment and capital markets expertise within the healthcare industry.

Jun Chul Whang is Chief Legal Officer and director of the Company as of February 14, 2025. Mr. Whang has been a director of the Company since August 2020. Mr. Whang has been an advisor to BCM since January 2015, and starting in June 2018, has served as General Counsel and consultant to BCM. In August 2020, he became a member of BCM. As a member, Mr. Whang provides legal and strategic advice to BCM on cross-border transactional matters. Since December 2020, Mr Whang has also served as General Counsel of Minetta Brook Capital LLC, a boutique financial advisory firm that also serves as general partner to investment vehicles. From April 2019 through July 2023, Mr. Whang also served as General Counsel to ELA Partners (an affiliate of Stonehaven, a global capital raising fintech platform), which specializes in capital raising for selective alternative investment opportunities globally. From May 2016 to May 2018, Mr. Whang was Partner at the law firm of Greenspoon Marder ("GM"). Mr. Whang was also Partner (having joined as an associate) at the law firm of Jacob, Medinger & Finnegan, LLP ("JMF") from July 1992 until May 2016, when JMF merged with GM. From 1990 to 1992, Mr. Whang was an associate attorney with Cadwalader Wickersham & Taft. During his career as an attorney, Mr. Whang represented major international companies in product liability litigation and regulatory risk management domestically and internationally (Europe and Korea). His language capabilities include Korean, Spanish, French and Japanese (conversational). Mr. Whang earned a BA in Government from Dartmouth College in 1986, a JD from Cornell Law School in 1989, and an LLM in International and Comparative Law (with Distinction) from Georgetown Law Center in 1990. We believe Mr. Whang is well qualified to serve as Chief Legal Officer and director of the Company because of his varied and extensive legal experience.

Gihyoun Bang has been the Chief Financial Officer of the Company since June 2024. Mr. Bang has over 22 years of experience in the Korean capital markets, with extensive expertise in investment banking, equity capital markets, credit analysis, and private equity. Mr. Bang previously held various roles at Shinhan Securities from 2002 to 2018, where he worked across IPO execution, deal evaluation, and equity capital markets, participating in a broad range of transactions including mezzanine financings and cross-border investments in the healthcare and biotechnology sectors. He subsequently served as Chief Operating Officer of Newlake Alliance Management from 2019 to 2024,

where he led investment and fundraising activities across multiple funds focused on healthcare and industrial sectors, and oversaw firm operations, including portfolio management and organizational strategy. His experience includes investments in international healthcare assets, including a hospital project in Guam. Mr. Bang holds a B.A. in Business Administration from Hansung University and is a U.S. Certified Public Accountant.

Dr. Constance Höfer has been the Chief Scientific Officer of the Company since March 24, 2025. Dr. Höfer is a seasoned leader in drug development with over 20 years of experience in oncology and immunology and will oversee OSR Holdings' scientific strategy and innovation pipeline. Dr. Höfer joins OSR Holdings from Merck Healthcare, where she led global programs spanning from preclinical to late-stage clinical development. Prior to Merck, she held senior leadership positions at Sandoz Biopharmaceuticals, Priaxon AG, and Medigene AG, playing a key role in advancing therapeutic programs across various modalities, including New Biological Entities (NBEs), New Chemical Entities (NCEs), nucleotides, and viral and cell-based therapies. Coupled with her extensive industry experience and a PhD in Pharmacology from the University of Newcastle, Dr. Höfer has a strong foundation in clinical pharmacology and translational medicine, ensuring a seamless transition from early-stage research to successful clinical development.

Dr. Alcide Barberis has been a director of the Company since the Closing of the Business Combination. He is a biotech entrepreneur, Board Member and Executive with over 25 years of management experience in the biotechnology industry, and scientific experience in the private and public research sectors. He is currently CEO & Director of Mabylon AG (since 2017). Before joining Mabylon, he was CEO & President of Humabs BioMed, now a subsidiary of VIR Biotechnology (2013-2016). His career has included senior positions at entrepreneurial startups (Co-Founder of ESBATech AG (1998) and Oncalis AG (2006) and senior Executive Management, R&D Management and Business Development positions. He has been member of the Board of Directors of ESBATech (now a Novartis company, 1998-2004), Oncalis (2006-2012) and EffRx Pharmaceuticals (2016-2023), and he is currently (since March 2023) on the Board of Directors of Ontrack Biomedical. From 2016 through 2021 he was also Coordinator of the Startup Promotion Center of the University of Svizzera Italiana in Lugano, Switzerland. Dr. Barberis earned a PhD in Molecular Biology and Biochemistry from the University of Zürich (1988). Dr. Barberis is well qualified to serve as a director because of his extensive management and leadership experience in the biotech industry, startup companies, and in the private and public scientific research sectors.

Dr. Seng Chin Mah has been a director of the Company since the Closing of the Business Combination. Dr. Mah has been Chairman of the Board of BioVersys AG since 2009. He was previously Chief Executive Officer of the Canyon Pharmaceuticals Group AG (2009-2021) and has over 30 years' experience in the pharma and biotech industry. Prior to Canyon Pharmaceuticals, he was Head of Development of the Integration Office during the integration of Chiron into Novartis (2005-2008) and held other positions at Novartis, including Global Head of Clinical Safety and Epidemiology (2001-2005); Head of Drug Regulatory Affairs Europe (1997-2001); and oversight responsibility for Clinical Quality Assurance (2001-2005). Dr. Mah was also a member of the Novartis Corporate Executive Group (2001-2005) and a member of the Board of Directors for Novartis Europharm Ltd. (1997-2005). During his tenure with Novartis and Ciba (1990-2008), he drove key drug development and regulatory programs, and led major business results including numerous global registrations of major products. He has held several research and academia positions (Ciba-Geigy Ltd., 1987-1988; National University of Singapore, 1989-1990). Dr. Mah was awarded The Frost & Sullivan 2011 Product Differentiation Excellence Award in Parenteral Anticoagulants, which recognized Canyon Pharmaceuticals Group AG for the development and launch of Iprivask® (desirudin for injection). Dr. Mah earned a BS in Pharmacology from University of London (1984) and a PhD in Biochemistry from University of Basel (1987). Dr. Mah is well qualified to serve as a director because of his extensive knowledge and experience in strategic decision-making, late-stage clinical development and regulatory experience within the Pharma and Biotech industry.

Hyuk Joo Jee has been a director of the Company since the Closing of the Business Combination. Mr. Jee has served as a Special Advisor to Chairman at DongKoo Bio Pharma Co., Ltd., a public company in Korea, since January 2024. Prior to joining DongKoo Bio Pharma, Mr. Jee served with HLB Co., Ltd., also a publicly-listed biopharmaceutical company in Korea, as Chief Operating Officer and the Head of Corporate Private Equity leading the firm's investments and resource allocations over a global pipeline of clinical-stage oncology programs from August 2018 through December 2023. During his tenure at HLB, Mr. Jee led the firm's global IR,

M&As and strategic investment activities. Prior to his careers in the biopharmaceutical industry, Mr. Jee has spent more than 15 years serving with brokerage and investment banking firms, mostly representing their European offices and providing services to the European and global fund clients investing in Korean equities market. Those engagements include Korea Investment Securities Europe (London), Daewoo Securities Europe (London), and Hyundai Securities Europe (London and Seoul) between July 2002 and January 2018. Mr. Jee has started his finance career as an Analyst and Portfolio Manager at Scudder Kemper and Schroders based in Seoul, Korea serving from 1998 to 2002. Mr. Jee has received his B.A. in Business Administration from the Korea University in 1994. Mr. Jee is well qualified to serve as a Director because of his well-balanced career between finance and biopharmaceutical industries, especially leading M&A transactions while serving from executive positions with his previous employer.

Dr. Joong Myung Cho has been a director of the Company since the Closing of the Business Combination. Dr. Cho has been Chairman and CEO of CG Pharmaceuticals, Inc. since October 2008 and previously served as Chairman and CEO of Hwail Pharmaceuticals Co. Ltd. from August 2013 to December 2022. Dr. Cho is the founder of Crystal Genomics and the former Chairman & President (July 2000 to March 2023). He has over 40 years of experience in biopharmaceutical industry covering from discovery of novel pharmaceuticals through R&D and commercialization. Dr. Cho has previously served as the executive Senior Vice President and Director of R&D Biotech Research Institute at LG Life Science (formerly LG Chem.) from 1984 to 2000. During his tenure, biopharmaceutical R&D at LG became the leading life science company in Korea where it grew from just a few research scientists to several hundred prior to his departure. He has successfully introduced 10 different recombinant products such as growth hormones of human, bovine, and porcine, hepatitis B vaccine, interferon alpha and gamma, GM-CSF, EPO, etc. Moreover, four drug candidates were licensed out to multinational pharmaceutical companies under his supervision and one of them is approved by FDA (US). On the basis of such achievements, Dr. Cho has received many awards and acted as a member of governmental committees. He received his Ph.D. from University of Houston and worked as a post-doc in Baylor College of Medicine. Dr. Cho is an author of more than 80 publications in books and journals including Nature, and an inventor of more than 200 patents filed. Dr. Cho is well qualified to serve as a director because of long-standing career experiences both as a biotech entrepreneur and the R&D Head of a major life sciences company in Korea (LG Group).

Reto Fierz has been a director of the Company since September 2025. He is a Swiss entrepreneur and executive with over 25 years of international experience in finance, institutional asset management, private equity, M&A, real estate, and digital assets. He is a Partner and Co-Founder of DA Value Group, investing in and developing early-stage projects in the digital assets and distributed ledger technology sectors. Previously, Mr. Fierz co-founded CROWDLITOKEN AG, the first public issuer of a regulated tokenized security in the real estate sector in Switzerland and the EEA and served as CEO and Partner of azemos partner ag, a Swiss-German asset manager and real estate developer. Earlier in his career, he held senior roles including CFO of Rianta Capital, CFO of Swiss Finance & Property, and audit and advisory roles at Ernst & Young. Mr. Fierz holds an MBA from the University of Zürich and is a Swiss Certified Accountant.

Number and Terms of Office of Officers and Directors

We have seven directors and four officers. Directors are elected at the Company's annual meeting of stockholders and hold office until the next annual meeting of stockholders and until their successors are duly elected and qualified, subject to their earlier death, or until their earlier resignation or removal.

Our officers are appointed by the board of directors and serve at the discretion of the board of directors, rather than for specific terms of office. Our board of directors is authorized to appoint persons to the offices set forth in our bylaws as it deems appropriate. Our bylaws provide that our officers may consist of a Chairman of the Board, a Chief Executive Officer, Chief Financial Officer, President, Vice Presidents, Secretary, Treasurer, Assistant Secretaries and such other offices as may be determined by the board of directors.

Changes in Company Directors during the reporting period

As previously disclosed on the Company's Current Report filed on Form 8-K on March 25, 2025, on March 24, 2025 the Company Board appointed Dr. Constance Höfer as the Company's Chief Scientific Officer, effective on that date. Dr. Höfer is a seasoned leader in drug development with over 20 years of experience in oncology and immunology and will oversee the Company's scientific strategy and innovation pipeline. Coupled with her extensive industry

experience and a PhD in Pharmacology from the University of Newcastle, Dr. Höfer has a strong foundation in clinical pharmacology and translational medicine, ensuring a seamless transition from early-stage research to successful clinical development.

In connection with Dr. Höfer's appointment, the Company entered into a consulting agreement in lieu of an employment agreement (the "*Agreement*") with Dr. Höfer, as dated March 24, 2025 and as amended by the Addendum No. 1 dated February 3, 2026, which provides for her compensation and other employment terms. Under the Agreement, Dr. Höfer will receive:

- A base salary of EUR300,000.00 per year (on a VAT-exclusive basis);
- Participation in Equity-based Compensation Plan of the Company, as determined at the discretion of the Company's Compensation Committee; and
- Other customary benefits available to executive officers of the Company.

There are no arrangements or understandings between Dr. Höfer and any other person pursuant to which she was selected as an officer. Additionally, Dr. Höfer does not have any family relationships with any director or executive officer of the Company. Further, Dr. Höfer has no related-party transactions reportable under Item 404(a) of Regulation S-K.

The Company issued a press release regarding Dr. Höfer's appointment, which is attached as Exhibit 99.1 to the Company's March 25, 2025 Form 8-K and is incorporated herein by reference.

As previously reported in the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 29, 2025 and Form 8-K filed on September 18, 2025, the Company held its annual meeting of stockholders on September 17, 2025 (the "Annual Meeting").

Annual General Meeting and Board Changes

As previously reported in the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 29, 2025, and Form 8-K filed on September 18, 2025, the Company held its annual meeting of stockholders on September 17, 2025 (the "Annual Meeting"). As of the record date of August 15, 2025, there were 21,585,360 shares of common stock outstanding and entitled to vote. A total of 13,325,691 shares (approximately 61.7% of the outstanding shares) were present in person or by proxy, constituting a quorum.

At the Annual Meeting, stockholders approved all proposals described in the Definitive Proxy Statement, including the following: (i) Director Proposal, (ii) Executive Compensation Proposal, (iii) Equity Incentive Plan Proposal, and (iv) Proposal to Exceed 20% Common Share Issuance Pursuant to Nasdaq Listing Rule 5635(d). No other matters were submitted for stockholder vote, and each of the four proposals was approved by the stockholders. As a result, the Board underwent the following changes: Reto Fierz was appointed as an Independent Director, and Jin Whan Park and Phil Geon Lee were removed.

The Board committees have been reconstituted as follows: Audit Committee — Reto Fierz and Hyuk Joo Jee, Compensation Committee — Seng Chin Mah, Alcide Barberis and Hyuk Joo Jee, Corporate Governance and Nominating Committee — Seng Chin Mah and Alcide Barberis and Joong Myung Cho. These changes reflect the Company's ongoing commitment to strengthening corporate governance and enhancing strategic oversight.

Committees of the Board of Directors

Upon the consummation of the Business Combination, the Company Board reconstituted its audit committee, compensation committee and corporate governance and nomination committee. The Board of Directors adopted a new charter for each of these committees, which complies with the applicable requirements of current SEC and Nasdaq rules. The Company intends to comply with future requirements to the extent applicable. The Company Board may from time to time establish other committees.

As of December 31, 2025, the Board committees have been reconstituted as follows: Audit Committee — Reto Fierz, Hyuk Joo Jee, and Joong Myung Cho, Compensation Committee — Seng Chin Mah, Alcide Barberis and Hyuk Joo Jee, Corporate Governance and Nominating Committee — Seng Chin Mah and Alcide Barberis and Reto Fierz. These changes reflect the Company's ongoing commitment to strengthening corporate governance and enhancing strategic oversight. As a Subsequent Event, in January 2026, the Company Board instituted the R&D Committee as the fourth committee whose members are Alcide Barberis, Seng Chin Mah and Joong Myung Cho.

