
RISK FACTORS

You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our financial position and need for additional capital; (ii) risks relating to development, clinical trials and regulatory approval of our drug candidates; (iii) risks relating to commercialization of our drug candidates; (iv) risks relating to our intellectual property rights; (v) risks relating to our reliance on third parties; (vi) risks relating to our operations; (vii) risks relating to doing business in China; and (viii) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant operating losses since our inception, and may continue to incur operating losses for the foreseeable future and may never become profitable. You may lose substantially all of [REDACTED] in us if our business fails.

Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable.

We have incurred significant expenses related to the research and development of our product candidates in the past. In 2018 and 2019, our research and development expenses amounted to RMB40.7 million and RMB99.5 million, respectively. In addition to our significant research and development expenses, we also incurred selling expenses and administrative expenses associated with our operations. As a result, we recorded net losses of RMB209.4 million and RMB1,325.5 million in the period ended December 31, 2018 and the year ended December 31, 2019, respectively. Excluding the effect of fair value loss of financial liabilities at FVTPL and share-based payment expenses, our non-IFRS adjusted net losses would be RMB47.0 million and RMB82.4 million for the same periods, respectively. See “Financial Information—Non-IFRS Measure.” The research and development of our drug

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candidates involves a lengthy and expensive process with an uncertain outcome. If the research and development of any of our drug candidates is not successful, our profitability and business prospects may be materially and adversely affected. Such failure may further impact [REDACTED] perception of our potential value and could impair our ability to expand our business or continue our operations.

We expect to continue to incur losses for the foreseeable future as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our commercialization and sales workforce in anticipation of the future roll-out of our late-stage drug candidates. In addition, we will continue to incur costs associated with operating as a public company going through a period of rapid growth. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or, if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. As a result, you may lose substantially all of your [REDACTED] in us if our business fails.

We had net operating cash outflows during the Track Record Period.

We had net cash used in operating activities of RMB43.4 million and RMB108.1 million in 2018 and 2019, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default in our payment obligations and may not be able to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need to raise additional capital to meet our operating cash requirements, and financing may not be available on terms acceptable to us, or at all.

Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the equity financing. Although we generated revenue from the limited sales of OT-401 under the Boao Pilot Program and have started marketing Ou Qin and brimonidine tartrate eye drop, and are conducting this [REDACTED], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. Our cash operating costs mainly consist of upfront and milestone payments, agency and consulting fees, staff costs and clinical trial expenses. Upfront and milestone payments primarily include in-license fees related to our in-licensed drug candidates, which, during the Track Record Period, included

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payments made to EyePoint, Nicox, Senju and GTS. Agency and consulting fees primarily include fees paid for CMC and regulatory affairs related to drug registration. Staff costs primarily include (i) share-based compensation expenses and (ii) salaries and welfare for research and development, sales and marketing and administrative personnel. Clinical trial expenses primarily include fees paid to CROs. We expect our cash operating costs in 2020 will increase significantly in light of our expanding pipeline and clinical trial programs. The estimated cash operating costs reflect current expectations of our business operations and may be subject to material changes. Our existing cash, cash equivalents and short-term investments may not be sufficient to enable us to complete all development or commercially launch of our current drug candidates for the currently anticipated indications and to invest in additional drug candidates. If the financial resources available to us after the [REDACTED] are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope and costs of the clinical trials of our drug candidates, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and costs of regulatory approvals of our drug candidates;
- the number and characteristics of drug candidates that we may in-license and develop;
- the amount and timing of the milestone and royalty payments that we may pay our licensing partners;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the selling expenses associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other pipeline drug candidates;

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- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities; and
- our headcount growth and associated costs.

It is uncertain whether financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects may be materially and adversely affected.

Our results of operations, financial condition and prospects may be adversely affected by fair-value changes in our Preferred Shares and the Share Purchase Option at fair value through profit or loss.

During the Track Record Period, we issued the Preferred Shares and the Share Purchase Option, which we recognized as financial liabilities at fair value through profit or loss on our consolidated statements of financial position. We recorded total deficits of RMB777.3 million and RMB2,068.5 million as of December 31, 2018 and 2019, respectively, primarily due to such financial liabilities. In 2018 and 2019, we realized net fair-value losses of financial liabilities at fair value through profit or loss of RMB158.7 million and RMB1,196.2 million, respectively. The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. For more details, see “Financial Information—Critical Accounting Policies and Estimates—Fair Value of Financial Assets and Financial Liabilities at Fair Value Through Profit or Loss.” As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect actual fair value of these derivative financial liabilities and result in significant fluctuations in profit or loss from year to year. The Share Purchase Option was exercised on September 18, 2019. The Preferred Shares will automatically convert into Shares upon [REDACTED], at which time we expect to record them as equity and, accordingly, turn into a net asset position. However, we do expect to recognize additional loss from the fair-value changes of financial liabilities after December 31, 2019 to the [REDACTED], and we may still retain accumulated losses due to the fair-value loss of our Preferred Shares prior to the [REDACTED].

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

The Company was set up in the Cayman Islands on February 27, 2018. Our operations to date have focused on organizing and staffing our Company, business planning, raising capital, establishing our ophthalmic drug portfolio, conducting preclinical studies and clinical trials of our drug candidates, developing manufacturing capabilities and building a sales network. Most of our portfolio drugs are still at various stages of development. We have not yet successfully obtained regulatory approval to market any drug candidates from our development pipeline, and have not manufactured or commercialized any such drug candidates. During the Track Record Period, we only derived a small amount of revenue from the limited sales of OT-401, our Core Product, under the Boao Pilot Program. See “Business—Advanced-Stage Drug

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Candidates—OT-401 (YUTIQ)—Boao Pilot Program.” We have only recently commenced commercial sales of two approved drugs with respect to which we had acquired rights from a partner. Our limited operating history, particularly in light of the rapidly evolving biopharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential [REDACTED] to lose substantially all of their [REDACTED] in our business.

We had net liabilities during the Track Record Period.