Audit Committee

The members of our audit committee consist of Mr. Fierz, Mr. Jee, and Dr. Cho with Mr. Fierz serving as the chairperson of this audit committee. The composition of the Company's audit committee will meet the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Each member of the audit committee is financially literate and the "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K will be Mr. Fierz. This designation does not impose on Mr. Fierz any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and the board of directors. The audit committee will be directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by our independent registered public accounting firm.

Our Audit Committee Charter is included as an exhibit to this Annual Report on Form 10-K. You can also review the Audit Committee Charter by accessing our public filings at the SEC's website at *www.sec.gov*.

Compensation Committee

The members of the Company's compensation committee consist of Dr. Barberis, Dr. Mah and Mr. Jee, with Mr. Jee serving as the chairperson. Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code, and meets the requirements for independence under the current Nasdaq listing standards. The Compensation Committee will be responsible for, among other things:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- administering our stock and equity incentive plans;
- reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and;
- reviewing our overall compensation philosophy.

Our Compensation Committee Charter is included as an exhibit to this Annual Report on Form 10-K. You can also review the Compensation Committee Charter by accessing our public filings at the SEC's website at *www.sec.gov*.

Corporate Governance and Nomination Committee

The members of Company's corporate governance and nomination committee consist of Dr. Mah, Dr. Barberis and Mr. Fierz, with Dr. Mah serving as the chairperson. Each member of this committee meets the requirements for independence under the current Nasdaq listing standards. The Company's corporate governance and nomination committee will be responsible for, among other things:

- determining the qualifications, qualities, skills and other expertise required to be a director of the Company, and developing and recommending to the Board for approval criteria to be considered in selecting nominees for director;
- identifying, reviewing and making recommendations of candidates to serve on the Board, including incumbent directors for reelection;
- evaluating the performance of the Board, committees of the Board and individual directors and determining whether continued service on the Board is appropriate;
- periodically reviewing and making recommendations to the Board regarding the Company's process for stockholder communications with the Board, and making such recommendations to the Board with respect thereto;
- evaluating nominations by stockholders of candidates for election to the Company Board;
- evaluating the structure and organization of the Board and its committees and making recommendations to the Board for approvals;
- periodically reviewing the Company's corporate governance guidelines and code of business conduct and ethics and recommending to the Board any changes to such policies and principles;
- reviewing periodically the nominating and corporate governance committee charter and recommending any proposed changes to the Board, including undertaking an annual review of its own performance.

Our Corporate Governance and Nomination Committee Charter is included as an exhibit to this Annual Report on Form 10-K. You can also review the Compensation Committee Charter by accessing our public filings at the SEC's web site at *www.sec.gov*.

R&D Committee

The members of Company's R&D committee consist of Dr. Mah, Dr. Barberis and Dr. Cho with Dr. Barberis serving as the chairperson. Each member of this committee meets the requirements for independence under the current Nasdaq listing standards. The Company's R&D committee will be responsible for, among other things:

- review and provide guidance on the Company's overall research and development strategy, including platform technologies and therapeutic focus areas;
- oversee the scientific rationale, differentiation, and competitive positioning of the Company's product candidates;
- review the status, progress, and prioritization of the Company's preclinical and clinical development programs.
- review key clinical development plans, trial designs, endpoints, and timelines for material programs;
- oversee regulatory strategy and major regulatory interactions, including pathways such as accelerated approval, breakthrough designation, or other expedited programs, where applicable;
- review significant clinical, regulatory, and development risks and mitigation strategies.
- review R&D budgets and resource allocation across programs;

- provide input to the Board on go/no-go decisions, program advancement, partnering, or discontinuation based on scientific merit, risk, capital requirements, and strategic fit;
- assess alignment between R&D priorities and the Company's capital allocation strategy.
- review opportunities for platform expansion, new indications, lifecycle management, and next-generation product development;
- assess the application of the Company's technology to additional therapeutic areas or disease indications;
- review the integration of external innovation, collaborations, licensing, or acquisition opportunities related to R&D.
- oversee and assess key scientific and technical risks, including translational risk, safety, manufacturing feasibility, and scalability;
- review material non-clinical safety, toxicology, and CMC considerations impacting development timelines or regulatory approval;
- coordinate, as appropriate, with the Audit Committee regarding R&D-related financial, operational, and compliance risks.
- review the role and effectiveness of scientific advisory boards and key external advisors;
- oversee engagement with academic institutions, CROs, CDMOs, and strategic R&D partners;

Our R&D Charter is included as an exhibit to this Annual Report on Form 10-K. You can also review the R&D Charter by accessing our public filings at the SEC's web site at *www.sec.gov*.

Director Nominations

We do not have a standing nominating committee though we formed a corporate governance and nominating committee. In accordance with Rule 5605 of the Nasdaq rules, a majority of the independent directors may recommend a director nominee for selection by the board of directors.

The board of directors believes that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee. The directors who will participate in the consideration and recommendation of director nominees are Dr. Barberis, Dr. Mah and Mr. Fierz. In accordance with Rule 5605 of the Nasdaq rules, all such directors are independent. As there is no standing nominating committee, we do not have a nominating committee charter in place.

The board of directors will also consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to our board of directors should follow the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the board of directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Code of Ethics

The Company adopted a code of ethics that applies to all of its employees, officers and directors, including its principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Company intends to disclose future amendments to its code of business conduct and ethics, or any waivers of such code, on its website.

Insider Trading Policy

The Company adopted an insider trading policy which requires insiders to (i) refrain from purchasing shares during certain blackout periods and when they are in possession of any material non-public information and (ii) to clear all trades with the Company's legal counsel or compliance officer prior to execution. In addition, the Company's Sponsor and any other holders of the Company's common stock prior to the Initial Public Offering (or their permitted transferees (the "Initial Stockholders")) agreed to waive their redemption rights with respect to their Founder Shares, Placement Shares and Public Shares in connection with the Business Combination. A copy of the Company's Insider Trading Policy has been filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation

Throughout this section, unless otherwise noted, "the Company," "we," "us," "our" and similar terms refer to BLAC prior to the Business Combination. This section discusses the material components of the executive compensation program for the Company's executive officers who are named in the "2025 Summary Compensation Table" below. In 2025, the Company's "named executive officers" and their positions at year-end were as follows:

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs.

2025 Summary Compensation Table

The following table sets forth information concerning the compensation of the Company's named executive officers for the year ended December 31, 2025.

Name and Principal Position	Salary ($)	Stock Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total
Kuk Hyoun Hwang *Chief Executive Officer*	400,000	0	0	0	400,000
Constance Höfer *Chief Scientific Officer*	345,000	0	0	0	345,000
Gihyoun Bang *Chief Financial Officer*	300,000	0	0	0	300,000
Jun Chul Whang *Chief Legal Officer*	300,000	0	0	0	300,000

Narrative to Summary Compensation Table

None of our officers has received any cash compensation for services rendered to us. We have paid and will continue to pay an affiliate of our Sponsor a total of $7,500 per month for office space, utilities and secretarial and administrative support. No compensation of any kind, including any finder's fee, reimbursement, consulting fee or monies in respect of any payment of a loan, will be paid by us to our Sponsor, officers, directors or any affiliate of our Sponsor, officers or directors, prior to, or in connection with any services rendered in order to effectuate, the consummation of our initial business combination (regardless of the type of transaction that it is) except that we may pay BCM and/or any of its affiliates, partners or employees a fee for financial advisory services rendered in connection with our identification, negotiation and consummation of our initial business combination; the amount of any fee we pay to BCM and/or any of its affiliates, partners or employees will be based upon the prevailing market for similar services for such transactions at such time, and will be subject to the review of our audit committee pursuant to the audit committee's policies and procedures relating to transactions that may present conflicts of interest. Our officers and directors will be reimbursed for any out-of-pocket expenses incurred in connection with activities on our behalf such as identifying potential target businesses and performing due diligence on suitable business combinations. Our audit committee will review on a quarterly basis all payments that were made to

our Sponsor, officers, directors, advisors or our or their affiliates. Any such payments prior to an initial business combination will be made using funds held outside the Trust Account. Other than quarterly audit committee review of such payments, we do not expect to have any additional controls in place governing our reimbursement payments to our directors and executive officers for their out-of-pocket expenses incurred in connection with identifying and consummating an initial business combination.

Clawback Policy

On November 15, 2023, the Board adopted an Incentive-Based Compensation Recovery Policy (the "Clawback Policy") in order to comply with Section 10D of the Exchange Act, Rule 10D-1 of the Exchange Act and the listing standards adopted by the Nasdaq Stock Market. The Clawback Policy provides for the mandatory recovery of erroneously awarded incentive-based compensation from current and former executive officers (as defined in the Clawback Policy) of the Company in the event that the Company is required to prepare an accounting restatement. The Clawback Policy is included as an exhibit to its annual report on Form 10-K for the fiscal year ended December 31, 2023. The Clawback Policy can also be reviewed by accessing the Company's public filings at the SEC's web site at *www.sec.gov*.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information regarding the beneficial ownership of the Company's common stock following the consummation of the Business Combination based on information obtained from the persons named below, with respect to the beneficial ownership of shares, by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;
- each of our executive officers and directors that beneficially owns shares of our common stock; and
- all our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days. Except as described in the footnotes below and subject to applicable community property laws and similar laws, we believe that each person listed below has sole voting and investment power with respect to such shares.

The beneficial ownership of the Company's Common Stock is based on 26,597,769 shares of the Company's Common Stock issued and outstanding immediately following consummation of the Business Combination.

Name and Address of Beneficial Owner[1]	Number of Shares Beneficially Owned	% of Ownership
Officer and Directors After the Transactions		
Kuk Hyoun Hwang[2]	13,069,106	48.5%
Jun Chul Whang[3]	—	*
Gihyoun Bang	—	*
Constance Höfer	—	*
Alcide Barberis	—	*
Joong Myung Cho	—	*
Hyuk Joo Jee	—	*
Reto Fierz	—	*
Seng Chin Mah	—	*
	—	*
All such executive officers and directors as a group (11 individuals)	13,069,106	48.5%

Name and Address of Beneficial Owner[1]	Number of Shares Beneficially Owned	% of Ownership
*Greater than 5% Stockholders***		
Bellevue Global Life Sciences Investors LLC[4]	1,332,500	5.0%
BCM Europe AG[5]	8,612,636	31.9%
Bellevue Capital Management LLC[6]	3,123,970	11.7%
Duksung Co., Ltd.[7]	1,500,471	5.6%

* Less than one percent.

(1) Unless otherwise noted, the address of each beneficial owner is c/o OSR Holdings, Inc., 10900 NE 4th Street, Suite 2300, Bellevue, WA 98004.

(2) Interest consists of (i) 1,725,000 founder shares of the Company's Common Stock, (ii) the transfer of 34,500 shares of the Company's common stock to Chardan Capital Markets, LLC ("Chardan"), (iii) 430,000 placement shares held of record by Bellevue Global Life Sciences Investors LLC ("BGLSI"), (iv) the transfer of 120,000 shares of the Company's Common Stock by BGLSI to officers and directors of the Company at the time of its initial public offering, and (v) the transfer of 310,000 private placement units held by BGLSI and 370,000 founder shaes held by BGLSI to BCM Europe AG ("BCME"). BGLSI's ownership an additional 12,000 shares underlying the private placement rights that convert at the closing of the Business Combination and the shares of the Company's Common Stock held by BCME and Bellevue Capital Management LLC ("BCM") upon the closing of the Business Combination. Mr. Hwang is the founder and managing partner of BCM, the general partner of BGLSI, and has voting and dispositive power over the shares.

(3) Interest does not include shares of the Company's Common Stock held by BGLSI. Mr. Whang is a minority owner of BCM but has no voting or dispositive power over the shares of the Company's Common Stock held by BGLSI.

(4) Interest consists of (i) 1,725,000 founder shares of the Company's Common Stock, (ii) the transfer of 34,500 shares of the Company's Common Stock to Chardan, (iii) 430,000 placement shares held of record by BGLSI, (iv) the transfer of 120,000 shares of the Company's Common Stock by BGLSI to officers and directors of BLAC at the time of its initial public offering, and (v) the transfer of 310,000 private placement units identical held by BGLSI and 370,000 founder shares held by BGLSI to BCME. BGLSI's ownership post-closing includes an additional 12,000 shares underlying the private placement rights that converted at the closing of the Business Combination. Mr. Hwang is the founder and managing partner of BCM, the general partner of BGLSI, and has voting and dispositive power over the shares.

(5) Interest consists of the 370,000 founder shares and 310,000 private placement units (including the exercise of 310,000 private placement warrants into 310,000 shares of the Company's Common Stock, the conversion of 310,000 private placement rights into 31,000 shares of the Company's Common Stock, and the exercise of 60,000 private placement warrants that were also transferred to BCME by BGLSI pursuant to the promissory note into 60,000 shares of the Company's Common Stock) and 581,031 shares of OSR Common Stock held by BCME prior to the closing of the Business Combination. The 581,031 shares of OSR Common Stock were exchanged for 7,531,636 shares of the Company's Common Stock upon the consummation of the Business Combination. BCME is a wholly-owned subsidiary of BCM. The business address of BCME is Gotthardstrasse 26 6300 Zug Switzerland.

(6) Interest consists of 241,000 shares of OSR Common Stock held by BCM prior to the closing of the Business Combination. The 241,000 shares of OSR Common Stock were exchanged for 3,123,970 shares of the Company's Common Stock upon the consummation of the Business Combination. Mr. Hwang has voting and dispositive over such shares.

(7) Interest consists of (i) 828,462 shares of the Company's Common Stock issued upon the consummation of the Business Combination in exchange for 63,912 shares of OSR Holdings Co., Ltd. held by Duksung Co., Ltd. ("Duksung"), (ii) 591,753 shares of the Company's Common Stock issued upon the consummation of the Business Combination in exchange for 45,651 shares of OSR Holdings Co., Ltd. held by Duksung P&T Co., Ltd., and (iii) 10 shares of the Company's Common Stock acquired through open market purchases. (iv) 80,246 shares of the Company's Common Stock issuable upon conversion of a $650,000 convertible bond. The business address of Duksung is 25 Sinwonro Yeongtonggu Suwonsi Gyeonggido, Republic of Korea.

Securities Authorized for Issuance under Equity Compensation Table

Equity Compensation Plan Information

As previously reported by the Company's Current Report on Form 8-K dated February 14, 2025, the Company held a special meeting of its stockholders on February 13, 2025 (the "*February 13, 2025 Special Meeting*"). At the February 13, 2025 Special Meeting, the Company's stockholders approved the Company's 2025 Omnibus Incentive

Plan ("Omnibus Plan"). A description of the material terms of the Omnibus Plan is set forth below. This summary is qualified in its entirety by reference to the complete text of the Omnibus Plan, a copy of which is filed as Exhibit 10.27 to the Company's January 29, 2025 Registration Statement on Form S-4 and incorporated herein by reference.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	0	n/a	6,300,000
Equity compensation plans not approved by security holders	0	n/a	0
Total	**0**	**n/a**	**6,300,000**

Awards Granted Prior to Filing Date — No stock-based compensation awards were granted prior to the filing date.

Shares Available — As of the filing date, a total of 6,300,000 shares remained available for issuance under the Omnibus Plan.

Future Considerations — The Company may consider issuing equity-based awards in future periods as part of its strategy to attract and retain key personnel.

The Omnibus Plan is intended to (i) provide eligible individuals with an incentive to contribute to the Company's success and to operate and manage the Company's business in a manner that provides for long-term growth and profitability and that benefits stockholders and other important stakeholders, including Company employees and customers, and (ii) provide a means of recruiting, rewarding, and retaining key personnel.

Equity awards may be granted under the Omnibus Plan to officers, directors, including non-employee directors, other employees, advisors, consultants or other service providers of the Company or the Company's subsidiaries or other affiliates, and to any other individuals who are approved by the Committee (as defined below) as eligible to participate in the Omnibus Plan. As of December 31, 2025, there are 30 employees or directors that are eligible to participate in the Omnibus Plan, and we expect that 22 full-time employees, and approximately 8 non-employee directors and officers, consultants, and advisors of the Company will be eligible to participate in the Omnibus Plan after the consummation of the Business Combination. Only the Company's employees or employees of the Company's corporate subsidiaries are eligible to receive incentive stock options.

The Omnibus Plan became effective on January 29, 2025, the date it was adopted by the Company Board (the "Effective Date"). The Omnibus Plan will terminate automatically at 11:59 PM ET on the day before the tenth (10^{th}) anniversary of the Effective Date unless earlier terminated by the Board or in accordance with the terms of the Omnibus Plan.

Changes in Control

None.

Item 13. Certain Relationships and Related Transactions, and Director Independence

On July 30, 2020, we issued an aggregate of 1,437,500 founder shares to our Sponsor for an aggregate purchase price of $25,000 in cash, or approximately $0.017 per share. On April 25, 2022, we executed a stock split, resulting in an aggregate of 1,725,000 founder shares held by our Sponsor (of which up to 225,000 shares were subject to forfeiture in the event the underwriter's Over-Allotment Option was not exercised in full). At the closing of our IPO, our Sponsor transferred 20,000 founder shares to each of our directors and 20,000 placement warrants to each of our directors who are serving as our Chairman of the Board of Directors and the chair of our audit committee. On March 23, 2023, our Sponsor also transferred 20,000 founder shares and 20,000 placement warrants to Mr. Yoo for his service as Chief Financial Officer.

Our Sponsor purchased an aggregate of 430,000 Private Placement Units at a price of $10.00 per unit, for an aggregate purchase price of $4,300,000, at the closing of our IPO. There were no redemption rights or liquidating distributions from the Trust Account with respect to the founder shares or placement shares, and the placement warrants and placement rights would have expired worthless if a business combination had not been consummated within the time period specified in the Company's Charter, as amended.

On March 31, 2022, our Sponsor entered into a promissory note with BCM Europe in the principal amount of $3,400,000 with a maturity date of December 9, 2023 (the "BCM Europe Note"). The proceeds of the BCM Europe Note were used to fund our Sponsor's purchase of the Private Placement Units. The BCM Europe Note is convertible at the election of either our Sponsor or BCM Europe into (i) 310,000 Units identical to the Private Placement Units held by our Sponsor, (ii) 370,000 founder shares held by our Sponsor, and (iii) 60,000 warrants held by our Sponsor. The BCM Europe Note was amended on March 27, 2024, to extend the maturity date to the earlier of (i) December 31, 2024, or (ii) the date on which the Company consummated a Business Combination. Additionally, on February 2, 2023, our Sponsor entered into a promissory note with BCM Europe in the principal amount of $3,400,000 with a maturity date of February 2, 2024 (the "BCM Europe Note 2023"). The proceeds of the BCM Europe Note 2023 were intended to be used, if necessary, to fund expenses in connection with our initial business combination. The BCM Europe Note 2023 is not convertible into any BLAC securities held by our Sponsor. The BCM Europe Note 2023 was amended on April 12, 2024, to extend the maturity date to the earlier of (i) December 31, 2024 or (ii) the date on which the Company consummated a Business Combination. As of the date of the filing of this Annual Report on Form 10-K, the outstanding balance of the BCM Europe Note and the BCM Europe Note 2023 is $1,200,000.

Our Sponsor had loaned to us $1,200,000 under promissory notes which was used to pay a portion of the expenses of our IPO. These loans were non-interest bearing, unsecured and were due at the earlier of November 29, 2023 or the closing of our IPO. At the closing of our IPO, the promissory notes were deemed to be repaid and settled in connection with the private placement.

We may pay BCM and/or any of its affiliates, partners or employees a fee for financial advisory services rendered in connection with our identification, negotiation and consummation of our initial business combination. The amount of any fee we pay to BCM and/or any of its affiliates, partners or employees will be based upon the prevailing market for similar services for such transactions at such time, and will be subject to the review of our audit committee pursuant to the audit committee's policies and procedures relating to transactions that may present conflicts of interest.

Commencing on the date of our prospectus issued in connection with our IPO, we have agreed to pay BCM, an affiliate of members of our Sponsor, a total of $7,500 per month for office space, utilities, and secretarial and administrative support. These payments were to cease upon the completion of our initial business combination. However, on February 15, 2025, the Company and BCM entered into an addendum to the Administrative Services Agreement, pursuant to which the Company agreed to continue paying the monthly fee of $7,500 for such services following the completion of the initial business combination.

In addition, the Company entered into a Venture Partner Agreement with Dr. Josh Pan, an individual member of Bellevue Capital Management, LLC ("BCM"), which wholly owns Bellevue Global Life Sciences Investors, LLC. Pursuant to this agreement, the venture partner provides strategic and scientific advisory services in

connection with the Company's portfolio companies, research initiatives and business development activities. The agreement was executed on July 21, 2025 and is deemed effective as of September 1, 2024. In consideration for such services, the Company pays a monthly advisory fee of $15,000, together with reimbursement of reasonable and pre-approved out-of-pocket expenses incurred in connection with the services. A copy of the Venture Partner Agreement is filed as Exhibit 10.33 to this Annual Report on Form 10-K.

In addition, the Company entered into a consulting arrangement with its Chief Scientific Officer, Dr. Constance Höfer, in connection with her appointment as an executive officer of the Company. Prior to her appointment, Dr. Höfer had entered into a consulting agreement with BCM Europe AG ("BCME") effective November 1, 2024, pursuant to which she provided consulting services for Vaximm AG, a subsidiary of the Company. From November 2024 through February 2025, the Company agreed to pay Dr. Höfer directly for services rendered under such arrangement, in the amount of approximately $14,532 per month, given that Vaximm AG is a subsidiary of the Company.

Following Dr. Höfer's appointment as Chief Scientific Officer on March 24, 2025, the Company entered into a separate consulting agreement directly with Dr. Höfer governing her services as an executive officer. Additional information regarding this arrangement is described under Item 10. "Directors, Executive Officers and Corporate Governance."

In November 2025, the Company approved an annual cash board fee of $50,000 for each non-employee director, which was deemed to commence as of February 2025 following the consummation of the Company's initial business combination. Additional information regarding director compensation, including the annual cash board fee, is provided under Item 11. "Executive Compensation — Director Compensation."

Other than the foregoing, no compensation of any kind, including any finder's fee, reimbursement, consulting fee or monies in respect of any payment of a loan, was by the Company to our Sponsor, officers, directors or any affiliate of our Sponsor, officers, directors prior to, or in connection with any services rendered to effectuate, the consummation of the Company's initial business combination. However, these individuals were reimbursed for any out-of-pocket expenses incurred in connection with activities on our behalf, such as identifying potential target businesses and performing due diligence on suitable business combinations. Our audit committee reviewed on a quarterly basis all payments that were made to our Sponsor, officers, directors, advisors or our or their affiliates and determined which expenses and the amount of expenses were eligible for reimbursement. There was no cap or ceiling on the reimbursement of out-of-pocket expenses incurred by such persons in connection with activities on our behalf.

Certain stockholders of the Company are entitled to registration rights pursuant to a registration rights agreement entered into in connection with the Company's initial public offering. Under this agreement, such holders are entitled to make up to two demands, excluding short-form registration demands, that the Company register the sale of such securities under the Securities Act. In addition, such holders have "piggyback" registration rights to include their securities in other registration statements filed by the Company. Chardan may not exercise its demand and piggyback registration rights after five and seven years, respectively, following the effective date of the applicable registration statement, and may not exercise its demand rights on more than one occasion.

Additionally, on the closing date of the Company's business combination (the "Closing Date"), the Company entered into Lock-Up Agreements (the "Lock-Up Agreements") with Bellevue Capital Management LLC ("BCM"), BCM Europe AG ("BCME") and certain other stockholders (collectively, the "Holders"). Pursuant to the Lock-Up Agreements, the Holders agreed to restrictions on the transfer of 70% of the shares of the Company's common stock received in the business combination (the "Lock-Up Shares").

These restrictions commenced on the Closing Date and expire with respect to BCM and BCME on the 36-month anniversary of the Closing Date. The lock-up restrictions applicable to certain other stockholders expired on January 1, 2026.

Promissory Notes with Related Parties

As previously reported by the Company on its Current Report Form 8-K filed on February 9, 2024, on that date the Company issued an unsecured promissory note in the principal amount of $75,000 to Jun Chul Whang, a member of the Company's Board of Directors (the "Jun Chul Whang Promissory Note."). On February 9, 2024, $60,000 was deposited in the trust account in connection with the extension of the date by which the Company must consummate a business combination from February 14, 2024 to March 14, 2024.

The Jun Chul Whang Promissory Note is non-interest bearing. The original maturity date of the note was the earlier of August 9, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on September 30, 2024 and February 12, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the Jun Chul Whang Promissory Note was $45,000. The foregoing description of the Jun Chul Whang Promissory Note is qualified in its entirety by reference to the full text of the note, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 9, 2024 and is incorporated herein by reference.

As previously reported by the Company on its Current Report Form 8-K filed on March 13, 2024, on March 8, 2024 the Company issued an unsecured promissory note in the principal amount of $60,000 to Josh Pan, an individual member of Bellevue Capital Management, LLC, which wholly owns Bellevue Global Life Sciences Investors, LLC, the sponsor of the Company (the "Pan Promissory Note"). On March 12, 2024, $60,000 was deposited in the trust account in connection with the extension of the date by which the Company must consummate a business combination from March 14, 2024 to April 15, 2024.

The Pan Promissory Note is unsecured and non-interest bearing. The original maturity date of the note was the earlier of August 8, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on September 20, 2024 and February 12, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the Pan Promissory Note was $60,000. The foregoing description of the Pan Promissory Note is qualified in its entirety by reference to the full text of the note, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 13, 2024 and is incorporated herein by reference.

As previously reported by the Company on its Current Report Form 8-K filed on April 8, 2024 (the "April 8, 2024 Promissory Note"), on that date the Company issued an unsecured promissory note in the principal amount of $1,200,000 to Bellevue Global Life Sciences Investors, LLC ("BGLSI"), the sponsor of the Company. On April 9, 2024, $60,000 was deposited in the trust account in connection with the extension of the date by which the Company must consummate a business combination from April 15, 2024 to May 14, 2024.

The April 8, 2024 Promissory Note is unsecured and non-interest bearing. The original maturity date of the note was the earlier of December 31, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on January 9, 2025, January 23, 2025 and September 29, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the April 8, 2024 Promissory Note was $715,000. The foregoing description of the BGLSI Promissory Note is qualified in its entirety by reference to the full text of the Note, a copy of which is filed as Exhibit 10.1 to the Company's April 11, 2024 Form 8-K and incorporated herein by reference.

As previously reported by the Company on its Current Report on Form 8-K filed on April 17, 2024, on that date the Company issued an unsecured promissory note in the principal amount of $50,000 (the "April 17, 2024 Promissory Note") to Bellevue Global Life Sciences Investors LLC ("BGLSI").

The April 17, 2024 Promissory Note is unsecured and non-interest bearing. The original maturity date of the note was the earlier of December 31, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on January 9, 2025, January 23, 2025 and September 29, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the April 17, 2024 Promissory Note was $23,000. The foregoing description of the April 17, 2024 Promissory Note is qualified in its entirety by reference to the full text of the note, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 17, 2024 and is incorporated herein by reference.

As previously reported by the Company on its Current Report on Form 8-K filed on May 14, 2024, on that date the Company issued an unsecured promissory note in the principal amount of $140,000 (the "May 14, 2024 Promissory Note") to Bellevue Global Life Sciences Investors LLC ("BGLSI").

The May 14, 2024 Promissory Note is unsecured and non-interest bearing. The original maturity date of the note was the earlier of December 31, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on January 9, 2025, January 23, 2025 and September 29, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the May 14, 2024 Promissory Note was $140,000. The foregoing description of the May 14, 2024 Promissory Note is qualified in its entirety by reference to the full text of the note, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 14, 2024 and is incorporated herein by reference.

As previously reported by the Company on its Current Report on Form 8-K filed on July 11, 2024, on that date the Company issued an unsecured promissory note in the principal amount of $300,000 (the "July 11, 2024 Promissory Note") to Bellevue Global Life Sciences Investors, LLC ("BGLSI").

The July 11, 2024 Promissory Note is unsecured and non-interest bearing. The original maturity date of the note was the earlier of December 31, 2024 or the date on which the Company consummated its initial business combination. The maturity date of the note was subsequently amended on January 9, 2025, January 23, 2025 and September 29, 2025, pursuant to which the maturity date was extended to December 31, 2026. As of December 31, 2025, the outstanding balance of the July 11, 2024 Promissory Note was $280,000. The foregoing description of the July 11, 2024 Promissory Note is qualified in its entirety by reference to the full text of the note, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 11, 2024 and is incorporated herein by reference.