As of December 31, 2018 and December 31, 2019, we had net liabilities of RMB777.3 million and RMB2,068.5 million, respectively. Our deficit position was in part due to the accounting treatment for our Preferred Shares and Share Purchase Option, which are classified as financial liabilities measured at FVTPL. The Share Purchase Option was exercised on September 18, 2019. The Preferred Shares will automatically convert into Shares upon [REDACTED], at which time we expect to record them as equity and, accordingly, turn into a net asset position.

Our results of operations, financial conditions, and prospects may be adversely affected by changes in fair value of other financial assets.

During the Track Record Period, we had certain financial assets at fair value through profit or loss, primarily consisting of wealth management products we purchased by using our free cash. These wealth management products comprised risk-free or low-risk financial products with short-term or flexible redemption options issued by commercial banks or reputable financial institutions in China and the United States. The fair value of these financial products was determined by discounted cash flow, which was estimated based on expected return, and discounted at a rate that reflects the risk of underlying investments. The financial assets at fair value through profit or loss are stated at fair value, and net changes in their fair value are recorded as other gains or losses, and therefore directly affect our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any losses from changes in fair value of other financial assets in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our growth strategies focus on identifying, developing and commercializing first- or best-in-class ophthalmic therapies. For more information, see “Business—Our Strategies.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to identify and develop promising drug candidates in the highly competitive global and Chinese

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biopharmaceutical market, effective coordination and integration of new facilities and new teams that we may develop, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

A significant portion of our assets is denominated in foreign currencies.

Certain of our time deposits, bank balances and cash, other financial assets and trade and other payables are denominated in foreign currencies, and are exposed to foreign currency risk. We recorded net foreign exchange losses of RMB1.3 million and gains of RMB15.1 million in 2018 and 2019, respectively. We currently do not have a hedging policy, and the occurrence of any of future currency exchange rate fluctuations could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATING TO DEVELOPMENT AND CLINICAL TRIALS OF OUR DRUG CANDIDATES

We may not be able to in-license new drug candidates with high potential.

Historically, we have in-licensed a number of drug candidates to develop and commercialize in the Greater China region. These assets are important for our portfolio and in-licensing will remain important for our portfolio strategy. We cannot guarantee that we will be able to continue to successfully identify and in-license new drug candidates with high potential. In addition, we have limited financial resources, our resource allocation decisions may cause us fail to capitalize on drug candidates that may later prove to have high commercial potential and profitable market opportunities. Further, if disagreements or disputes arise between us and our current licensing partners, our existing collaborations may be harmed and we may not be able to in-license new drug candidates from our current licensing partners or other global pharmaceutical companies. As a result, we may not be able to successfully expand our drug portfolio and our future growth and prospects may be adversely affected.

We may be unable to successfully complete clinical trials, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so.

Our business will depend on the successful development, regulatory approval and commercialization of the drug candidates in our development pipeline, most of which are still in preclinical or clinical development, and other drug candidates we may in-license, acquire or develop. We have invested a significant amount of efforts and financial resources in our existing drug candidates. The success of our drug candidates will depend on several factors, including:

- successful patient enrollment in, and completion of, clinical trials;

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- the performance by CROs, or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining sufficient supplies, including, where applicable, suppliers from our in-licensing partners, that may be necessary for use in clinical trials for evaluation of our drug candidates;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals for our drug candidates;
- developing sufficient commercial manufacturing capabilities;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- gaining competitive advantage over other drug candidates and drugs; and
- continued acceptable safety profile for our drug candidates following regulatory approval, if and when received.

If we experience difficulty in one or more of these factors, we may not successfully commercialize our drug candidates. Our business may be materially harmed as a result and we may not be able to generate sufficient revenues and cash flows to continue our operations.

We may not be able to discover new drug candidates.

We may fail to discover new drug candidates for clinical development for a number of reasons. Research programs to discover new drug candidates and new formulations or pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs may initially show promise in discovering new drug candidates or new formulations or developing additional potential indications, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in discovering new drug candidates or formulations or developing additional potential indications;

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- there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, our efforts and resources in discovering new drug candidates or other potential programs that ultimately prove to be unsuccessful. We may not be able to successfully expand our drug portfolio, which could materially adversely affect our future growth and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

The timely completion of a clinical trial in accordance with its protocol depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocols. Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. The competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect that some of our clinical trials may be conducted at the same clinical trial sites that some of our competitors use, which may reduce the number of patients available for our clinical trials at such clinical trial sites. Patient enrollment may also be delayed as a result of epidemics such as the COVID-19 pandemic, or similar events. For example, due to the COVID-19 pandemic, we had enrolled 29 patients as of the Latest Practicable Date for our Phase III clinical trial for OT-401, which is slower than what we had expected. This may, among other things, result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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The research and development of our drug candidates involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. You may lose all or part of your [REDACTED] in us if our research and development fails.

Before obtaining regulatory approval to market our drug candidates, we must do substantial pre-clinical research and conduct extensive clinical trials to demonstrate their safety and efficacy in humans. Clinical trials are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the research and development process. The results of preclinical research and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may not be favorable.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to complete the clinical trials, receive regulatory approval or commercialize our drug candidates, including:

- regulators may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- our drug candidates, or the substance of our drug candidates, may prove to cause adverse events, have undesirable side effects or other unexpected characteristics, causing us to suspend or terminate the trials;

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- our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- our other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- clinical trials of our drug candidates may produce negative or inconclusive results, and additional clinical trials or abandon drug development programs may be required;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- regulators may require us to suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, we may be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

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If competing drugs are more effective, have fewer side effects, are more effectively marketed and cost less than our drugs or drug candidates, or receive regulatory approval or reach the market earlier, our drug candidates may not be approved, and our drugs or drug candidates may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.

We believe that other pharmaceutical companies, research organizations and other entities are or may be seeking to develop drugs, therapies or approaches to treat our targeted diseases or their underlying causes. For some of our targeted diseases, competitors have alternative therapies that are already commercialized or are in various stages of development. Any of these competing drugs may receive government approval or gain market acceptance more rapidly than our future approved drugs and drug candidates, may offer therapeutic or cost advantages, or may more effectively treat the targeted diseases or their underlying causes, or have fewer side effects or may be more easier to use, which could result in our drug candidates not being approved, reduce demand for our future approved drugs and drug candidates or render them noncompetitive or obsolete.