On November 14, 2025, the Company issued an unsecured promissory note in the principal amount of $60,000 (the "November 14, 2025 Promissory Note") to BCM Europe AG ("BCME"). The November 14, 2025 Promissory Note is unsecured and non-interest bearing. The maturity date of the note is November 14, 2027.

As previously reported by the Company on its Current Report on Form 8-K filed on October 25, 2024, on that date the Company advanced a loan to OSR Holdings Co., Ltd. ("OSR"), a subsidiary of the Company, in the amount of $300,000, evidenced by a promissory note (the "Company Promissory Note"). The Company Promissory Note bears interest at a rate of 3.96% per annum, compounded semi-annually, and was originally due on October 25, 2025, with interest payable only upon maturity. The following events constitute events of default under the Company Promissory Note: (i) failure to pay the outstanding balance due within five (5) business days of the maturity date and (ii) the commencement of a voluntary or involuntary bankruptcy proceeding. The funds were used by OSR for working capital and other corporate purposes.

During 2025, the Company advanced additional loans totaling $2,734,000 to OSR for working capital and other operating expenses. These additional advances are non-interest bearing and have maturity dates ranging from April 11, 2026 to December 30, 2026.

As of December 31, 2025, the total outstanding balance of loans receivable from OSR was $2,909,000, consisting of $175,000 outstanding under the Company Promissory Note described above and $2,734,000 of non-interest-bearing advances made during 2025.

Related Party Policy

We have not yet adopted a formal policy for the review, approval or ratification of related party transactions. Accordingly, the transactions discussed above were not reviewed, approved or ratified in accordance with any such policy.

We have adopted a code of ethics requiring us to avoid, wherever possible, all conflicts of interests, except under guidelines or resolutions approved by our board of directors (or the appropriate committee of our board) or as disclosed in our public filings with the SEC. Under our code of ethics, conflict of interest situations will include any financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) involving the company.

In addition, our audit committee is responsible for reviewing and approving related party transactions to the extent that we enter into such transactions. An affirmative vote of a majority of the members of the audit committee present at a meeting at which a quorum is present will be required in order to approve a related party transaction. A majority of the members of the entire audit committee will constitute a quorum. Without a meeting, the unanimous written consent of all of the members of the audit committee will be required to approve a related party transaction. We also require each of our directors and executive officers to complete a directors' and officers' questionnaire that elicits information about related party transactions.

These procedures are intended to determine whether any such related party transaction impairs the independence of a director or presents a conflict of interest on the part of a director, employee or officer.

To further minimize conflicts of interest, we agreed not to consummate an initial business combination with an entity that is affiliated with any of our Sponsor, officers or directors unless we have obtained an opinion from an independent investment banking firm or another independent entity that commonly renders valuation opinions that our initial business combination is fair to our company from a financial point of view and a majority of our disinterested independent directors approve such business combination. Furthermore, no finder's fees, reimbursements, consulting fee, monies in respect of any payment of a loan or other compensation will be paid by us to our Sponsor, officers, directors or any affiliate of our Sponsor, officers, directors prior to, for services rendered to us prior to, or in connection with any services rendered in order to effectuate, the consummation of our initial business combination (regardless of the type of transaction that it is). However, the following payments will be made to our Sponsor, officers, directors or our or their affiliates, none of which has been made from the proceeds of our IPO held in the Trust Account prior to the completion of our initial business combination:

- Payment to an affiliate of our Sponsor of $7,500 per month for office space, utilities and secretarial and administrative support on an ongoing basis until we decide to use the same services from other vendors or landlords;
- We may pay BCM and/or any of its affiliates, partners or employees a fee for financial advisory services rendered in connection with our R&D pipeline or subsidiary portfolio expansion; the amount of any fee we pay to BCM and/or any of its affiliates, partners or employees will be based upon the prevailing market for similar services for such transactions at such time, and will be subject to the review of our audit committee pursuant to the audit committee's policies and procedures relating to transactions that may present conflicts of interest;
- Reimbursement for any out-of-pocket expenses related to identifying, investigating and completing additional acquisitions of R&D assets or subsidiaries; and
- Repayment of loans which have been made historically by our Sponsor, officers and directors or their affiliates to finance transaction costs in connection with an intended initial business combination, the terms of which have not been determined nor have any written agreements been executed with respect thereto.

Our audit committee has reviewed, and will continue to review, all payments that were made to our Sponsor, officers, directors, advisors or our or their affiliates.

Director Independence

Nasdaq listing standards require that a majority of our board of directors be independent. An "independent director" is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship which, in the opinion of the company's board of directors, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that each director is an "independent director" as defined in the Nasdaq listing standards and applicable SEC rules. Our independent directors will have regularly scheduled meetings at which only independent directors are present.

Item 14. Principal Accountant Fees and Services

The following is a summary of fees paid or to be paid to RSM Shinhan Accounting Corporation, or RSM Korea, and WithumSmith+Brown, PC, or Withum, for services rendered.

Audit Fees. Audit fees for the fiscal year ended December 31, 2025 were $422,531, which consist of fees billed by RSM Korea, our independent registered public accounting firm, for the audit of our annual consolidated financial statements for the year ended December 31, 2025 and services that are normally provided by the independent auditor in connection with statutory and regulatory filings or engagements for that fiscal year. The aggregate fee of RSM

Audit fees for the fiscal year ended December 31, 2024 were $152,940, which consist of fees billed by Withum our former independent registered public accounting firm, for the audit of our annual financial statements for the year ended December 31, 2024 and services that are normally provided by the independent auditor in connection with statutory and regulatory filings or engagements for that fiscal year.

Audit-Related Fees. Audit-related fees consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our financial statements and are not reported under "Audit Fees." These services include attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards. During the fiscal years ended December 31, 2025 and December 31, 2024, we did not pay RSM Korea or Withum any audit-related fees.

Tax Fees. We did not pay RSM Korea or Withum for tax services, planning or advice for the fiscal years ended December 31, 2025 and December 31, 2024.

All Other Fees. We did not pay RSM Korea or Withum for any other services for the fiscal years ended December 31, 2025 and December 31, 2024.

Pre-Approval Policy

The audit committee has and will pre-approve all auditing services and permitted non-audit services to be performed for us by our auditors, including the fees and terms thereof (subject to the de minimis exceptions for non-audit services described in the Exchange Act which are approved by the audit committee prior to the completion of the audit).

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this report:

1. Financial Statements: See "Index to Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedule: Not applicable.

3. Exhibits: The exhibits listed in the accompanying "Exhibit Index" are filed or incorporated by reference as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit	Description
2.1	First Amendment to Amended and Restated Business Combination Agreement, dated as of December 20, 2024 between Bellevue Life Sciences Acquisition Corp. and OSR Holdings Co., Ltd. (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on December 23, 2024)
2.2*	Amended and Restated Business Combination Agreement, dated as of May 23, 2024, between Bellevue Life Sciences Acquisition Corp. and OSR Holdings Co., Ltd. (Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 30, 2024)
3.1	Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 13, 2025)
3.2	Amended and Restated Bylaws of OSR Holdings, Inc. (Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the Company's Form S-1 (File No. 333-264597) filed with the SEC on April 29, 2022)
4.2	Specimen Warrant Certificate (Incorporated by reference to Exhibit 4.3 to Amendment No. 2 to the Company's Form S-1 (File No. 333-264597) filed with the SEC on May 13, 2022)
4.3	Warrant Agreement, dated February 9, 2023, between Continental Stock Transfer & Trust Company and the Registrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 15, 2023)
10.1	Promissory Note, dated February 9, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Jun Chul Whang (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 13, 2024)
10.2	Promissory Note, dated March 8, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Josh Pan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on March 13, 2024)
10.3	Promissory Note, dated April 8, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Bellevue Global Life Sciences Investors, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on April 11, 2024)
10.4	Promissory Note, dated April 17, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Bellevue Global Life Sciences Investors LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on April 22, 2024)
10.5	Promissory Note, dated May 14, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Bellevue Global Life Sciences Investors LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 14, 2024)
10.6	Form of First Amendment to Subscription Agreement, by and among Bellevue Life Sciences Acquisition Corp. and the investors signatory thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on December 23, 2024)

Exhibit	Description
10.7	Form of Participating Stockholder Joinder Agreement (Incorporated by reference to Exhibit 10.1 to BLAC's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on November 16, 2023)
10.8	Form of Non-Participating Stockholder Joinder Agreement (Incorporated by reference to Exhibit 10.2 to BLAC's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on November 16, 2023)
10.9	Promissory Note, dated July 11, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Bellevue Global Life Sciences Investors, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on July 16, 2024)
10.10	Second Amendment to Promissory Notes, dated January 23, 2025, between Bellevue Life Sciences Acquisition Corp. and Bellevue Global Life Sciences Investors, LLC ((Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on January 23, 2025)
10.11	Amendment to Promissory Note, dated September 20, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Jun Chul Whang (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on September 24, 2024)
10.12	Amendment to Promissory Note, dated September 20, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Josh Pan (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on September 24, 2024)
10.13	Amendment to Promissory Notes, dated January 9, 2025, between Bellevue Life Sciences Acquisition Corp. and Bellevue Global Life Sciences Investors, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on January 10, 2025)
10.14	Form of Subscription Agreement, by and among Bellevue Life Sciences Acquisition Corp. and the investors signatory thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on October 10, 2024)
10.15	Promissory Note, dated October 11, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Jun Chul Whang (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on October 15, 2024)
10.16	Promissory Note, dated October 16, 2024, issued by Bellevue Life Sciences Acquisition Corp. to Duksung Co., LTD. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on October 22, 2024)
10.17	Promissory Note, dated October 25, 2024, issued by OSR Holdings Co., Ltd. to Bellevue Life Sciences Acquisition Corp. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on October 28, 2024)
10.18	Form of Participating Joinder (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
10.19	Form of Non-Participating Joinder (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
10.20	Form of Lock-Up Agreement (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
10.21	Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
10.22	2025 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-4 (File No. 333-280590) filed with the SEC on January 29, 2025)
10.23	Common Stock Purchase Agreement, dated as of December 31, 2024, by and between OSR Holdings, Inc. and White Lion Capital LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 28, 2025)
10.24	Registration Rights Agreement, dated as of December 31, 2024, by and between OSR Holdings, Inc. and White Lion Capital LLC (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 28, 2025)
10.25	Second Amendment to Promissory Note, dated February 12, 2025, issued by OSR Holdings, Inc. to Jun Chul Whang
10.26	Second Amendment to Promissory Note, dated February 12, 2025, issued by OSR Holdings, Inc. to Josh Pan

Exhibit	Description
10.27	Note Purchase Agreement, dated May 6, 2025, by and between OSR Holdings, Inc. and White Lion Capital, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 12, 2025)
10.28	Senior Secured Convertible Promissory Note, issued May 6, 2025, by OSR Holdings, Inc. to White Lion Capital LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 12, 2025)
10.29	Common Stock Purchase Warrant, issued May 6, 2025, by OSR Holdings, Inc. to White Lion Capital LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 12, 2025)
10.30	Amendment No. 1 to Common Stock Purchase Agreement, dated May 6, 2025, by and between OSR Holdings, Inc. and White Lion Capital LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on May 12, 2025)
10.31	Amendment No. 1 to Note Purchase Agreement, dated June 30, 2025, by and between OSR Holdings, Inc. and White Lion Capital LLC
10.32	Amendment No. 1 to Common Stock Purchase Warrant, dated June 30, 2025, by and between OSR Holdings, Inc. and White Lion Capital LLC
10.33	Venture Partner Agreement, dated July 21, 2025 (effective as of September 1, 2024), by and between OSR Holdings, Inc. and Josh Pan
10.34	Term Sheet, dated July 24, 2025, by and among OSR Holdings Co., Ltd. and Woori IO Co., Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on July 25, 2025)
10.35	Third Amendment to Promissory Notes, dated September 29, 2025, between OSR Holdings, Inc. and Bellevue Global Life Sciences Investors, LLC
10.36	Promissory Note, dated November 14, 2025, issued by OSR Holdings, Inc. to BCM Europe AG
10.37*	Annex 2 (Conditions for Exchange into OSR Holdings Inc. Shares), excerpted from the Share Exchange Agreement dated October 13, 2025, by and among OSR Holdings Co., Ltd. and Woori IO Co., Ltd. (incorporated by reference to Exhibit 2.1A to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on October 16, 2025)
10.38	Binding Term Sheet, dated January 13, 2026, by and between Vaximm AG and BCM Europe AG, relating to a global exclusive license of VXM01 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on January 14, 2026)
10.39	Amendment No. 1 to Duksung Promissory Note, dated October 16, 2025, issued by Bellevue Life Sciences Acquisition Corp. to Duksung Co., Ltd.
19.1	Insider Trading Policy
21.1	Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)
23.1	Consent of RSM Shinhan Accounting Corporation
31.1	Certification of Principal Executive Officer pursuant to rule 13a-14(a) or rule 15d-14(a) of the securities exchange act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to rule 13a-14(a) or rule 15d-14(a) of the securities exchange act of 1934, as amended
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley act of 2002
99.1	Press Release, dated February 13, 2025 (Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 13, 2025)
99.2	Press Release, dated February 14, 2025 (Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 18, 2025)
99.3	Corporate Governance and Nomination Charter. (Incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K (File No. 001-41390) filed with the SEC on February 21, 2025)

Exhibit	Description
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)*

* Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the SEC upon request for this exhibit.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OSR HOLDINGS, INC.

By: /s/ Kuk Hyoun Hwang
Name: Kuk Hyoun Hwang
Title: Chief Executive Officer

Date: March 31, 2026

Pursuant to the requirements of the Securities Exchange Act of 1934, the report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Kuk Hyoun Hwang Kuk Hyoun Hwang	*Chief Executive Officer and Director (Principal Executive Officer)*	March 31, 2026
/s/ Jun Chul Whang Jun Chul Whang	*Chief Legal Officer and Secretary*	March 31, 2026
/s/ Gihyoun Bang Gihyoun Bang	*Chief Financial Officer (Principal Financial Officer)*	March 31, 2026
/s/ Alcide Barberis Alcide Barberis	*Director*	March 31, 2026
/s/ Seng Chin Mah Seng Chin Mah	*Director*	March 31, 2026
/s/ Hyuk Joo Jee Hyuk Joo Jee	*Director*	March 31, 2026
/s/ Joong Myung Cho Joong Myung Cho	*Director*	March 31, 2026
/s/ Reto Fierz Reto Fierz	*Director*	March 31, 2026

OSR HOLDINGS, INC.
(f/k/a Bellevue Life Sciences Acquisition Corp.)
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Shinhan Accounting Corporation
8th FL, 8,
Uisadang-daero
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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of
Directors of OSR Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of OSR Holdings Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024 and the related consolidated statement of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations, available cash and cash used in operations raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain and understanding of internal control over financial reporting but not for the purposes of expressing and opinion of the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

RSM Shinhan Accounting Corporation

Shinhan Accounting Corporation

We have served as the Company's auditor since

2023. Seoul, Korea
March 30, 2026

OSR HOLDINGS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2025 and 2024

	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,700,273	$ 341,543
Trade and other receivables, less allowance for credit losses of $62,370.40 and $67,579.81 as of December 31, 2025 and December 31, 2024, respectively	392,096	933,824
Inventories, net	196,432	922,107
Prepaid income taxes	1,750	39
Other current financial assets	262,722	54,422
Other current assets	263,548	74,555
Total current assets	2,816,821	2,326,490
Equipment and vehicles, net	169,130	2,334
Operating lease right-of-use assets, net	60,425	78,484
Intangible assets, net	142,462,634	148,056,852
Goodwill	24,949,806	24,354,066
Other non-current financial assets	578,917	329,252
Deferred tax assets	200,515	92,101
Total assets	$ 171,238,248	$ 175,239,579
Liabilities and Stockholders' Equity		
Current liabilities:		
Short-term borrowing	$ 2,323,471	$ 1,799,796
Short-term corporate bond	2,019,804	—
Trade and other payables	7,830,104	1,078,760
Accrued expenses	957,879	459,883
Operating lease liabilities-current	46,961	44,741
Other current liabilities	971,445	79,777
Income taxes payable	485,452	255
Derivative liabilities	2,530,176	—
Total current liabilities	17,165,292	3,463,212
Long-term debt	—	497,615
Operating lease liabilities – non-current	12,551	33,372
Other non-current liabilities	1,697	1,656
Deferred tax liabilities	27,021,305	28,035,508
Total liabilities	44,200,845	32,031,363
Stockholders' equity:		
Common stock, $0.0001 par value, Authorized 100,000,000 shares; 26,597,769 shares and 2,155,000 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	2,660	216
Additional paid-in capital	110,966,975	162,606,449
Accumulated deficit	(37,169,881)	(19,173,063)
Accumulated other comprehensive income	3,835,861	(225,386)
Non-controlling interests	49,401,788	—
Total stockholders' equity	127,037,403	143,208,216
Total liabilities and stockholders' equity	$ 171,238,248	$ 175,239,579

The accompanying notes are an integral part of the consolidated financial statements.

OSR HOLDINGS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Income
Years ended December 31, 2025 and 2024

	2025	2024
Net sales	$ 2,905,805	$ 3,530,303
Cost of sales	2,312,900	2,719,067
Gross profit	592,905	811,236
Selling, general, and administrative expenses	18,928,908	12,503,433
Operating loss	(18,336,003)	(11,692,197)
Other income (expense):		
Interest income	63,883	21,294
Interest expense	(506,196)	(51,335)
Other income	4,335,888	99,194
Other expenses	(14,445,933)	(269,635)
Loss before income taxes	(28,888,361)	(11,892,678)
Income tax benefit	1,829,820	1,563,768
Net loss	(27,058,541)	(10,328,910)
Attributable to:		
OSR Holdings, Inc. and subsidiaries	(18,010,899)	(10,328,910)
Non-controlling interests	(9,047,642)	—
Other comprehensive income for the year, net of tax		
Gain(loss) on foreign currency translation	5,988,163	50,489
Total comprehensive loss for the year	$ (21,070,378)	$ (10,278,422)
Attributable to:		
OSR Holdings, Inc. and subsidiaries	(14,025,016)	(10,278,422)
Non-controlling interests	(7,045,362)	—
loss per share attributable to OSR Holdings, Inc. and subsidiaries		
Basic loss per ordinary share	$ (0.92)	$ (4.79)

The accompanying notes are an integral part of the consolidated financial statements.

OSR HOLDINGS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

Years ended December 31, 2025 and 2024

	Common stock		Additional paid-in capital	Retained Earnings (accumulated deficit)	Accumulated other comprehensive Income (loss)	Non-controlling interests	Total stockholders' equity
	Shares	Amounts					
Balance at January 1, 2024	2,155,000	$ 216	$ 162,606,449	$ (8,844,153)	$ (275,875)	$ —	$ 153,486,637
Net loss	—	—	—	(10,328,910)	—	—	(10,328,910)
Foreign currency translation adjustment	—	—	—	—	50,489	—	50,489
Balance at December 31, 2024	2,155,000	$ 216	$ 162,606,449	$ (19,173,063)	$ (225,386)	$ —	$ 143,208,216
Balance at January 1, 2025	2,155,000	$ 216	$ 162,606,449	$ (19,173,063)	$ (225,386)	$ —	$ 143,208,216
Net loss	—	—	—	(18,010,899)	—	(9,047,642)	(27,058,541)
Changes in Exercise tax	—	—	—	14,081	—	—	14,081
Foreign currency translation adjustment	—	—	—	—	4,061,247	1,926,916	5,988,163
Business Combination	17,121,978	1,712	(56,524,226)	—	—	56,522,514	—
Issuance of share captial	529,481	732	4,884,752	—	—	—	4,885,484
Balance at December 31, 2025	19,806,459	$ 2,660	$ 110,966,975	$ (37,169,881)	$ 3,835,861	$ 49,401,788	$ 127,037,403

The accompanying notes are an integral part of the consolidated financial statements.

OSR HOLDINGS, INC.
Consolidated Statements of Cash Flows
Years ended December 31, 2025 and 2024

	2025	2024
Cash flows from operating activities:		
Net loss	$ (27,058,541)	$ (10,328,910)
Adjustments to reconcile net loss to cash used in operating activities:		
Income tax benefit	(1,829,820)	(1,563,768)
Depreciation	7,269	5,900
Amortization	9,298,838	9,684,074
Loss on inventory valuation	(8,832)	12,991
Loss on disposal of tangible assets	—	2,159
Lease expense	54,844	73,681
Bad debts	42,257	57,706
Severance pay	—	80,706
Commissions and professional fees	3,350,364	—
Loss on change in fair value of financial liabilities	5,652,376	—
Merger and acquisition costs	8,645,747	—
Loss on foreign currency translation	74,079	169,014
Gain on change in fair value of financial liabilities	(4,216,055)	—
Gain on foreign currency translation	(46,018)	—
Changes in operating assets and liabilities:		
Decrease in trade and other receivables	570,733	87,785
Decrease in inventories, net	763,734	305,604
Decrease (increase) in other current assets	350,645	(15,465)
Decrease in trade and other payables	(510,232)	(344,032)
Increase in accrued expenses	476,645	3,392
Decrease in lease liabilities	(54,844)	(73,681)
Increase (decrease) in tax payables	153,618	(14,792)
Increase (decrease) in other liabilities	(44,841)	8,162
Net cash used in operating activities	(4,328,034)	(1,849,474)
Cash flows from investing activities:		
Decrease in deposits	—	8,319
Decrease in short-term loan	—	696,279
Purchase of FVTPL financial assets	(433,126)	—
Disposal of equipment and vehicles	1,022	6,221
Purchase of tangible assets	(176,385)	—
Increase in deposits	—	(7,331)
Increase in short-term loan	(3,225,530)	(199,877)
Increase in long-term loan	(33,766)	—
Increase in cash and cash equivalents from business combination	1,224,794	—
Net cash provided by (used in) investing activities	(2,642,991)	503,611

OSR HOLDINGS, INC.
Consolidated Statements of Cash Flows — (Continued)
Years ended December 31, 2025 and 2024

	2025	2024
Cash flows from financing activities:		
Proceeds from long-term debt	—	236,672
Proceeds from short-term borrowing	4,132,912	1,652,144
Extension of lease liability	22,097	—
Repayment of long-term debt	(514,333)	(49,250)
Repayment of short-term borrowing	(500,316)	(655,232)
Issuance of convertible bonds	1,083,547	—
Repayment of short-term corporate bond	(652,207)	—
Proceeds from issuance of common stock	4,796,471	—
Net cash provided by financing activities	8,368,171	1,184,334
Net change in cash and cash equivalents	1,397,145	(161,529)
Effects of changes in exchange rate on cash and cash equivalents	(38,415)	(37,135)
Cash and cash equivalents at beginning of year	341,543	540,207
Cash and cash equivalents at end of year	$ 1,700,273	$ 341,543
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 506,801	$ 53,993
Cash paid for income taxes (net of refunds received)	153,618	14,792

The accompanying notes are an integral part of the consolidated financial statements.

(1) Organization and nature of business

OSR Holdings, Inc. (the Company) and its subsidiaries (collectively the Group) are a global healthcare company dedicated to advancing healthcare outcomes and improving the quality of life for people and their families. The Group aims to build and develop a robust portfolio of innovative and potentially transformative therapies and healthcare solutions. The Group's current operating businesses (through the four wholly owned subsidiaries) include (i) developing oral immunotherapies for the treatment of cancer, (ii) developing design-augmented biologics for age-related and other degenerative diseases and (iii) neurovascular intervention medical device and systems distribution in Korea. The Group's vision is to acquire and operate a portfolio of innovative health-care related companies globally.

The Company (formerly known as Bellevue Life Sciences Acquisition Corp. or BLAC) was incorporated in Delaware on February 25, 2020. The Company was incorporated for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities (the "Business Combination"). The Company is an emerging growth company and, as such, the Company is subject to all of the risks associated with emerging growth companies.

On February 14, 2025 (the "Closing Date"), the Company consummated its previously announced business combination (the "Business Combination") with OSR Holdings Co., Ltd., a corporation organized under the laws of the Republic of Korea ("OSRK" or "the Parent"), pursuant to the Amended and Restated Business Combination Agreement dated May 23, 2024, as amended on December 20, 2024 (the "Business Combination Agreement"). The Business Combination Agreement was entered into among the Company, OSR, and certain OSR stockholders that executed joinder agreements thereto. In connection with the consummation of the Business Combination, the Company changed its name from "Bellevue Life Sciences Acquisition Corp. or BLAC" to "OSR Holdings, Inc."

The Business Combination was consummated on February 14, 2025, which, for accounting and reporting purposes under U.S. generally accepted accounting principles (US-GAAP), was treated as the equivalent of OSR Holdings Co., Ltd. exchanging its stock for the net assets of OSR Holdings, Inc, accompanied by an equity recapitalization of OSR Holdings, Inc, which was determined to fall within the scope of Accounting Standards Codification (ASC) 805 *Business Combinations*. OSR Holdings, Inc. was treated as the acquired company, and its net assets were stated at historical cost, with no goodwill or other intangible assets recorded. The excess of the fair value of shares exchanged to OSR Holdings, Inc. over the fair value of OSR Holdings, Inc's identifiable net assets acquired represented compensation for the service of a stock exchange listing for its shares and was expensed as incurred. The identifiable net assets was negative $9.3 million, which consists of cash and cash equivalents ($1.2 million), current financial assets ($1.0 million), other assets ($0.1 million), accounts and other payable ($6.2 million), other current financial liabilities ($4.2 million), other liabilities ($1.2 million).

The accompanying consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. This assumption contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. Since its inception through December 31, 2025, the Group has continued to incur significant operating losses and negative cash flows from operating activities. The Group recorded an operating loss of approximately $18.34 million for the year ended December 31, 2025, which increased compared to an operating loss of approximately $11.69 million for the same period in 2024. As of December 31, 2025, the Group had an accumulated deficit of approximately $37.17 million.

To date, the Group has funded its operations primarily through the issuance of common stock and convertible bonds, bank borrowings, loans from affiliates, and, to a relatively limited extent, product revenue generated by its subsidiary, RMC. As of December 31, 2025, the Group had cash and cash equivalents of approximately $1.7 million, consisting primarily of bank deposits.

(1) Organization and nature of business (cont.)

The Group incurred significant expenses in connection with the business combination and the filing of its Form S-4 registration statement, and these expenses, together with other general operating expenses, reduced the funds available for operations and increased the urgency of the need for additional capital. In response, in February 2025, OSR Holdings entered into an Equity Line of Credit ("ELOC") agreement with an investor, which provides for potential financing of up to $80 million. As of December 31, 2025, the Company had issued a total of 1,692,500 shares under the ELOC and raised gross proceeds of $1,259,753. In addition, the Company has executed or is reviewing various financing initiatives, including the issuance of warrants and convertible notes.

OSR Holdings expects to continue utilizing the ELOC until the end of the commitment period on December 31, 2026, under the ELOC agreement with White Lion; however, OSR Holdings plans to operate the ELOC in a more prudent and controlled manner in order to minimize share dilution and the impact on the stock price. In addition, OSR Holdings plans to introduce new equity financing facilities that are generally considered less dilutive and more controllable than an ELOC, such as an At-the-Market offering, following the filing of this Form 10-K.

To fund its operations over the long term, the Group must begin generating positive cash flows, renegotiate its existing debt obligations, and raise additional capital through debt or equity financing. Management's plans include pursuing additional financing through the issuance of equity securities and debt and/or convertible debt instruments. The issuance of additional equity securities, convertible debt, or warrants may result in dilution to existing stockholders. The Group will require significant additional financing to meet its planned capital needs and is pursuing opportunities to obtain additional financing through equity and/or debt alternatives. However, there can be no assurance that such additional debt or equity financing will be available on terms acceptable to the Group, or at all. These factors raise substantial doubt about the Group's ability to continue as a going concern for the twelve months from the date of this report. The accompanying consolidated financial statements do not include any adjustments that may be necessary as a result of this uncertainty.

Details of shareholders as of December 31, 2025 are as follows:

Name of Shareholder	Number of ordinary share	Percentage of ownership
Bellevue Global Life Sciences Investors LLC	1,332,500	5.01%
BCM Europe AG	8,242,636	30.99%
Bellevue Capital Management LLC	3,123,970	11.75%
Duksung Co., Ltd.	1,420,225	5.34%
Others	12,478,438	46.92%
Total	26,597,769	100.00%

As of December 31, 2025, there were 26,597,769 shares of the registrant's common stock outstanding.

Details of investments in subsidiaries as of December 31, 2025 are as follows:

Name of subsidiary	Share capital	Percentage of ownership	Principal activities
VAXIMM AG ("VAXIMM")	$ 760,474	100.00%	Biotech (drug development)
RMC Co., Ltd. ("RMC")	24,392	100.00%	Medical device distribution
Darnatein Co., Ltd. ("Darnatein")	4,506,702	100.00%	Biotech (drug development)
OSR Holdings, Inc. ("OSRI")(*1)	2,687	100.00%	SPAC

(1) Organization and nature of business (cont.)