Our approved drugs 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.

Our approved drugs 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 requirements of regulatory authorities in China and applicable regulatory authorities in other countries.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidate. The NMPA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the NMPA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GMP and GCP for any clinical trials that we conduct post-approval.

The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA and other regulatory authorities 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.

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Adverse drug reactions and negative results from off-label use of our future approved drugs could materially harm our business reputation, product brand name, financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our future approved drugs be subject to off-label drug use and prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our future approved drugs less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, brand name, commercial operations and financial condition. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing drugs from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our future approved drugs. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our future approved drugs and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future

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approved drug candidates. Moreover, counterfeit products may or may not have the same chemical composition as our products do, which may make them less effective than our products, entirely ineffective or more likely to cause severe adverse side effects. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies, if applicable, and well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA must include significant CMC information for a drug candidate. If we submit an NDA to the NMPA, the NMPA can decide whether to accept or reject the submission. We cannot be certain that our submissions will be accepted for filing and review by the NMPA.

We have limited experience in filing for regulatory approval for our drug candidates, and have not yet demonstrated ability to receive regulatory approval for our drug candidates from our development pipeline. So far, we have not independently submitted an NDA. Hence, our ability to successfully submit an NDA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, or cost more than it would if we were a company with more experience in obtaining regulatory approvals.

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly, and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

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We have limited experience in launching and marketing drug candidates.

Our operations to date have been largely focused on raising capital and developing our drug candidates, including undertaking preclinical studies and conducting clinical trials. We have only recently begun to market Ou Qin and brimonidine tartrate eye drop, two NMPA-approved products with respect to which we acquired rights from a partner. Although members of our management have years of experience relating to drug marketing and commercialization, we have not yet demonstrated our ability to manufacture drugs at a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. We may develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates. There can be no assurance that we will be able to build an effective sales team.

Our future approved drugs may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Our future approved drugs may fail to gain sufficient market acceptance by physicians, patients and others in the medical community. Doctors and patients may continue to prefer current treatments to the exclusion of our drugs for the same or similar indications. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- the cost effectiveness of our future approved drugs;
- the effectiveness of our marketing, sales and distribution strategies and operations;
- our ability to work with our CMOs to manufacture commercial supplies of our drugs before we successfully develop our own manufacturing capabilities;
- our ability to manufacture commercial supplies of our future approved drugs, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with GMP regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;

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- a continued acceptable safety profile of our future approved drugs;
- results from additional clinical trials of our drug candidates or further analysis of clinical data from completed clinical trials of our future approved drugs by us or our competitors;
- our ability to enforce our intellectual property rights;
- potential advantages of future approved drugs over other therapies;
- our ability to avoid any third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

If any approved drug candidates that we commercialize fail to achieve market acceptance in the medical professional community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete.

We may not be able to effectively build and manage our sales network.

In anticipation of the commercialization of our drug candidates, we started building our commercialization team in 2019. We cannot assure you that our pre-launch efforts will guarantee immediate market success. There may be circumstances during the actual sales of our future approved drugs that we did not anticipate prior to commercialization that may require us to adjust our sales and marketing strategies, recruit additional personnel or incur unforeseen costs and expenses to address those circumstances. For example, we may not be able to maintain proper inventory levels for our drug candidates. Inventory levels in excess of demand may result in inventory write-downs, expiration of future approved drugs and increase in inventory holding costs. Conversely, we may experience inventory shortages if we underestimate demand for our future approved drugs, which may result in unfilled orders and have a negative impact on our relationship with distributors, hospitals and doctors. Moreover, we may not be able to effectively manage and grow our sales network, which may affect our business and future prospects.

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The manufacture of pharmaceutical drugs is a highly exacting and complex process. If we encounter problems in manufacturing our drug candidates, our business could suffer.

The manufacture of pharmaceutical drugs is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of our future manufacturing facility, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Reimbursement may not be available for our drug candidates.

Our ability to commercialize any future approved drugs successfully will depend in part on the extent to which reimbursement for these drugs and related treatments will be available to hospitals and other medical institutions ordering these drugs for use by their patients. Under the national medical insurance program in China, patients purchasing pharmaceutical products that are listed on the NRDL are entitled to reimbursement of all or a portion of their purchase costs from the social medical fund. Consequently, the inclusion or exclusion of a pharmaceutical product in the NRDL will significantly affect the demand for such drug in China. We plan to pursue reimbursement opportunities at a national level. However, we cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize certain drug candidates that we successfully develop.

If our future approved drugs are listed on the NRDL, changes in pricing regulations could restrict the amount that we are able to charge for our current and future approved drugs.

We price our future approved drugs after receiving NDA approval. According to currently effective PRC laws and regulations, the prices of approved drugs are determined by market competition. The government regulate prices mainly by establishing a consolidated procurement mechanism, revising the NRDL and strengthening regulation of medical and pricing practices. We cannot predict the extent to which our business may be affected by potential future legislative or regulatory developments. Changes in pricing regulation could restrict the amount that we are able to charge for our future approved drugs, which would adversely affect our revenue, profitability and results of operations.

RISK FACTORS

We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.

The ophthalmic pharmaceutical industry is highly competitive. We face potential competition from many different actors, including pharmaceutical and biopharmaceutical companies, academic institutions and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. Many of the companies we are competing against or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA or other comparable regulatory authorities for their drugs more rapidly than we, which could result in their establishing a strong market position before we are able to enter. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing our drug candidates.

Guidelines, recommendations and studies published by various organizations could disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

The increasing use of social media platforms presents new risks and challenges.

Social media are increasingly being used to communicate about the diseases that our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a drug product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may

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not be able to defend our own or the public’s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our drug candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events occur or we otherwise fail to comply with applicable regulations, we may incur liability, face overly restrictive regulatory actions or incur other harm to our business.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by licensing partners.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our drug candidates and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensing partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such licensed rights could be adversely affected.