Key financial information of the subsidiaries at December 31, 2025 are as follows:

Name of subsidiary	Asset	Liability	Equity	Sales	Net Income (loss)
VAXIMM AG	$ 288,859	$ 134,287	$ 154,572	$ 74,956	$ (857,516)
RMC Co., Ltd	1,066,762	752,212	314,550	2,830,849	(384,880)
Darnatein Co., Ltd	297,391	1,284,426	(987,035)	—	(554,431)
OSR Holdings, Inc.(*1) . .	4,574,578	13,366,902	(8,792,324)	—	(7,414,649)

(*1) Aforementioned above, the Company is treated as the acquired company under ASC 805 Business Combinations. As such, it is shown as subsidiary for the subsidiary investment details.

Summaries of entities, which are newly included in consolidation scope for the years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025	
Name of subsidiary	**Reason**	**Type of purchase consideration**
OSR Holdings, Inc.	Acquisition(*2)	Equity swap with shares of the Parent and OSR inc.'s share

(*2) The Parent acquired subsidiary in February 2025 and accounted for the acquisitions at March 31, 2025, which is deemed the acquisition date.

(2) Summary of significant accounting policies

a. Basis of presentation

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (US-GAAP).

b. Principle of consolidation

The consolidated financial statements include the accounts of OSR Holdings, Inc. and its subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

The Company consolidates entities in which it has a controlling financial interest based on either the variable interest entity (VIE) or voting interest model. The Company is required to first apply the VIE model to determine whether it holds a variable interest in an entity, and if so, whether the entity is a VIE. If the Company determines it does not hold a variable interest in a VIE, it then applies the voting interest model. Under the voting interest model, the Company consolidates an entity when it holds a majority voting interest in an entity.

The Company accounts for investments in which it has significant influence but not a controlling financial interest using the equity method of accounting.

c. Use of estimates

The preparation of the consolidated financial statements in conformity with US-GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include allowance for credit losses, valuation of inventories, valuation of deferred tax assets, the useful lives of equipment and vehicles, lease liabilities and right-of-use assets, and other contingencies.

(2) Summary of significant accounting policies (cont.)

d. Cash and cash equivalents

The Group considers all highly liquid financial instruments with original maturities of three months or less when purchased to be cash equivalents.

e. Allowance for credit losses

The Group records an allowance for credit losses (ACL) under Subtopic 326-20 *Financial Instruments — Credit Losses — Measured at Amortized Cost* for the current expected credit losses inherent in its financial assets measured at amortized cost and contract assets. The ACL is a valuation account deducted from the amortized cost basis to present the net amount expected to be collected. The estimate of expected credit losses includes expected recoveries of amounts previously written off as well as amounts expected to be written off.

Accounts receivable

The Group uses an aging schedule to estimate the ACL for trade accounts receivable. This method categorizes trade receivables into different groups based on industry and the number of days past due. Past due status is measured based on the number of days since the payment due date. The trade receivables are evaluated individually for expected credit losses if they no longer share similar risk characteristics. The Group determines that the receivables no longer share similar risk characteristic if they are past due balances over 90 days and over a specified amount. The Group evaluates the collectability of trade accounts receivables with payments that are more than 90 days past due on an individual basis to determine if any are deemed uncollectible. Trade accounts receivable balances are deemed uncollectible and written off as a deduction from the allowance after all means of collection have been exhausted.

f. Accounts receivable

Accounts receivables are recorded at the invoiced amount and do not bear interest. Amounts collected on trade accounts receivable are included in cash flows from operating activities in the consolidated statements of cash flows.

g. Inventories

Inventories are stated at the lower of cost or net realizable value and cost is determined by the first-in, first-out method. Cost comprises of direct materials and delivery costs, direct labor, import duties and other taxes, an appropriate proportion of variable and fixed overhead expenditure based on normal operating capacity, and, where applicable, transfers from cash flow hedging reserves in equity. Costs of purchased inventory are determined after deducting rebates and discounts received or receivable.

Stock in transit is stated at the lower of cost and net realizable value. Cost comprises of purchase and delivery costs, net of rebates and discounts received or receivable.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

h. Equipment and vehicles

Equipment and vehicles are stated at historical cost less accumulated depreciation and accumulated impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

(2) Summary of significant accounting policies (cont.)

Depreciation of all equipment and vehicles is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over their estimated useful lives as follows:

	Estimated useful lives
Vehicle	5 years
Office equipment	5 years
Facility equipment	3 to 13 years

The assets' depreciation method, residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

i. Goodwill and intangible assets

Goodwill represents the excess purchase price over the estimated fair value of net assets acquired in a business combination.

The Group accounts for intangible assets in accordance with Accounting Standards Codification (ASC) Topic 350, *Intangibles — Goodwill and Other* (ASC 350). ASC 350 requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives and reviewed for impairment in accordance with accounting standards.

When impairment indicators are identified, the Group compares the reporting unit's fair value to its carrying amount, including goodwill. An impairment loss is recognized as the difference, if any, between the reporting unit's carrying amount and its fair value, to the extent the difference does not exceed the total amount of goodwill allocated to the reporting unit.

Indefinite-lived intangible assets are tested for impairment annually, and more frequently when there is a triggering event. Annually, or when there is a triggering event, the Group first performs a qualitative assessment by evaluating all relevant events and circumstances to determine if it is more likely than not that the indefinite-lived intangible assets are impaired; this includes considering any potential effect on significant inputs to determining the fair value of the indefinite-lived intangible assets. When it is more likely than not that an indefinite-lived intangible asset is impaired, then the Group calculates the fair value of the intangible asset and performs a quantitative impairment test.

j. Impairment of long-lived assets

Long-lived assets, such as equipment, vehicles and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Group first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment loss is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary.

k. Leases

The Group is a lessee in several noncancellable operating leases, primarily for plants and main offices. The Group does not have a finance lease.

(2) Summary of significant accounting policies (cont.)

The Group accounts for leases in accordance with ASC Topic 842, *Leases*. The Group determines if an arrangement is or contains a lease at contract inception. The Group recognizes a right-of-use (ROU) asset and a lease liability at the lease commencement date.

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. For finance leases, the lease liability is initially measured in the same manner and date as for operating leases and is subsequently measured at amortized cost using the effective-interest method.

Key estimates and judgments include how the Group determines (1) the discount rate it uses to discount the unpaid lease payments to present value, (2) lease term, and (3) lease payments.

- Topic 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. Generally, the Group cannot determine the interest rate implicit in the lease because it does not have access to the lessor's estimated residual value or the amount of the lessor's deferred initial direct costs. Therefore, the Group generally uses its incremental borrowing rate as the discount rate for the lease. The Group's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. Because the Group does not generally borrow on a collateralized basis, it uses the interest rate it pays on its noncollateralized borrowings as an input to deriving an appropriate incremental borrowing rate, adjusted for the amount of the lease payments, the lease term, and the effect on that rate of designating specific collateral with a value equal to the unpaid lease payments for that lease.
- The lease term for all of the Group's leases includes the noncancellable period of the lease plus any additional periods covered by either a Group option to extend (or not to terminate) the lease that the Group is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor.
- Lease payments included in the measurement of the lease liability comprise the following:
  - Fixed payments, including in-substance fixed payments, owed over the lease term (includes termination penalties the Group would owe if the lease term reflects the Group's exercise of a termination option);
  - Variable lease payments that depend on an index or rate, initially measured using the index or rate at the lease commencement date;
  - Amounts expected to be payable under a Group-provided residual value guarantee; and
  - The exercise price of a Group option to purchase the underlying asset if the Group is reasonably certain to exercise the option.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

(2) Summary of significant accounting policies (cont.)

ROU assets are periodically reduced by impairment losses. The Group uses the long-lived assets impairment guidance in ASC Subtopic 360-10, *Property, Plant, and Equipment — Overall*, to determine whether an ROU asset is impaired, and if so, the amount of the impairment loss to recognize.

The Group monitors for events or changes in circumstances that require a reassessment of one of its leases. When a reassessment results in the remeasurement of a lease liability, a corresponding adjustment is made to the carrying amount of the corresponding ROU asset unless doing so would reduce the carrying amount of the ROU asset to an amount less than zero. In that case, the amount of the adjustment that would result in a negative ROU asset balance is recorded in profit or loss.

Operating lease ROU assets are presented as operating lease right of use assets on the consolidated balance sheets. The current portion of operating lease liabilities are presented separately on the consolidated balance sheets.

The Group has elected not to recognize ROU assets and lease liabilities for short-term leases that have a lease term of 12 months or less. The Group recognizes the lease payments associated with its short-term leases as an expense on a straight-line basis over the lease term.

l. Foreign currency translation

The Group has operations in South Korea, Switzerland, and Germany. Accounting records in foreign operations are maintained in local currencies and remeasured to the US dollars during the consolidation. Assets and liabilities are translated at exchange rates in effect at the end of the year. Income statement accounts are translated at average rates for the year. Gains or losses from remeasurement of foreign currency financial statements into the US dollars are included in current results of comprehensive income.

m. Revenue recognition

The Group only has revenue from customers. The Group recognizes revenue when it satisfies performance obligations under the terms of its contracts, and control of its products is transferred to its customers in an amount that reflects the consideration the Group expects to receive from its customers in exchange for those products. This process involves identifying the customer contract, determining the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it (a) provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and (b) is separately identified in the contract. The Group considers a performance obligation satisfied once it has transferred control of a good or product to a customer, meaning the customer has the ability to direct the use and obtain the benefit of the good or product.

n. Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Group recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Valuation allowances are established when management determines it is more likely than not that some

(2) Summary of significant accounting policies (cont.)

portion, or all, of the deferred tax assets will not be realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs**.** The Group reports income tax-related interest and penalties relating to uncertain tax positions, if applicable, as a component of income tax expense.

o. Fair value measurements

The Group utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Group determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

— Level 1 inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

— Level 2 inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

— Level 3 inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

The carrying value of cash and cash equivalents, trade and other receivables, inventories, prepaid expenses and other current and financial assets, trade and other payable, short-term borrowing, current operating lease liabilities, and accrued expenses and other current liabilities approximates their fair value due to the short-term nature of these instruments. The carrying amount reported in the consolidated balance sheets for notes payable to related party may differ from fair value since the interest rate is fixed.

p. Compound Financial Instruments

Compound financial instruments are convertible bonds that can be converted into equity instruments at the option of the holder. The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity conversion right and subsequently measured at amortized cost until extinguished on conversion or maturity of the bonds. The equity component is recognized initially on the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts.

q. Accounting pronouncements adopted as of December 31, 2025

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides an exception to fair value measurement for contract assets and contract liabilities related to revenue contracts acquired in a business combination. The ASU requires an entity (acquirer) to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with Topic 606 as if it had originated the contracts. The ASU is effective for the Company for annual and interim periods in fiscal years beginning after December 15, 2023. The ASU is applied to business combinations occurring on or after the effective date. The Group adopted this ASU as of January 1, 2024 and there is no impact on the Group’s consolidated financial statements.

(2) Summary of significant accounting policies (cont.)

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires enhanced disclosure of significant segment expenses on an annual and interim basis. This ASU will be effective for the annual periods beginning the year ended December 31, 2024, and for interim periods beginning January 1, 2025. Early adoption is permitted. Upon adoption, this ASU should be applied retrospectively to all prior periods presented in the financial statements. The Group adopted this ASU as of January 1, 2025 and there is not impact on the Group's consolidated financial statements.

r. Accounting pronouncements issued, but not adopted as of December 31, 2025

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements — Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The ASU modifies the disclosure or presentation requirements of a variety of Topics in the Codification to align with the SEC's regulations. The ASU also makes those requirements applicable to entities that were not previously subject to the SEC's requirements. The ASU is effective for the Company two years after the effective date to remove the related disclosure from Regulation S-X or S-K. As of the date these financial statements have been made available for issuance, the SEC has not yet removed any related disclosure. The Group does not expect the adoption of ASU 2023-06 to have a material effect on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This ASU will be effective for the annual periods beginning the year ended December 31, 2026. Early adoption is permitted. Upon adoption, this ASU can be applied prospectively or retrospectively. The Group is currently evaluating the impact this ASU will have on the Group's consolidated financial statements.

(3) Critical accounting estimates and assumptions

The preparation of consolidated financial statements requires the Group to make estimates and assumptions concerning the future. Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

Income taxes

The Group's taxable income generated from these operations are subject to income taxes based on tax laws and interpretations of tax authorities in numerous jurisdictions. There are many transactions and calculations during the ordinary course of business for which the ultimate tax determination is uncertain.

Deferred tax assets are recognized for deductible temporary differences and unused tax losses to the extent that it is probable that taxable profit will be available against which the temporary differences and the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits, together with future tax planning strategies.

(3) Critical accounting estimates and assumptions (cont.)

Business combinations

Business combinations are initially accounted for on a provisional basis. The fair value of assets acquired, liabilities and contingent liabilities assumed are initially estimated by the Parent taking into consideration all available information at the reporting date. Fair value adjustments on the finalization of the business combination accounting is retrospective, where applicable, to the period the combination occurred and may have an impact on the assets and liabilities, depreciation and amortization reported.

Patent technology

Patent technology is recognized in Intangible assets on the consolidated balance sheets. The Group considers both qualitative and quantitative factors when determining whether the patent technology may be impaired. For the purposes of assessing impairment, the Group follows its accounting policy disclosed in Note 2. In assessing whether there is any indication that the patent technology may be impaired, the Group considers, at minimum, the following indications:

External sources of information

- there are observable indications that the patent technology's value has declined during the period significantly more than would be expected as a result of the passage of time or normal use.
- significant changes with an adverse effect on the Group have taken place during the period, or will take place in the near future, in the technological, market, economic or legal environment in which the entity operates or in the market to which an asset is dedicated.
- market interest rates or other market rates of return on investments have increased during the period, and those increases are likely to affect the discount rate used in calculating an asset's value in use and decrease the asset's recoverable amount materially.
- the carrying amount of the net assets of the entity is more than its market capitalization.

Internal sources of information

- evidence is available of obsolescence or physical damage of the patent technology.
- significant changes with an adverse effect on the entity have taken place during the period, or are expected to take place in the near future, in the extent to which, or manner in which, the patent technology is used or is expected to be used. These changes include the patent technology becoming idle, plans to discontinue or restructure the operation to which the patent technology belongs, and plans to dispose of the patent technology before the previously expected date.
- evidence is available from internal reporting that indicates that the economic performance of the patent technology is, or will be, worse than expected.

(4) Financial risk management

The Group is exposed to various financial risks such as market risk (exchange risk, interest rate risk), credit risk and liquidity risk due to various activities. The Group's overall risk management policy focuses on volatility in the financial markets and focuses on minimizing any negative impact on financial performance. Risk management is conducted under the supervision of the finance department according to the policy approved by the Board of Directors. The finance department identifies, evaluates and manages financial risks in close cooperation with the

(4) Financial risk management (cont.)

sales departments. The Board of Directors provides written policies on overall risk management principles and specific areas such as foreign exchange risk, interest rate risk, credit risk, use of derivative and non-derivative financial instruments, and investments in excess of liquidity.

Market risk management

Market risk is the risk of possible losses which arise from the changes of market factors, such as interest rate, stock price, foreign exchange rate, commodity value and other market factors related to the fair value or future cash flows of the financial instruments, such as securities, derivatives and others.

a. Currency risk

The functional currency of the foreign subsidiary's operations is the local currency. Therefore, for purposes of the consolidated financial statements, the results of foreign operations are translated from the local currency into U.S. dollars. Local currency assets and liabilities are translated at the rates of exchange on the balance sheet date, and local currency revenues and expenses are translated at average rates of exchange during the period. Resulting translation gains or losses are included in the accompanying consolidated financial statements as a component of accumulated other comprehensive loss.

b. Interest rate risk

Interest rate risk refers to the risk that interest income and interest expenses arising from deposits or borrowings will fluctuate due to changes in market interest rates in the future, which mainly arises from deposits and borrowings with floating interest rates. The goal of interest rate risk management is to maximize corporate value by minimizing uncertainty caused by interest rate fluctuations.

As of the end of the reporting period, there are no financial instruments subject to a variable interest rate.

c. Price risk

Price risk is the risk that the fair value of a financial instrument or future cash flows will change due to changes in market prices other than interest rate or foreign exchange rate. As of the end of the reporting period, the Group is not exposed to commodity price risk. Investments in financial instruments are made on a non-recurring basis according to management's judgment.

Credit risk management

Credit risk is the risk of possible losses in an asset portfolio in the events of counterparty's default, breach of contract and deterioration in the credit quality of the counterparty. For the risk management reporting purposes, the Group manages the credit risk systematically and pursues value maximization and continuous growth of the Group by efficient resource allocation and monitoring non-performing loans. In order to reduce the risks that may occur in transactions with financial institutions, such as cash and cash equivalents and various deposits, the Group conducts transactions only with financial institutions with high creditworthiness. As of December 31, 2025, the Group believes that there are low signs of material default, and the maximum exposure to credit risk as of December 31, 2025 is equal to the book value of financial instruments (excluding cash).

Liquidity risk management

The Group constantly monitors its liquidity positions to ensure that no borrowing limits or commitments are breached to meet operating capital needs. In estimating liquidity, we also take into account external laws or legal requirements, such as the group's financing plan, compliance with agreements, internal target financial ratios and currency restrictions.

(4) Financial risk management (cont.)

The Group's liquidity risk analysis details as of December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025				
			Remaining maturity		
	Book Value	Cashflow by contract	Within a year	1 year to 3 years	More than 3 years
Financial liabilities	$ 4,343,276	$ 4,388,129	$ 4,388,129	$ —	$ —
Other Payables	8,787,983	8,800,013	8,800,013	—	—
Lease liabilities	59,512	66,555	51,223	15,332	—
Total	$ 13,190,771	$ 13,254,697	$ 13,239,365	$ 15,332	$ —

	December 31, 2024				
			Remaining maturity		
	Book Value	Cashflow by contract	Within a year	1 year to 3 years	More than 3 years
Borrowings	$ 2,297,411	$ 2,423,008	$ 1,840,406	$ 35,048	$ 547,555
Other Payables	1,538,643	1,538,643	1,538,643	—	—
Lease liabilities	78,113	93,537	48,980	44,558	—
Total	$ 3,914,167	$ 4,055,188	$ 3,428,028	$ 79,605	$ 547,555

Capital risk management

Capital includes issued capital, share premium and all other equity reserves attributable to the equity holders of the Group. The primary objective of the Group's capital management is to maximize the shareholder value.

The Group manages its capital structure and makes adjustments in light of changes in economic conditions and the requirements of the financial covenants. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group uses the debt ratio as a capital management indicator. This ratio is calculated by dividing total liabilities by total equity, and total liabilities and total equity are calculated based on the amounts in the Group's consolidated financial statements.

The group's debt ratio as of December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025	December 31, 2024
Net borrowings (A)		
Borrowings	$ 6,873,451	$ 2,297,411
Lease liabilities	59,512	78,113
Less: cash and cash equivalents	(1,700,273)	(341,543)
	5,232,690	2,033,981
Total equity (B)	127,037,403	143,208,215
Net borrowings & Total equity (A+B)	132,270,093	145,242,196
Debt ratio (A/B)	4.0%	1.4%

(5) Fair value measurements

Book value and fair value of financial instruments

The difference between the carrying amount and fair value of the Group's financial assets and liabilities as of December 31, 2025 and December 31, 2024 are insignificant.

Fair value hierarchy

All financial assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

Fair values of the Group's financial assets and liabilities as of December 31, 2025 and December 31, 2024, which are accounted as amortized cost, are categorized as Level 3.

Recurring transfer between levels of the fair value hierarchy

Fair value hierarchy classifications of the financial instruments that are measured at fair value level 3 as at December 31, 2025 is as follows (Null at December 31, 2024):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Recurring fair value measurements				
Financial liabilities at fair value through profit or loss	$ —	$ —	$ 2,530,176	$ 2,530,176

Valuation Techniques and the Inputs

Valuation techniques and inputs used in the recurring and non-recurring fair value measurements categorized within Level 3 of the fair value hierarchy as at December 31, 2025 is as follows (Null at December 31, 2024):

The Group did not change any valuation techniques in determining the fair value, which is categorized within Level 3 of the fair value hierarchy.

	December 31, 2025			
	Fair Value	Level	Valuation Techniques	Inputs
Financial liabilities at fair value through profit or loss	$ 2,530,176	3	Tsiveriotis-Fernandes model	Stock Volatility, Risk-free rate

(6) Financial instruments by category

The carrying value of financial instruments category as of December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025			
Financial assets:	**Financial assets at amortized cost**	**Financial liabilities at fair value**	**Financial liabilities at amortized cost**	**Total**
Cash and cash equivalents	$ 1,700,273	$ —	$ —	$ 1,700,273
Trade and other receivables	392,096	—	—	392,096
Other current financial assets	262,722	—	—	262,722
Other non-current financial assets	578,917	—	—	578,917
Financial liabilities:				
Trade and other payables	—	—	7,830,104	7,830,104
Accrued expenses	—	—	957,879	957,879
Current financial liabilities	—	—	4,343,276	4,343,276
Derivative liabilities	—	2,530,176	—	2,530,176

	December 31, 2024			
Financial assets:	**Financial assets at amortized cost**	**Financial liabilities at fair value**	**Financial liabilities at amortized cost**	**Total**
Cash and cash equivalents	$ 341,543	$ —	$ —	$ 341,543
Trade and other receivables	933,824	—	—	933,824
Other current financial assets	54,422	—	—	54,422
Other non-current financial assets	329,252	—	—	329,252
Financial liabilities:				
Trade and other payables	—	—	1,078,760	1,078,760
Accrued expenses	—	—	459,883	459,883
Borrowings	—	—	2,297,411	2,297,411

Net gains or losses by financial instrument category for the years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025	**For the year ended December 31, 2024**
Amortized cost:		
Interest income	$ 63,883	$ 21,294
Foreign exchange gains	48,472	37,419
Gains on foreign currency translation	46,018	38,416
Interest expense	(506,196)	(51,335)
Losses on foreign currrency transaction	(73,517)	(207,430)
Losses on foreign currrency translation	(74,079)	(2,159)
Financial assets measured at fair value through profit and loss:		
Gains on change in fair value of financial liabilities	4,216,055	—
Losses on change in fair value of financial liabilities	(5,652,376)	(54,257)

(7) Cash and cash equivalents

The Group considers all money market funds and highly liquid financial instruments with original maturities of three months or less to be cash equivalents.

	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 1,700,273	$ 341,543

(8) Trade and other receivables, net

All trade receivables are recorded at the invoiced amount and do not bear interest. Amounts collected on trade receivables are included in net cash provided by operating activities in the statements of cash flows. The Group does not have any off-balance sheet credit exposure related to its customers.

	December 31, 2025	December 31, 2024
Trade receivables	$ 381,674	$ 972,036
Less: Allowance for credit losses	(62,370)	(67,580)
Net trade receivables	319,304	904,456
Other receivables	72,792	29,368
Total	$ 392,096	$ 933,824

(9) Inventories, net

Inventories consisted of the following as of December 31, 2025 and December 31, 2024:

	December 31, 2025	December 31, 2024
Merchandised goods	$ 215,971	$ 949,724
Less inventory reserves	(19,539)	(27,617)
	$ 196,432	$ 922,107

(10) Other financial assets

Details of other financial assets as of December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025		December 31, 2024	
	Current	Non-current	Current	Non-current
Leasehold guarantee deposits	$ 55,753	$ 22,612	$ 54,422	$ 21,669
Other deposits	—	1,115	—	1,088
Loan	206,969	555,190	—	306,494
Total	$ 262,722	$ 578,917	$ 54,422	$ 329,252

(11) Other assets

Details of other assets as of December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025		December 31, 2024	
	Current	Non-current	Current	Non-current
Prepayments	$ 35,614	$ —	$ 53,908	$ —
Prepaid expenses	227,935	—	20,646	—
Total	$ 263,548	$ —	$ 74,555	$ —

(12) Equity method investment

Details of investment under the equity method are as follows:

			December 31, 2025		December 31, 2024	
	Location	Main business	Ownership	Book value	Ownership	Book value
Taction Co., LTD. .	Korea	Software development	33.3%	$ —	33.3%	$ —

The summarized financial information of investment under the equity method as of the closing date and for the current period is as follows:

	As of and for the year ended December 31, 2025				
	Assets	Liabilities	Revenue	Net loss	Comprehensive loss
Taction Co., LTD.	$ 48,123	$ 21,203	$ —	$ (12,958)	$ (12,958)

There is no equity method valuation applied on investments in associate for the years ended December 31, 2025 or 2024.

Taction Co., Ltd. was incorporated to engage in software development and IT consulting. As no practical plan to generate revenue and maintain going-concern basis in the foreseeable future was provided, the Parent recognized impairment loss amounting to acquisition cost.

(13) Equipment and vehicles, net

Equipment and vehicles consist as of December 31, 2025 and December 31, 2024:

	December 31, 2025	December 31, 2024
Office equipment	$ 35,138	$ 26,912
Tools and instruments	23,242	22,687
Machinery and equipment	22,795	22,251
Facilities	369,450	210,613
Vehicles	9,604	9,375
	460,229	291,838
Less accumulated depreciation	(291,099)	(289,504)
Equipment and vehicles, net	$ 169,130	$ 2,334

(14) Goodwill

Changes of goodwill for the years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025				
	Beginning	Business combination	Impairment loss	Effects of changes in exchange rate	Ending
Goodwill	$ 24,354,066	$ —	$ —	$ 595,740	$ 24,949,806

	For the year ended December 31, 2024				
	Beginning	Business combination	Impairment loss	Effects of changes in exchange rate	Ending
Goodwill	$ 27,765,222	$ —	$ —	$ (3,411,156)	$ 24,354,066

(15) Intangible assets, net

The acquired intangible assets, all of which are being amortized, have an average useful life of approximately 20 years. Intangible assets consist of the following as of December 31, 2025 and December 31, 2024.

	As of December 31, 2025			
	Average useful life	Gross carrying amount	Accumulated amortization	Net carrying amount
Technology license	20 years	$ 100,221	$ 94,586	$ 5,635
Customer relationship	20 years	593,273	355,964	237,309
Patent technology	20 years	168,845,947	26,626,257	142,219,690
		$ 169,539,441	$ 27,076,807	$ 142,462,634

	As of December 31, 2024			
	Average useful life	Gross carrying amount	Accumulated amortization	Net carrying amount
Technology license	20 years	$ 97,828	$ 78,439	$ 19,389
Customer relationship	20 years	579,107	231,643	347,464
Patent technology	20 years	164,814,319	17,124,320	147,690,000
		$ 165,491,254	$ 17,434,402	$ 148,056,852

Accumulated amortization expense for intangible assets is $9,298,838 and $9,630,728 for the years ended December 31, 2025 and 2024, respectively.

(16) Short-term borrowings and short-term corporate bonds

The Group has a loan agreement with BCM Europe AG and as of December 31, 2025, the outstanding balance was $1,062,091 (3.00% interest rate at December 31, 2025), which matures in 2026.

The Group has multiple loan agreements with an individual and as of December 31, 2025, the outstanding balance was $1,261,380 (0% interest rate at December 31, 2025), which mature various dates in 2026.

The Group has a loan agreement with Duksung Co., Ltd and as of December 31, 2025, the outstanding balance was $650,000 (7.00% interest rate at December 31, 2025), which matures in October 2026.

The Group has a loan agreement with BGLSI and as of December 31, 2025, the outstanding balance was $1,218,000 (0% interest rate at December 31, 2025), which matures in 2026.

The Group has multiple loan agreements with an individual and as of December 31, 2025, the outstanding balance was $105,000 (0% interest rate at December 31, 2025), which mature various dates in 2026.

The Group has a convertible note agreement with White Lion Capital and as of December 31, 2025, the outstanding balance was $46,804 (5.00% interest rate at December 31, 2025), which mature various dates in 2026.

The Group has a loan agreement with BCM Europe AG and as of December 31, 2024, the outstanding balance was $600,000 (3.00% interest rate at December 31, 2024).

The Group has a loan agreement with BCM Europe AG and as of December 31, 2024, the outstanding balance was $260,000 (3.00% interest rate at December 31, 2024).

The Group has a loan agreement with OSR Holdings, Inc. (f/k/a Bellevue Life Sciences Acquisition Corp.) and as of December 31, 2024, the outstanding balance was $300,000 (3.96% interest rate at December 31, 2024), which matures in October 2025.

(16) Short-term borrowings and short-term corporate bonds (cont.)