Our licensing partners may have relied on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our licensing partners are not the sole and exclusive owners of the intellectual property rights we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensing partners might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If any of our licensing partners goes bankrupt, some or all of our rights under the licensing agreements may be rejected during the bankruptcy proceeding. For details, see “Business—Collaboration and License Arrangements.” As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensing partners in a manner that may be

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more favorable to the licensing partners, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our licensing partners do not own some of the patents which they have licensed to us. Our licensing partners have obtained the rights to such patents through license agreements with the entities that own or control such patents and have in turn sub-licensed such rights to us. We are not a party to the license agreements under which our licensing partners obtain their rights and therefore cannot ensure that our licensing partners will comply with their obligations under such agreements. If any of our licensing partners breach or otherwise violate any such agreements, their rights thereunder may be terminated and our licensing partners may no longer be able to sublicense such rights to us. In addition, our licensing partners may not control prosecution and enforcement such patents. If our licensing partners lose their rights to any patents or other intellectual property rights upon which we depend and we lose our sublicense rights to such patents and other intellectual property, we may be required to cease the development and commercialization of our products and it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings.

We or our licensing partners may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property. If we or our licensing partners are unsuccessful in any interference proceedings or other priority or validity or enforceability disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensing partners are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensing partners are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

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, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensing partners or the ultimate owners of the patent rights might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we or our licensing partners or the ultimate owners of the patent rights might not have been the first to file patent applications covering certain of our the inventions that we own or exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of the technologies that we own or license without infringing our or our licensing partners' or the ultimate owners' intellectual property rights;
- it is possible that or our licensing partners' or the ultimate owners' pending patent applications will not lead to issued patents;
- 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 by our competitors;
- we or our licensing partners or the ultimate owners of the patent rights may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we or our licensing partners or the ultimate owners of the patent rights do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

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- we or our licensing partners or the ultimate owners of the patent rights may fail to develop additional proprietary technologies that are patentable;
- we or our licensing partners or the ultimate owners of the patent rights may not be able to protect our intellectual property rights that we own or license across the world or prevent unfair competitions from third parties;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our drug candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates or development pipeline.

Our commercial success will depend, where relevant, on our ability to obtain and maintain patent and other intellectual property protection with respect to our drugs, drug candidates and development pipeline. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of the patents and patent applications that we own or license have been, are being or may be challenged at a future point in time in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. We cannot be certain whether patents will be issued or granted with respect to our owned or in-licensed patent applications that are currently pending, the coverage claimed in our owned or in-licensed patents applications will be limited before patent is issued or granted, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates and development pipeline, or otherwise provide us with any competitive advantage.

Publication of discoveries often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as competing applications and may not be approved in the end.

As such, we do not know the degree of future protection that we will have on our drugs and technology, if any. If the patent applications we or our licensing partners had applied are not granted in the end, or the scope of intellectual property rights we obtained is not adequate,

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third parties could develop or commercialize drugs similar to ours and compete against us. As a result, a failure to obtain adequate intellectual property protection with respect to our drug candidates or development pipeline could have a material adverse impact on our business.

The active pharmaceutical ingredient for certain of our products, including OT-401, is off-patent and we therefore cannot prevent competitors from utilizing the same active pharmaceutical ingredient.

Compound patent claims on the active pharmaceutical ingredient, or API, in pharmaceutical drug products are generally considered to be the favored form of intellectual property protection for drug products because such patents may provide protection without regard to any particular method of use or manufacture or formulation of the API used. The chemical structure of the API in certain of our products, including fluocinolone acetonide in OT-401, is in the public domain given that patents covering such API have expired and as a result such API can no longer be patented. Accordingly, we cannot prevent third parties, including our competitors, from commercializing products in our field using the same API, based on a compound patent claiming the API.

Claims that our drug candidates or the sale or use of our future products infringes, misappropriates or otherwise violates the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the compounds we have developed or are developing. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access

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to the same intellectual property. Ultimately, we could be prevented from commercializing a future approved drug, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement, including treble damages and attorneys' fees if we are found to willfully infringe a third party's patent.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain future approved drugs.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing certain future approved drugs. Prohibitions against using certain technologies, or prohibitions against commercializing certain future approved drugs, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Further, not all of our licensing partners have represented and warranted under the licensing agreements that our use of in-licensed technologies in connection with the development, manufacture or commercialization of our drug or drug candidates will not infringe upon intellectual property rights owned by third parties, or have agreed to indemnify, defend or hold us harmless against any intellectual property infringement claims asserted by third parties.

There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our future approved drugs in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render our future approved drugs less competitive, or may delay or prevent the entry of our future approved drugs to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more drug candidates, or both.

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Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if [REDACTED] or [REDACTED] perceive these results to be negative, it could have a material adverse effect on the [REDACTED] of our Shares.

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 for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the National Intellectual Property Administration of the PRC or World Intellectual Property Organization and other patent agencies in several stages over the lifetime of a patent. The National Intellectual Property Administration of the PRC or World Intellectual Property Organization and various patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensing partners to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although 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 non-compliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

We rely on employee and third-party confidentiality agreements to safeguard our intellectual property, such as trade secrets, know-how and other proprietary information. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we collaborated with CROs or potential strategic partners, or recruited our senior management, key members of our research and development team, and employees who have access to our trade secrets or confidential information. In addition, each of our employees is required to sign a standard employment agreement with invention assignment clause upon joining our Company. Such agreement ensure our employees assign the rights of all inventions, technologies, know-how and trade secrets derived during the course of his employment to us. We take steps to protect our proprietary information, and our confidentiality agreements and invention assignment arrangements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or a third party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

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In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or business partners might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable.

We sometimes engage third parties to conduct research relevant to our drug candidates. The ability of these individuals or research institutions to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized, which could adversely affect our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

Future changes in laws and regulations governing patents and relevant procedures through which patents may be obtained and by which the validity of patents may be challenged could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Future changes in laws surrounding patent eligibility may narrow the scope of patent protection available in certain circumstances and weaken our rights as a patent owner in certain situations.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or future approved drugs in a non-infringing manner.

Our competitors may seek approval to market their own drugs that are the same as, similar to or otherwise competitive with our future approved drugs or drug candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may

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also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

The registered or unregistered trademarks or trade names that we own or license may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our products. 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.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We expect to rely on third parties (including our licensing partners) to supply drug candidates or raw materials for manufacturing our future approved drugs, and our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

During the Track Record Period, we did not procure raw materials or equipment for commercial manufacturing. As of the Latest Practicable Date, we had not produced drug products by ourselves. We expect to engage Huonland as our CMO for Ou Qin and to rely on certain third parties to supply APIs and key raw materials for manufacturing our drug candidates. Our future reliance on third party suppliers may expose us to the following risks, any of which could limit commercial supply of our future approved drugs or limit supply of our drug candidates used in clinical trials, result in higher costs, or impair our ability to continue our research and development or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand or clinical trial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;

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- our CMOs, or other third parties we rely on, could default on their agreements with us to meet our requirements for commercial supply of our future approved drugs or supply our drug candidates used in clinical trials;
- our CMOs, or other third parties we rely on, may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute our future approved drugs and we may incur additional cost; and
- if our CMOs, or other third parties we rely on, were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay the commercialization of our future approved product or impair our ability to continue our research and development.

Furthermore, in line with industry norm, we rely on our licensing partners to, among others, supply some of our drug candidates to support both clinical development and commercialization, and thus may be at risk if the business of any of such licensing partners runs into difficulties that would, as the case may be, undermine its ability to guarantee sufficient clinical or commercial supplies of drugs to us, provide technical assistance that we may from time to time require, or fulfill other contractual obligations that may be material to our business. Our current or future licensing partners are typically biotech or pharmaceutical companies themselves, some of which may be at early stage of development with limited cash flow from operations. These early-stage biotech or pharmaceutical companies may experience difficulties in their business operations, financial position or liquidity for a variety of reasons that are relevant to them, within or out of their control. For example, EyePoint, our licensing partner of OT-401 (YUTIQ), our Core Product, and OT-502 (DEXYCU), previously disclosed uncertainties associated with achieving sufficient cash flows and risks about its liquidity position leading to substantial doubt about its ability to continue as a going concern. If the difficulties and uncertainties are not well managed, the business could deteriorate or even fail. While we have contingency plans to mitigate risks associated with business disruptions caused by third parties, including adjusting inventory levels by stockpiling or obtaining contractual rights to seek alternative supplies in the event of shortage, there is no assurance that our contingency plans would be effective.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the NMPA require that our drug candidates and any products that we may eventually commercialize be manufactured according to GMP. Any failure by our third-party manufacturers to comply with GMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of drug candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates or supply the commercial volume of our future approved drugs. In addition, such failure could be the basis for the regulatory authorities to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of

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production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

We may rely on third parties (including our licensing partners) to manufacture or import our clinical and commercial drug supplies, and our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently use third parties (including, in some cases, our in-licensing partners) for the clinical and commercial supply of our drug candidates. Before our own manufacturing capabilities are fully developed, we may continue to use contract manufacturers. Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA or other comparable regulatory authorities must evaluate and approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

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- our contract manufacturers may be subject to natural or man-made disasters, epidemics, hostilities, social unrest, and other factors out of their control.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drug candidates. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error and availability of qualified personnel. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future, either relating to our third-party CMOs or our future manufacturing facilities. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drug candidates for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If we fail to comply with our obligations in the license agreements or otherwise experience disruptions to our business relationships with our licensing partners, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with licensing partners providing us with rights to various intellectual property, including rights in patents and patent applications. For details, see “Business—Collaboration and License Arrangements.” These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any future approved drugs or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these

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agreements. Such an occurrence could diminish the value of these future approved drugs and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may need to obtain additional licenses from our existing licensing partners and others to advance our research or allow commercialization of drug candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensing partner that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensing partners and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from licensing partners are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could eliminate or narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and

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prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to generate, monitor or manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs 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 clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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Switching or adding CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including obtaining regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If third parties fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

We had a limited number of suppliers during the Track Record Period.

In 2018 and 2019, our purchases from our five largest suppliers in the aggregate accounted for 56.5% and 92.8% of our total purchases, respectively. During the Track Record Period, we had a small number of suppliers, and the largest purchase amounts related to upfront payments for drug in-licensing and acquisition arrangements, which were not recurring in nature. In an in-licensing arrangement, it is customary for the licensee to pay an upfront payment to the licensor. Our other major purchases were fees paid to CROs we engaged to manage, conduct and support our preclinical research and clinical trials. We expect to continue our purchases from these suppliers as we fund the continuing research and development activities of OT-401, our Core Product, and other drug candidates in our pipeline. The stability of operations and business strategies of our suppliers are beyond our control but may affect us. Any material disruption to their operations due to natural or other causes could adversely affect our collaborations.

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Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- NMPA regulations, including those laws requiring the reporting of true, complete and accurate information to the NMPA;
- manufacturing standards; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation.

We may not be able to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from the NRDL, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

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RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel.

Our success depends in part on our continued ability to attract, retain and motivate qualified management, clinical and scientific personnel. Accordingly, we are highly dependent upon our senior management, as well as other key scientific personnel and consultants. In particular, our executive Director and CEO, Mr. Liu Ye, and the other principal members of our management and scientific teams, such as our chief scientific officer, Dr. Liu Changdong, our chief medical officer, Dr. Chen DongHong, our chief development officer, Dr. Hu Zhaopeng, and our vice president (commercialization), Mr. Zuo Qinglei, are crucial to our operations. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, we currently do not have a full time chief financial officer, and we may not be able to find a suitable candidate within the timeframe we would like, or at all.

In recognition of the contributions of our Directors and employees and to incentivize them to further promote our development, our Company adopted the Employee Stock Option Plan on May 23, 2018. The value to employees of equity grants under such plan that vest over time may be significantly affected by movements in the [REDACTED] of our Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, they could decide to terminate employment with us.

Recruiting and retaining qualified scientific, technical, clinical, manufacturing and sales and marketing personnel in the future will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our drug portfolio, clinical development and commercialization strategies. The loss of the services of these key employees and consultants could impair our ability to maintain daily operation and to achieve research, development and commercialization objective.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. Any inability to attract, motivate or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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We may not be able to develop our manufacturing capabilities as planned.