The Group has a loan agreement with an individual and as of December 31, 2024, the outstanding balance was $50,000 (7.00% interest rate at December 31, 2024), which matures in December 2025.

The Group has multiple loan agreements with an individual and as of December 31, 2024, the outstanding balance was $408,163 (0% interest rate at December 31, 2024), which mature various dates in 2025.

Details of convertible note agreement with White Lion Capital issued on May 6, 2025 and outstanding as of December 31, 2025 are as follows:

Classification	Details
Par value	USD 1,110,000
Stated interest rate	5%
Guaranteed yield upon conversion	—
Exercise price adjustments	Issuance of new shares for consideration (paid-in capital increase), stock dividends and capitalization of reserves, mergers, capital reduction, stock split and consolidation, reduction of capital and stock consolidation, etc.
Conversion condition	Variable Conversion Price. At any time, and from time to time, the Holder may utilize the Variable Conversion Price for conversions of this Note into Common Stock. The Variable Conversion Price shall be a rate per share equal to 95% multiplied by the Market Price (as defined herein) (representing a discount rate of 5%) (the "Variable Conversion Price"). "Market Price" means the lowest daily VWAP of the Common Stock during the fifteen (15) Trading Day period ending on the latest complete Trading Day prior to the Conversion Date. "Trading Price" means the lowest volume-weighted average daily price as reported on the principal securities exchange or trading market where such security is quoted, listed or traded or, if no trading price of such security is available in any of the foregoing manners, the average of the trading prices of any market makers for such security that are listed in the "pink sheets" by the National Quotation Bureau, Inc. "Trading Day" shall mean any day on which the Common Stock is tradable for any period on the NASDAQ stock market or on the principal securities exchange or other securities market on which the Common Stock is then being quoted or traded.

The conversion right on the above convertible bonds is classified as other financial liabilities.

(17) Long-term debt

The Group has long-term debt agreements with individuals and as of December 31, 2024, the total outstanding balance was $497,615 (4.6% interest rate at December 31, 2024), which matures in 2030.

(18) Leases

The Group has operating leases for properties, including manufacturing plants and offices.

Leases have remaining lease terms of longer than 12 months, some of which include options to extend the lease and some include options to terminate the lease before term. The Group does not assume renewals in our determination of the lease term, unless the renewals are deemed to be reasonably certain as of the commencement date of the lease. Lease agreements do not contain any material residual value guarantees or material variable lease payments.

(18) Leases (cont.)

The Group has entered into various operating leases with a lease term of 12 months or less. The Group has elected to not capitalize leases with a lease term of 12 months or less.

As the rate implicit in most of our leases is not readily determinable, the Group uses its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of the lease payments.

The lease expense is included in rent expense of Selling, general and administrative expenses in the consolidated statements of operation and the amounts for the years ended December 31, 2025 and 2024, are as follows:

	Years ended December 31	
	2025	2024
Operating lease expense	$ 54,844	$ 73,681

Supplemental balance sheet information related to leases is as follows:

	As of December 31	
	2025	2024
Operating leases:		
Total operating lease right-of-use assets	$ 60,425	$ 78,484
Current operating lease liabilities	$ 46,961	$ 44,741
Non-current operating lease liabilities	12,551	33,372
Total operating lease liabilities	$ 59,512	$ 78,113
Weighted-average remaining lease term		
Operating leases	16.3 months	24.1 months
Weighted-average discount rate		
Operating leases	16.6%	17.9%

The following table summarizes maturities of lease liabilities in undiscounted basis as of December 31, 2025

2026	$ 51,223
2027	15,332
Total undiscounted lease payments	66,555
Less imputed interest	(7,043)
Total lease liabilities	$ 59,512

Other information related to leases as of December 31, 2025 and 2024 were as follows:

	2025	2024
Supplemental cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Cash used in operations for operating leases	$ 54,844	$ 70,734
ROU assets obtained in exchange for lease obligations:		
Operating leases	22,097	—
Reductions to ROU assets resulting from reductions to lease obligations:		
Operating leases	—	7,532

(19) Post-employment benefits

The Group maintains a defined contribution retirement benefit plan for its employees. The Group is obligated to pay fixed contributions to an independent fund, and the amount of future retirement benefits to be paid to employees is determined by the contributions made to the fund, etc., and the investment income generated from those contributions. Plan assets are managed independently from the Group's assets in a fund managed by a trustee.

Darnatein's pension plan has converted from the DB type to the DC type at the end of March 31, 2017, and is obligated to pay severance payment as DB type which incurred before the March 31, 2017.

Meanwhile, expenses recognized by the Group in relation to the defined contribution retirement benefit plan for the years ended December 31, 2025 and 2024 are $405,201 and $122,035, respectively.

(20) Related party transactions

As of December 31, 2025, the Group's related parties are as follows:

Type	Related parties
Ultimate parent entity	Bellevue Capital Management LLC
Major shareholder of the Parent	BCM Europe AG
Subsidiaries	RMC, VAXIMM, Darnatein, OSR Holdings Co., Ltd.
Associates	Taction Co., Ltd.
Other related parties	Bellevue Global Life Sciences Investors LLC
	Bellevue Global Life Sciences Acquisition Corp

There are no sales and procurement transactions and treasury transactions with related parties for the years ended December 31, 2025 and 2024.

Details of receivables and payables from related party transactions as at December 31, 2025 and December 31, 2024 are as follows:

	December 31, 2025	
	Related parties	Short-term borrowings
BCM Europe AG.	Major shareholder of the Parent	$ 1,062,091
Key management.	Individuals	1,261,380

	December 31, 2024	
	Related parties	Short-term borrowings
BCM Europe AG.	Major shareholder of Parent	$ 860,000
Bellevue Life Sciences Acquisition Corp.	Other related parties	300,000
Key management.	Individuals	639,796

Compensations paid or accrued to key management of the Parent for the years ended December 31, 2025 and 2024 are as follows:

	For the years ended	
	December 31, 2025	December 31, 2024
Salaries	$ 589,220	$ 344,693

(20) Related party transactions (cont.)

The Group's key management includes registered directors who have important authority and responsibility for planning, operation, and control of the Group's business activities.

No collateral or guarantee were provided for related parties and were received from related parties as of December 31, 2025 and December 31, 2024.

(21) Administrative expenses

Details of administrative expenses for the years ended December 31, 2025 and 2024 are as follows:

	For the year ended December 31, 2025	For the year ended December 31, 2024
Salary	$ 1,470,776	$ 918,786
Retirement payment	405,201	122,035
Employee benefits	95,383	53,793
Travel expenses	41,846	56,108
Entertainment expenses	43,675	40,589
Communication cost	1,908	2,222
Tax and due	34,495	23,478
Depreciation cost	7,269	60,535
Amortization of intangible assets	9,298,838	9,630,728
Rental cost	97,527	113,472
Repair fee	3,364	140
Insurance cost	16,962	13,170
Vehicle maintenance fee	33,393	33,640
Allowance for expected credit losses	42,257	57,706
Research and development expenses	318,446	161,155
Transportation cost	2,080	3,102
Training cost	1,215	—
Publishing fee	953	375
Office supplies fee	237	294
Consumable cost	11,685	22,507
Commisions and professional fee	6,984,086	1,167,215
Building management fee	17,312	19,608
Advertising expenses	—	2,775
Total	$ 18,928,908	$ 12,503,433

(22) Income taxes

A summary of income tax benefit for the years ended December 31, 2025 and 2024, is as follows:

	Year ended December 31	
	2025	2024
Current:		
Primary jurisdiction (Republic of Korea)	$ 1,829,820	$ 1,563,768
Foreign	—	—
	1,829,820	1,563,768
Deferred:		
Primary jurisdiction (Republic of Korea)	—	—
Foreign	—	—
	—	—
Income tax benefits	$ 1,829,820	$ 1,563,768

There is no deferred tax recognized in other than net income for the years ended December 31, 2025 and 2024.

The provision for income taxes differs from that computed by applying statutory rates to loss before income taxes. Explanations of the relationship between income tax benefits and accounting loss for the years ended December 31, 2025 and 2024 are as follows:

	2025	2024
Loss before income taxes	$ (28,888,361)	$ (11,892,678)
Income tax based on statutory tax rate	5,806,050	2,493,699
Adjustments:		
Tax credit	—	(1,284)
Special tax for rural areas	—	198
Unrecognized changes in temporary differences	(2,110,974)	(449,656)
Others (changes in effective tax rate)	(1,865,256)	(479,189)
Income tax benefits	$ 1,829,820	$ 1,563,768

In assessing the reliability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon these considerations as of December 31, 2025 and 2024, the Company had a full valuation allowance for the net deferred tax assets on one of its Asian subsidiaries and certain of its European subsidiaries. Also, as of December 31, 2025 and 2024, the Company had a partial valuation allowance offsetting certain deferred tax assets of another one of its Asian subsidiaries. Management believes that it is more likely than not that the Company will realize the benefits of the remaining deductible differences, net of valuation allowances, at December 31, 2025.

(22) Income taxes (cont.)

Items that result in deferred tax assets and liabilities at December 31, 2025 and 2024 are as follows:

	Year ended December 31	
	2025	2024
Deferred tax assets:		
Account payable (severance)	$ 35,818	$ 54,400
Interest payable	80,894	69,942
Amortization of intangible assets	511,742	386,589
Net operating loss carryforward	1,204,917	627,897
Other	(220,736)	(202,597)
Gross Deferred tax assets	1,612,635	936,231
Valuation allowance	(1,412,120)	(844,130)
Total deferred tax assets	200,515	92,101
Deferred tax liabilities:		
PPA effect	(27,021,305)	(28,035,508)
Total deferred tax liabilities	(27,021,305)	(28,035,508)
Net deferred tax liabilities	$ (26,820,790)	$ (27,943,407)

The Company did not have any material uncertain tax positions, which should be recognized in the consolidated financial statements as of December 31, 2025. In addition, the Company did not have any unrecognized tax benefits, which, if recognized, would affect the effective tax rate for the years then ended.

(23) Loss per share

Basic loss per share for the years ended December 31, 2025 and 2024 are calculated as follows:

	For the year ended December 31	
(The United States Dollar in unit and number of shares)	2025	2024
Net loss (A)	$ (18,010,899)	$ (10,328,910)
Weighted average number of ordinary shares outstanding (B)	19,515,034	2,155,000
Basic loss per ordinary share (A/B)	$ (0.92)	$ (4.79)

Weighted average number of ordinary shares outstanding for the years ended December 31, 2025 and 2024 are calculated as follows:

	For the year ended December 31	
(Number of shares)	2025	2024
Ordinary shares outstanding at the beginning	2,155,000	2,155,000
Changes due to business combination	15,057,959	—
Shares issued due to ELOC	719,100	—
Shares issued due to Convertible note conversion	1,129,663	—
Shares issued due to Warrant conversion	453,312	—
Weighted average number of ordinary shares outstanding	19,515,034	2,155,000

(23) Loss per share (cont.)

Diluted loss per share for the years ended December 31, 2025 and 2024 are calculated as follows:

	For the year ended December 31	
(The United States Dollar in unit and number of shares)	**2025**	**2024**
Net loss (A)	$ (17,997,745)	$ (10,328,910)
Weighted average number of ordinary shares outstanding (B)	22,560,443	2,155,000
Diluted loss per ordinary share (A/B)	$ (0.80)	$ (4.79)

Weighted average number of ordinary shares including diluted effects outstanding for the years ended December 31, 2025 and 2024 are calculated as follows:

	For the year ended December 31	
(Number of shares)	**2025**	**2024**
Weighted average number of ordinary shares outstanding beginning	19,515,034	2,155,000
Diluted effect) Convertible bonds conversion effect	444,856	—
Diluted effect) Warrant conversion effect	2,600,553	—
Weighted average number of ordinary shares outstanding	22,560,443	2,155,000

(24) Commitment and contingencies

The Group has no pending litigation cases arising in the ordinary course of business as of December 31, 2025 and December 31, 2024. OSRK has entered into various contractual commitments related to the acquisition of VAXIMM including a future financial obligation of CHF 28,898 underlying as of December 31, 2025. Meanwhile, both parties have agreed to remove section 6.1.3 of the license agreement that states that in the event of the Parent's sale to a third party, the Licensor shall reimburse the Licensee for reasonable costs and expenses incurred in the preparation, submission, maintenance, prosecution, and enforcement process.

(25) Segment reporting

The Group operates in one operating segment. Operating segments are defined as components of an enterprise about which separate financial information is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and assessing performance. The Group's CODM role is fulfilled by the Executive Leadership Team, who allocates resources and assesses performance based upon consolidated financial information. The geographic segments for the long-lived assets and ROU assets are disclosed below.

There are no external customers that account for more than 10% of sales for the reporting period.

(26) Subsequent events

The Group has evaluated subsequent events from the balance sheet date through March 27, 2026, the date at which the consolidated financial statements were available to be issued and determined that there are no other items to disclose, except the following:

(1) To be updated regarding Woori IO

On January 26, 2026, OSRK completed a comprehensive share exchange with Woori IO Co., Ltd. ("Woori IO") pursuant to a Share Exchange Agreement dated October 13, 2025. As a result of the share exchange, Woori IO became a wholly-owned subsidiary of the Group. In connection with the transaction, OSRK issued 84,338 shares of registered common stock (par value of KRW 5,000 per share) as newly issued shares.

(26) Subsequent events (cont.)

Woori IO is a medical device company engaged in the development of a non-invasive blood glucose monitoring device based on near-infrared spectroscopy ("NIRS") technology. Woori IO is currently in a technology development collaboration with Samsung Electronics Co., Ltd.

Following the completion of the acquisition of Woori IO, the Group is evaluating potential strategic collaboration initiatives between Woori IO and the Group's existing medical device distribution subsidiary, RMC.

In addition, pursuant to agreements with Woori IO and its management, OSRK advanced loans of approximately $0.4 million (KRW 640 million) during the year ended December 31, 2025.

(2) Joinder Agreement for Share Exchange with Non-Participating Shareholders

Pursuant to the Business Combination Agreement, the Group had previously entered into a joinder agreement with certain non-participating shareholders on February 10, 2025, which contemplated a share exchange arrangement. Under this agreement, the non-participating shareholders were entitled to transfer their shares of OSR Holdings Co., Ltd. ("OSRK") to OSRH in exchange for shares of OSRH upon the occurrence of specified conditions.

Subsequent to the reporting period, certain non-participating shareholders exercised their put options, and an aggregate of 410,721 shares of OSRK were transferred in exchange for 5,323,986 shares of OSRH. The effective date of the share exchange was January 30, 2026.