We plan to develop our own manufacturing capabilities through an agreement with a local government in Suzhou, whereby the government party will construct a manufacturing facility and we will acquire the facility from the government party upon the satisfaction of certain conditions. See “History, Restructuring and Corporate Structure—Major Acquisitions, Disposals and Mergers.” If the construction of the manufacturing facility is significantly delayed by epidemics such as the COVID-19 pandemic or similar events, the development of our manufacturing capabilities will be adversely impacted. If regulatory or other problems (including breach of contract) require the construction of the Suzhou facility to be suspended or even abandoned or impede our acquisition of the Suzhou facility, we will not be able to develop the manufacturing capabilities as planned, which would materially and adversely impact our business. Once completed and in operation, if the facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our facility. In the event of a temporary or protracted loss of either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with necessary regulatory requirements.

We may fail to comply with laws, regulations and industry standards or any adverse actions by the drug approval authorities, obtain or renew certain approvals, licenses, permits and certificates required for our business.

A number of governmental agencies or industry regulatory bodies in China impose strict rules, regulations and industry standards governing pharmaceutical and biotechnology research and development activities, which apply to us. In addition, we are also subject to laws and regulations with respect to our overall operations. Pursuant to applicable laws and regulations, we are required to obtain and maintain various approvals, licenses, permits and certificates from the relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and reassessment by the relevant authorities. Such laws, regulations and the standards of such renewal and reassessment may change from time to time. Any failure to comply with such laws and regulations or any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in termination of ongoing research, administrative penalties imposed by regulatory bodies, the disqualification of data for submission to regulatory authorities or enforcement actions. These may lead to cease of operations and corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our reputation, business, financial condition and results of operations.

Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain such approvals, permits,

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licenses or certificates. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, decrease our revenues and increase our costs, which could materially reduce our profitability and prospects.

We are subject to risks in relation to acquisitions or strategic partnerships.

From time to time, we may evaluate various acquisitions and strategic partnerships, including in-licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements and increase our near and long-term expenditures;
- difficulties in assimilating operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic transaction;
- 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 drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits. Any collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

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- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates;
- collaborators with marketing and distribution rights to one or more of our drug candidates may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- the business of collaborators may run into difficulties. See “—Risks Relating to Our Reliance on Third Parties—We expect to rely on third parties to supply drug candidates or raw materials for manufacturing our future approved drugs, and our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices”;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

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As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or the license of our third-party drugs if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

PRC regulations and rules concerning mergers and acquisitions, including the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《商務部實施外國投資者並購境內企業安全審查制度的規定》), or the Security Review Rules, issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions

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in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

We face potential liabilities, in particular, product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical trials of our drug candidates, and we will face an even greater risk if we produce, market, promote and commercialize any drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our drug candidates; and
- a decline in our Share [REDACTED].

If we are unable to defend ourselves against such claims in the PRC, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are

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found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

Existing PRC laws and regulations do not require us to, nor do we, maintain liability insurance to cover product liability claims. We currently only maintain insurance for adverse effects in clinical trials. Such insurance may not fully cover our potential liabilities. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Even if we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, may have a material adverse impact on us.

The drug market is heavily regulated in China. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may cause difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects. Our licensing partners gain exposure to the China market through license arrangements with us. If China modifies regulations which materially and adversely affects collaboration with foreign pharmaceutical or biopharmaceutical companies, our business, financial condition, results of operations and prospects may be materially and adversely affected as well.

If we fail to comply with anti-corruption, environmental, health and safety laws and regulations in the future, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to anti-corruption laws and regulations. Our business activities create the risks of unauthorized payments or offers of payments by our employees. It is our policy to implement strict safeguards to discourage these practices. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities. Noncompliance with anti-corruption laws could subject us investigations, enforcement actions, fines, or civil or criminal penalties.

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We may be subject to numerous environmental, health and safety laws and regulations when we operate our manufacturing facilities, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. When we operate manufacturing facilities in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes, but we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may be required to incur substantial costs to comply with environmental, health and safety laws and regulations when we operate our manufacturing facilities. These laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our operations and business plans may be adversely affected by the COVID-19 pandemic.

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand across the PRC and globally. In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. The COVID-19 outbreak is expected to have an unprecedented impact on the global economy as it has significantly reduced market liquidity and depressed economic activities.

The COVID-19 outbreak has caused and may continue to cause a long-term adverse impact on the economy and social conditions in China and other affected countries, which may have an indirect impact on the Chinese ophthalmic drug market, and adversely affect our business operations. We experienced a delay in patient screening for the ongoing Phase III clinical trial of OT-401 due to travel restrictions implemented to contain the spread of COVID-19 in China. See “Summary—Recent Developments—Impact of the COVID-19 Outbreak.” We are uncertain as to when the COVID-19 pandemic will be contained in China and globally, and we also cannot predict whether COVID-19 will have long-term impact on our business operations. In addition, the commencement of new clinical trials for other drug candidates in our development pipeline could also be delayed or prevented by any delay or failure in patient recruitment or enrollment. Our commercial plan for commercial-ready or near

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commercial-ready assets could also be disrupted. If we are not able to effectively and efficiently develop and commercialize our drug candidates as planned, we may not be able to grow our business and generate revenue from sales of our drug candidates as anticipated, our business operations, financial condition and prospects may subsequently be materially and adversely affected.

We face risks related to natural disasters, health epidemics and other outbreaks or other unforeseen catastrophic events.

We are vulnerable to natural disasters and other calamities. Fire, floods, typhoons, earthquakes, power loss, telecommunications failures, break-ins, war, riots, terrorist attacks or similar events may adversely affect our drug development progress, on-going clinical trials, manufacturing and commercialization. Natural disasters, health epidemics or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, earthquakes, terrorist attacks and wars, could significantly impair our ability to operate our business. Our business could also be adversely affected by the effects of Ebola virus disease, Zika virus disease, H1N1 flu, H7N9 flu, avian flu, SARS, COVID-19 or other epidemics, since it could require our employees to be quarantined and/or our offices to be disinfected. In addition, our results of operations could be adversely affected to the extent that any of these epidemics harms the PRC economy in general and the business of our customers and suppliers. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by our CROs or partners or other contractors or consultants, may fail or suffer security breaches.

Our internal computer systems and those of our CROs, partners and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. Information systems, networks and other technologies are critical to our operating activities, shutdowns or service disruptions at our offices or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events, such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our

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operations, damage to our reputation or a loss of revenues. We could be subject to regulatory actions and/or claims involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. In addition, as we outsource more of our information systems to vendors and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may explore various forms of collaboration outside of China, which will expose us to additional risks of conducting business in additional international markets.

We currently have rights to our in-licensed products in the Greater China region and, in some cases, Southeast Asia and Korea. We may continue to explore commercialization rights licenses in select international markets. For certain of our in-house developed drugs, we may also consider obtaining global rights. Engaging in international business relationships subject us to additional risks, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management’s attention;
- unexpected changes in laws and regulatory requirements and difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection such as third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;

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- failure of our employees and contracted third parties to comply with anti-corruption and anti-bribery laws, such as United States Department of the Treasury’s Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended, or FCPA; and
- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to procure equipment and raw material and to attain or sustain any future revenue from international markets.

Increased labor costs could slow our growth and affect our profitability.

Our operations require a sufficient number of qualified employees. We cannot assure you that there will be no further increase in labor cost. If there is a significant increase in our labor cost, our operations and profitability may be adversely affected.

In addition, we adopted the Employee Stock Option Plan and the RSU Scheme for the primary purpose of providing incentives and reward to employees of the Group. See “Appendix IV—Statutory and General Information—D. Share Incentive Schemes.” We will not grant any further option under the Employee Stock Option Plan after the [REDACTED]. Share options granted under our existing or future share-based compensation scheme could adversely affect our net income.

We may be involved in claims, disputes or legal proceedings in the ordinary course of business.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. As of the Latest Practicable Date, we were not involved in any litigations and legal proceedings that may materially affect our business and results of operations. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to defective supplies sold to us by our suppliers, who may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

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We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or product liability insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Negative publicity may adversely affect our reputation, business and growth prospect.

Any negative publicity concerning us, our affiliates or any entity that shares the “Ocumension” name, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicity about us or any of our affiliates or any entity that shares the “OcuMension” name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. In addition, referrals have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us or any of our affiliates or any entity that shares the “OcuMension” name could adversely affect our ability to maintain our existing collaboration arrangements or attract new partners.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China that generally prohibits companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under such laws for actions taken by our agents, employees and intermediaries with respect to our business or any businesses that we acquire. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the federal government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

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The political relationships between China and other countries may affect our business operations.

During the Track Record Period, we have formed partnerships with entities in foreign countries, including the United States, France and Japan, and establishing new collaboration partnerships is key to our future growth. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, including international trade relationships, and local conditions in those foreign countries. As a result, China's political relationships with those foreign countries may affect the prospects of maintaining existing or establishing new collaboration partnerships. There can be no assurance that potential collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries. Any tensions and political concerns between China and the relevant foreign countries may adversely affect our business, financial condition, results of operations, cash flows and prospects.

RISKS RELATING TO DOING BUSINESS IN CHINA

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

During the Track Record Period, most of our business operation were located in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek government approval before any scientific data involving a “state secret” may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term “state secret” is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

The PRC legal system has inherent uncertainties that could limit the legal protection available to you.

Our business is conducted in China and is governed by PRC laws and regulations. Our business operation is supervised by competent regulatory authorities in China. The PRC legal system is based on written statutes and prior court decisions can only be cited as reference. Additionally, written statutes in the PRC are often principle-oriented and require detailed interpretations by the enforcement bodies to further apply and enforce such laws. Since 1979, the PRC government has developed a comprehensive system of laws, rules and regulations in relation to economic matters, such as foreign investment, corporate organization and governance, commerce, taxation and trade. However, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and may not be as consistent or predictable as in other more developed jurisdictions. As these laws and regulations are continually evolving in response to changing economic and other conditions, and because of the limited volume of published cases and their non-binding nature, any particular interpretation of PRC laws and regulations may not be definitive. Moreover, we cannot predict the effect of future developments in the PRC legal system and regulatory structure. Such unpredictability towards our contractual, property and procedural rights as well as our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations. In addition, the PRC legal system is based in part on government policies and internal rules (some of which are not published on

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a timely basis, if at all) that some rules may have a retroactive effect. Hence, we may not be aware of violation of these policies and rules until after such violation has occurred. Furthermore, the legal protections available to us and our investors under these laws, rules and regulations may be limited.

Uncertainties exist with respect to the interpretation and implementation of the PRC Foreign Investment Law, which may impose new burdens on us.

The PRC Foreign Investment Law, or the FIL, was enacted by the NPC on March 15, 2019 and became effective on January 1, 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, uncertainties exist with respect to interpretation and implementation of the FIL and its Implementation Rules, which may adversely impact our corporate governance practice and increase our compliance costs. For instance, we might be required by government interpretations or implementing rules of the FIL to adjust the corporate governance of certain of our PRC subsidiaries in a five-year transition period. In addition, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate

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amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

In response to the persistent capital outflow in China and the Renminbi’s depreciation against the U.S. dollar, People’s Bank of China, or PBOC, and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than what we currently anticipate.

The EIT Law and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.

Pursuant to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income and we have obtained the approval of the competent tax authority. On February 3, 2018, the STA issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《關於稅收協定中“受益所有人”有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner.

If our Hong Kong subsidiary holds any equity interest in a PRC subsidiary and does not engage in any substantive business activity in the future, based on the abovementioned principles, PRC tax authorities would not consider our Hong Kong subsidiary as the “beneficial owner” of any dividends paid from our PRC subsidiaries and would deny the claim for the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary

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is not considered as a “beneficial owner,” dividends from our PRC subsidiaries to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and it would impact our ability to pay dividends in the future.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency denominated obligations. The Renminbi is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.

Some of our Directors and management personnel reside in China and substantially all of assets of our Directors and management personnel are located within China. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final

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judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, most other western countries or Japan. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

Any failure by the Shareholders or beneficial owners of our Shares to comply with certain PRC foreign exchange regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including SAFE Circular 37. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (1) the requirement by the SAFE

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to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《國家外匯管理局關於發佈境內機構境外直接投資外匯管理規定的通知》), or SAFE Circular 30, and other regulations, if our Shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our Shareholders may be required to suspend or stop the investments and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

Pursuant to the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or SAFE Circular 13, local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and procuring that our Shareholders who are subject to the regulations comply with the relevant SAFE rules and regulations. However, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not always be practically available in all circumstances as prescribed in those regulations. In addition, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other related regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

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Any failure to comply with the PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. Our PRC subsidiaries and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our PRC subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our Directors and employees under PRC law.

We face uncertainty relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.

On February 3, 2015, the STA issued the Announcement on Issues of Enterprising Income Tax Arising from Indirect Property Transfer Between Nonresident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (《關於加強非居民企業股權轉讓企業所得稅管理的通知》), or Circular 698, which was previously issued by the STA on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets.

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this

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Document and the [REDACTED]” in this document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of [REDACTED] for, purchasing, holding, disposing of and [REDACTED] in the Shares.

Under China’s EIT Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under the EIT Law, an enterprise established outside of China with “*de facto* management bodies” within China is considered a “resident enterprise,” meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Under the Circular of the STA on Issues Concerning the Identification of Chinese-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the Actual Standards of Organizational Management (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by the STA on April 22, 2009, or Circular 82, dividends and other distributions paid by resident enterprises will be considered to be PRC source income, subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “*de facto* management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises will be classified as resident enterprises. On July 27, 2011, the STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which the competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Despite the foregoing, the STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “*de facto* management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by PRC enterprise would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities

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and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by PRC enterprise like us. Finally, the EIT Law and its implementing rules issued by PRC tax authorities provide that dividends paid by us to our non-PRC shareholders and, while less clear, capital gains recognized by them with respect to the sale of our Shares may be subject to tax of 10% for non-PRC resident enterprise shareholders and 20% for non-PRC resident individual shareholders. In the case of dividend payments, such PRC tax may be withheld at source.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, our capital contributions must be registered with the SAMR or its local branch. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial condition and results of operations.

We may be subject to fines due to the lack of registration of our leases.

Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we leased certain properties primarily as office space in China and did not register all of our seven lease agreements as tenant. We may be required by relevant government authorities to file these lease agreements for registration within a time limit, and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each lease agreement. As of the Latest Practicable Date, we were not aware of any action, claim or investigation being conducted or threatened by the competent governmental authorities with respect to such defects in our leased properties.

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RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares; an active [REDACTED] market for our Shares may not develop and the market [REDACTED] for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied to the [REDACTED] for the [REDACTED] in, the Shares. A [REDACTED] on the [REDACTED], however, does not guarantee that an active and liquid [REDACTED] for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

The [REDACTED] of our Shares may be volatile, which could lead to substantial losses to [REDACTED].

The [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [REDACTED] of the shares of other companies engaging in similar business may affect the [REDACTED] of our Shares. In addition to market and industry factors, the [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, [REDACTED] and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] the Stock Exchange with significant operations and assets in China have experienced [REDACTED] in the past, and it is possible that our Shares may be subject to [REDACTED] not directly related to our performance.

There will be a gap of several days between [REDACTED] of our Shares, and the [REDACTED] of our Shares when [REDACTED] begins could be lower than the [REDACTED].

The initial [REDACTED] to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise [REDACTED] the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the [REDACTED] of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time [REDACTED] begins.

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Future sales or perceived sales of our Shares in the public market by major Shareholders following the [REDACTED] could materially and adversely affect the [REDACTED] of our Shares.

Sales of substantial amounts of Shares in the public market after the completion of the [REDACTED], or the perception that these sales could occur, could adversely affect the [REDACTED] of our Shares. Although our Controlling Shareholders are subject to restrictions on its sales of Shares within 12 months from the [REDACTED] as described in “[REDACTED]” in this document, future sales of a significant number of our Shares by our Controlling Shareholders in the public market after the [REDACTED], or the perception that these sales could occur, could cause the [REDACTED] of our Shares to decline and could materially impair our future ability to raise capital through [REDACTED] of our Shares. We cannot assure you that our Controlling Shareholders will not dispose of Shares held by them or that we will not issue Shares pursuant to the [REDACTED] to issue shares granted to our Directors as described in “Appendix IV—Statutory and General Information” or otherwise, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by our Controlling Shareholders, or the availability of Shares for sale by our Controlling Shareholders, or the issuance of Shares by the Company may have on the [REDACTED] of the Shares. Sale or issuance of a substantial amount of Shares by our Controlling Shareholders or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing [REDACTED] of the Shares.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.

The [REDACTED] of the [REDACTED] is higher than the [REDACTED] immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] value. In order to expand our business, we may consider [REDACTED] and issuing additional Shares in the future. [REDACTED] of the [REDACTED] may experience dilution in the net [REDACTED] of their Shares if we issue additional Shares in the future at a [REDACTED] which is lower than the net [REDACTED] at that time.

We do not expect to pay dividends in the foreseeable future after the [REDACTED].

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements

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and surplus, the amount of distributions received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. As a result, we cannot assure you that we will make any dividend payments on our Shares in the future.

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Law and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III—Summary of the Constitution of Our Company and Cayman Companies Law.”

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Controlling Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

Facts, forecasts and statistics in this document relating to the ophthalmic pharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the ophthalmic pharmaceutical industry in and outside China are obtained from sources that we believe are reliable, including official government publications as well as the Frost & Sullivan Report that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the ophthalmic pharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risks and uncertainties and are subject to change and should not be unduly relied upon.

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[REDACTED] should read the entire document and should not consider any particular statements in this document or in published media reports without carefully considering the risks and other information contained in this document.

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

You should rely solely upon the information contained in this document in making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED].