

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 20-F

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022
OR
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
 SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report
Commission File Number: 001-41636

OCULIS HOLDING AG

(Exact name of Registrant as specified in its charter)

Not applicable
(Translation of Registrant's name into English)

Switzerland
(Jurisdiction of incorporation or organization)

Bahnhofstrasse 7
CH-6300
Zug, Switzerland
(Address of principal executive offices)

Riad Sherif, MD
EPFL Innovation Park, Bat D 3e Route J-D.
Colladon, CH-1015 Lausanne, Switzerland
+41-21-711-3970
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares	OCS	The Nasdaq Stock Market LLC
Warrants	OCSAW	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual company report: **32,733,373 Ordinary Shares** and **4,403,294 Warrants to purchase Ordinary Shares**.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

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

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

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP <input type="checkbox"/>	International Financial Reporting Standards as issued	Other <input type="checkbox"/>
	by the International Accounting Standards Board ®	<input checked="" type="checkbox"/>

If “Other” has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

TABLE OF CONTENTS

<u>DEFINED TERMS</u>	2
<u>GENERAL INFORMATION</u>	6
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	7
<u>PART I</u>	9
<u>Item 1. Identity of Directors, Senior Management and Advisers.</u>	9
<u>Item 2. Offer Statistics and Expected Timetable.</u>	9
<u>Item 3. Key Information</u>	9
A. <u>[Reserved]</u>	9
B. <u>Capitalization and indebtedness.</u>	9
C. <u>Reasons for the offer and use of proceeds.</u>	9
D. <u>Risk factors.</u>	9
<u>Item 4. Information on the Company.</u>	80
A. <u>History and Development of the Company.</u>	80
B. <u>Business Overview</u>	80
C. <u>Organizational Structure</u>	122
D. <u>Property, Plants and Equipment</u>	123
<u>Item 4A. Unresolved Staff Comments</u>	123
<u>Item 5. Operating and Financial Review and Prospects</u>	123
A. <u>Operating Results</u>	129
B. <u>Liquidity and Capital Resources</u>	132
C. <u>Research and Development, Patents and Licenses, etc</u>	137
D. <u>Trend Information</u>	137
E. <u>Critical Accounting Policies and Estimates</u>	137
<u>Item 6. Directors, Senior Management and Employees</u>	138
A. <u>Directors and senior management.</u>	138
B. <u>Compensation</u>	141
C. <u>Board Practices</u>	144
D. <u>Employees</u>	148
E. <u>Share Ownership</u>	148
F. <u>Disclosure of a registrant's action to recover erroneously awarded compensation.</u>	148
<u>Item 7. Major Shareholders and Related Party Transactions</u>	149
A. <u>Major Shareholders</u>	149
B. <u>Related Party Transactions</u>	151
C. <u>Interests of Experts and Counsel</u>	152
<u>Item 8. Financial Information.</u>	152
A. <u>Consolidated Statements and Other Financial Information</u>	152
B. <u>Significant Changes</u>	152
<u>Item 9. The Offer and Listing.</u>	153
A. <u>Offer and Listing Details</u>	153
B. <u>Plan of Distribution</u>	153

C.	Markets	153
D.	Selling Shareholders	153
E.	Dilution	153
F.	Expenses of the Issue	153
Item 10. Additional Information.		153
A.	Share Capital	153
B.	Memorandum and Articles of Association	153
C.	Material Contracts	153
D.	Exchange Controls	155
E.	Taxation	155
F.	Dividends and Paying Agents	163
G.	Statement by Experts	163
H.	Documents on Display	164
I.	Subsidiary Information	164
J.	Annual Report to Security Holders	164
Item 11. Quantitative and Qualitative Disclosures About Market Risk		164
Item 12. Description of Securities Other than Equity Securities.		164
A.	Debt Securities	164
B.	Warrants and Rights	164
C.	Other Securities	164
D.	American Depositary Shares	165
PART II		165
Item 13. Defaults, Dividend Arrearages and Delinquencies.		165
Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.		165
Item 15. Controls and Procedures.		165
Item 16. [Reserved]		166
Item 16A. Audit Committee Financial Expert		166
Item 16B. Code of Ethics		166
Item 16C. Principal Accountant Fees and Services		167
Item 16D. Exemptions from the Listing Standards for Audit Committees.		167
Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.		167
Item 16F. Change in Registrant's Certifying Accountant.		167
Item 16G. Corporate Governance.		167
Item 16H. Mine Safety Disclosure.		168
Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.		168
PART III		169
Item 17. Financial Statements		169
Item 18. Financial Statements.		169
Item 19. Exhibits		169

DEFINED TERMS

In this Annual Report:

“**2023 Plan**” means the Stock Option and Incentive Plan Regulation 2023 of the registrant.

“**Acquisition Closing**” means the closing of the First Merger, Second Merger and Oculis Share Contribution.

“**Acquisition Closing Date**” means March 2, 2023, the date upon which the Acquisition Closing occurred.

“**Ancillary Agreements**” means the Business Combination Agreement (together with the Oculis Disclosure Letter and the EBAC Disclosure Letter), the Subscription Agreements, the Convertible Loan Agreements, the Sponsor Support Agreement, the Non-Redemption Agreement, the Confidentiality Agreement, dated as of February 22, 2022, by and between Oculis and EBAC, the Oculis Shareholders Support Agreement and when entered into at the Acquisition Closing, the Registration Rights and Lock-Up Agreement and the Warrant Assignment And Assumption Agreement.

“**Annual Report**” means this annual report of Oculis on Form 20-F.

“**Business Combination**” means the transactions contemplated by the Business Combination Agreement, including the Mergers and the Oculis Share Contribution.

“**Business Combination Agreement**” means the Business Combination Agreement, dated as of October 17, 2022, as may be amended from time to time, by and among EBAC, Legacy Oculis, and Oculis.

“**Closing**” means the consummation of the Business Combination, which occurred on March 2, 2023.

“**Closing Date**” means March 2, 2023, the date upon which the Closing occurred.

“**Code**” means the Internal Revenue Code of 1986, as amended.

“**Company**” means the legal entity named Oculis Holding AG, individually or together with its consolidated subsidiaries.

“**Company Share Capital**” has the meaning ascribed to such term in the Business Combination Agreement.

“**Continental**” means Continental Stock Transfer & Trust Company, the transfer agent and warrant agent of EBAC and the Company.

“**Convertible Loan Agreements**” means the convertible loan agreements, dated as of October 17, 2022 and January 20, 2023 (as amended and restated on February 22, 2023), by and among Oculis and certain lenders party thereto.

“**EBAC**” means European Biotech Acquisition Corp., a Cayman Islands exempted company.

“**EBAC Class A Common Stock**” means Class A ordinary shares, par value \$0.0001 per share, of EBAC.

“**EBAC Class B Common Stock**” or “**Founder Shares**” means Class B ordinary shares, par value \$0.0001 per share, of EBAC.

“**EBAC Common Stock**” means EBAC Class A Common Stock and EBAC Class B Common Stock.

“**EBAC Disclosure Letter**” means that certain disclosure letter delivered to Oculis by EBAC on the date of the Business Combination Agreement.

“**EBAC Private Placement Warrants**” means a warrant to purchase one share of EBAC Class A Common Stock at an exercise price of \$11.50 issued to the Sponsor.

“**EBAC Public Warrants**” means a warrant to purchase one share of EBAC Class A Common Stock at an exercise price of \$11.50 that was included in the units sold as part of EBAC’s initial public offering.

“**EBAC Shareholders**” means the shareholders of EBAC as of any applicable determination time prior to the Acquisition Closing.

“**EBAC Share Redemption**” means the election of an eligible (as determined in accordance with EBAC’s amended and restated memorandum and articles of association) holder of shares of EBAC Class A Common Stock to redeem all or a portion of the shares of EBAC Class A Common Stock held by such holder in return for the right to receive a per-share price, payable in cash by Oculis, equal to a pro rata share of the aggregate amount on deposit in the Trust Account (including any interest earned on the funds held in the Trust Account) (as determined in accordance with EBAC’s amended and restated memorandum and articles of association) in connection with the Transactions. The redeemed shares of EBAC Class A Common Stock shall be held in treasury for re-issuance to new investors.

“**EBAC Share Redemption Amount**” means the aggregate amount payable by Oculis with respect to all EBAC Share Redemptions.

“**EBAC Warrants**” means the EBAC Public Warrants and the EBAC Private Placement Warrants.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Exchange Agent**” means Continental, which was selected by Oculis, Legacy Oculis and EBAC to act on behalf of EBAC, EBAC Shareholders, Oculis and Oculis Shareholders.

“**Exchange Agent Contribution**” means the contribution by the Exchange Agent of Surviving EBAC Shares to the Company.

“**Exchange Agent Contribution Actions**” means the distribution by the Exchange Agent of Ordinary Shares and Warrants to the holders of Surviving EBAC Shares and Surviving EBAC Warrants, respectively.

“**Existing Warrant Agreement**” means the Warrant Agreement, dated March 15, 2021, between EBAC and the Exchange Agent, as warrant agent.

“**First Merger**” means when Merger Sub 1 merges with and into EBAC, with EBAC as the surviving company.

“**First Merger Effective Time**” means the time at which the First Merger became effective pursuant to the filing and registration of the plan of merger with the Cayman Islands Registrar of Companies or at such later time as may be agreed by Oculis and Legacy Oculis in writing and specified in such plan of merger.

“**IFRS**” means International Financial Reporting Standards as adopted by the International Accounting Standards Board.

“**Initial PIPE Financing**” means the private placement pursuant to which the Initial PIPE Investors subscribed for EBAC Class A Common Stock, for a subscription price of \$10.00 per share.

“**Initial PIPE Investors**” means the institutional investors that committed to subscribe for EBAC Class A Common Stock in the Initial PIPE Financing.

“**Initial Subscription Agreements**” means the subscription agreements, each dated as of October 17, 2022, by and among EBAC and the Initial PIPE Investors party thereto.

“**Legacy Oculis**” means Oculis SA, a stock corporation (*Aktiengesellschaft*) incorporated and existing under the laws of Switzerland having its registered office at EPFL Innovation Park, Bat D 3e Route J-D. Colladon, CH-1015 Lausanne, Switzerland, individually or together with its consolidated subsidiaries.

“**Lenders**” means those certain Oculis Shareholders party to the Convertible Loan Agreements pursuant to which, among other things, such Oculis Shareholders agreed to grant Oculis a right to receive a convertible loan with certain conversion rights in an aggregate amount of \$19,670,000.

“**Merger Sub 1**” means Oculis Merger Sub I Company, a Cayman Islands exempted company that was a direct wholly owned subsidiary of Oculis prior to the Acquisition Closing.

“**Merger Sub 2**” means Oculis Merger Sub II Company, a Cayman Islands exempted company that is a direct wholly owned subsidiary of Oculis.

“**Merger Sub 3**” means Oculis Operations GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated and existing under the laws of Switzerland that is a direct wholly owned subsidiary of Oculis.

“**Nasdaq**” means The Nasdaq Stock Market LLC.

“**Ordinary Shares**” means ordinary shares, nominal value CHF 0.01 per share of Oculis.

“**New Parent Interests**” means the Ordinary Shares and Warrants which were held by the Exchange Agent solely on behalf of holders of Surviving EBAC Shares and Surviving EBAC Warrants.

“**Warrants**” means a right to acquire Ordinary Shares, on substantially the same terms as the EBAC Warrants.

“**Oculis**” means as the context requires, (a) the registrant, a legal entity named Oculis Holding AG, a stock corporation (*Aktiengesellschaft*) incorporated and existing under the laws of Switzerland having its registered office at Bahnhofstrasse 7, CH-6300, Zug, Switzerland, individually or together with its consolidated subsidiaries; or (b) Legacy Oculis.

“**Oculis Disclosure Letter**” means that certain disclosure letter delivered to EBAC by Oculis on the date of the Business Combination Agreement.

“**Oculis Shareholders**” means, collectively, the holders of shares of Company Share Capital as of any applicable determination time prior to the Acquisition Closing.

“**Oculis Shareholders Support Agreement**” means that certain agreement entered into concurrently with the execution of the Business Combination Agreement, dated as of October 17, 2022, by and among Oculis, EBAC and the Oculis Shareholders party thereto.

“**Oculis Share Contribution**” means the contribution by the Oculis Shareholders of the full legal and beneficial ownership of the applicable Company Share Capital to Oculis.

“**PIPE Financing**” means the Initial PIPE Financing and the Subsequent PIPE Financing, pursuant to which the PIPE Investors subscribed for EBAC Class A Common Stock, for a subscription price of \$10.00 per share.

“**PIPE Investors**” means the Initial PIPE Investors and the Subsequent PIPE Investors.

“**PIPE Shares**” means the shares of EBAC Class A Common Stock purchased by the PIPE Investors and transferred to them by EBAC from treasury.

“**Prospectus**” means the final proxy statement/prospectus filed with the SEC on February 3, 2023.

“**Registration Rights and Lock-Up Agreement**” means the Amended and Restated Registration Rights and Lock-Up Agreement, dated as of the Acquisition Closing Date, by and among Oculis, Sponsor and certain Legacy Oculis Shareholders.

“**SEC**” means the U.S. Securities and Exchange Commission.

“**Second Merger**” means when EBAC merged with and into Merger Sub 2, with Merger Sub 2 as the surviving company.

“**Second Merger Effective Time**” means the time at which the Second Merger became effective pursuant to the filing and registration of the plan of merger with the Cayman Islands Registrar of Companies or at such later time as may be agreed by Oculis and Legacy Oculis in writing and specified in such plan of merger.

“**Securities Act**” means the Securities Act of 1933, as amended.

“**Share Cancellation**” means the cancellation of the Ordinary Shares held by EBAC concurrently with the Exchange Agent Contribution.

“**Sponsor**” means LSP Sponsor EBAC B.V. a Dutch limited liability company.

“**Sponsor Support Agreement**” means the Sponsor Support Agreement, dated October 17, 2022, by and among EBAC, Oculis and Sponsor.

“**Subscription Agreements**” means the Initial Subscription Agreements and the Subsequent Subscription Agreements.

“**Subsequent PIPE Financing**” means the private placement pursuant to which the Subsequent PIPE Investors subscribed for EBAC Class A Common Stock, for a subscription price of \$10.00 per share.

“**Subsequent PIPE Investors**” means the institutional investors that committed to subscribe for EBAC Class A Common Stock in the Subsequent PIPE Financing.

“**Subsequent Subscription Agreements**” means the subscription agreements, entered into in January 2023, by and among EBAC and the Subsequent PIPE Investors party thereto.

“**Surviving EBAC Shares**” means EBAC Common Stock, including those held by the PIPE Investors, automatically converted into one class of common stock of EBAC, as the surviving company of the First Merger.

“**Surviving EBAC Warrants**” means EBAC Warrants outstanding immediately prior to the First Merger Effective Time automatically converted into warrants of EBAC, as the surviving company of the First Merger.

“**Swiss Code of Obligations**” means the Swiss Federal Act on the Amendment of the Swiss Civil Code of March 30, 1911.

“**Third Merger**” means when Legacy Oculis merges with and into Merger Sub 3, with Merger Sub 3 as the currently planned surviving company and wholly owned subsidiary of Oculis.

“**Third Merger Effective Time**” means the time at which the Third Merger becomes effective pursuant to the filing and the registration of the plan of merger in accordance with the provisions of the Swiss Code of Obligations or at such later time as may be agreed by Oculis and Legacy Oculis in writing and specified in such plan of merger.

“**Transfer Agent**” means Continental.

“**Trust Account**” means that certain trust account with Continental, as trustee, containing the cash proceeds of EBAC from its initial public offering and private placement of securities (and all accrued interest earned thereon), deposited therein for the benefit of EBAC and EBAC’s public shareholders.

“**U.S. GAAP**” means United States generally accepted accounting principles.

“**Warrant Agreement Assumption**” means the assignment by EBAC of all its right, title and interest in the Existing Warrant Agreement to the Company and the acceptance by Company of such assignment.

“**Warrant Assignment and Assumption Agreement**” means the Warrant Assignment and Assumption Agreement entered into among EBAC, the Company and the Exchange Agent, which became effective immediately following the completion of the Exchange Agent Contribution and concurrent Share Cancellation.

GENERAL INFORMATION

Unless context otherwise requires, all references in this Annual Report on Form 20-F (“Annual Report”) to “Oculis,” the “Company,” “we,” “us” and “our” refer to Oculis and, where appropriate, its consolidated subsidiaries. Unless otherwise stated or unless the context otherwise requires, references to “Oculis” or the “Company” are to the registrant named “Oculis Holding AG” and its subsidiaries after the consummation of the Business Combination, whereas references to “Legacy Oculis” are to Oculis SA and its subsidiaries prior to the Closing.

This Annual Report includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to

in this Annual Report appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F (the "Annual Report") contains or may contain forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve significant risks and uncertainties. All statements other than statements of historical facts are forward-looking statements. These forward-looking statements include information about our possible or assumed future results of operations or our performance. Words such as "may," "might," "will," "could," "would," "should," "expects," "intends," "plans," "believes," "anticipates," "estimates," "potential," "continue," "ongoing," "targets," "possible," "project," and "predict" and variations of such words and similar expressions are intended to identify the forward-looking statements. Forward-looking statements in this Annual Report may include, for example, statements about:

- the benefits of the Business Combination;
- our financial performance;
- the ability to maintain the listing of our Ordinary Shares and Warrants on the Nasdaq Global Market;
- timing and expected outcomes of clinical trials, preclinical studies, regulatory submissions and approvals, as well as commercial outcomes;
- expected benefits of our business and scientific approach and technology;
- the potential safety and efficacy of our product candidates;
- our ability to successfully develop, advance and commercialize our pipeline of product candidates;
- the effectiveness and profitability of our collaborations and partnerships, our ability to maintain current collaborations and partnerships and enter into new collaborations and partnerships;
- expectations related to future milestone and royalty payments and other economic terms under our collaborations and partnerships;
- estimates regarding future revenue, expenses, capital requirements, financial condition, and need for additional financing;
- estimates of market opportunity for our product candidates;
- the effects of increased competition as well as innovations by new and existing competitors in our industry;
- our strategic advantages and the impact those advantages may have on future financial and operational results;
- our expansion plans and opportunities;
- our ability to grow our business in a cost-effective manner;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;

- the impact of the COVID-19 pandemic, macroeconomic factors and other global events, such as the Russia-Ukraine conflict, on our business;
- changes in applicable laws or regulations; and
- the outcome of any known and unknown litigation and regulatory proceedings.

These forward-looking statements are based on information available as of the date of this Annual Report, and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, you should not place undue reliance on these forward-looking statements in deciding to invest in our securities. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. You should refer to the section titled “*Item 3.D Risk Factors*” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

PART I

Item 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

Item 3. Key Information.

A. [Reserved]

B. *Capitalization and indebtedness.*

Not applicable.

C. *Reasons for the offer and use of proceeds.*

Not applicable.

D. *Risk factors.*

An investment in our securities carries a significant degree of risk. In addition to the other information contained in this Annual Report on Form 20-F, including the matters addressed under the heading "Forward-Looking Statements," you should carefully consider the following risk factors in deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect relating to our business, financial condition, and results of operations and future prospects, in which event the market price of our securities could decline, and you could lose part or all of your investment. Additional risks and uncertainties of which we are not presently aware or that we currently deem immaterial could also affect our business operations and financial condition.

Summary Risk Factors

Our business is subject to a number of risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in this section titled "Risk Factors" in Part I, Item 3.D. of this Annual Report. Set forth below is a summary list of the principal risk factors as of the date of the filing of this Annual Report:

- We have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.
- If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.
- We have identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future or fail to maintain effective internal control over financial reporting. If we are unable to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely

affected, which could hurt our business, lessen investor confidence and depress the market price of our securities.

- We have not yet successfully completed any Phase 3 clinical trials, received any marketing approvals or commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.
- We depend significantly on our product candidates, OCS-01, OCS-02, and OCS-05, which we are developing for treatment of multiple diseases. If we are unable to complete the clinical development of any of these product candidates, if we are unable to obtain marketing approvals for any of these product candidates, or if any of these product candidates are approved and we fail to successfully commercialize the product candidate or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates may cause undesirable side effects, such as an increase in intraocular pressure caused by OCS-01, or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action. OCS-05 was placed on a clinical hold with the FDA in 2016. If we are unable to establish a NOAEL, or if our studies otherwise do not satisfy the FDA's requirements, OCS-05 may not receive clearance from the FDA to proceed with human clinical trials, may never receive regulatory approval from the FDA, and we may not be able to market and commercialize OCS-05 in the United States, which could materially adversely affect our business, financial condition, results of operations and growth prospects.
- The manufacture of OCS-02, a biologic, is highly complex, costly and requires substantial lead time to produce.
- Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.
- Even if we receive marketing approval for OCS-01, OCS-02, OCS-05, or any future product candidate, we may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receives regulatory approval and for any future product candidates.
- Our rights to develop and commercialize our technology are subject, in part, to the terms and conditions of licenses granted to us by others. In particular, we depend on licenses for development and commercialization rights to OCS-02 and OCS-05. If these rights are terminated or we fail to comply with our obligations under these agreements or any other license, collaboration or other agreement, we may be required to pay damages and we could lose intellectual property rights that are necessary for the development and protection of our product candidates.
- If we are unable to obtain, maintain, protect and enforce patent or other intellectual property protection for our current and future technology and products, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- The regulatory approval processes of the FDA and non-U.S. regulatory authorities are highly complex, lengthy, and inherently unpredictable. If we are unable to obtain regulatory approval for our product candidates, or to do so in a timely manner, we will be unable to generate product revenue and our business will be substantially harmed.

- If the FDA does not conclude that OCS-01 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for OCS-01 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

Risks related to our business, financial condition, capital requirements, or financial operations

We have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company specializing in novel therapeutics to treat ophthalmic diseases. We commenced operations in December 2017, have no products approved for commercial sale and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product, or conducted sales and marketing activities necessary for successful product commercialization.

Our limited operating history as a company and early stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, financial condition, results of operations and growth prospects may be impaired.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net losses of CHF 38.7 million and CHF 18.6 million for the fiscal years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of CHF 111.0 million.

We have invested significant financial resources in research and development activities, including for our product candidates. We do not expect to generate revenue from product sales in the foreseeable future, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter to quarter or year to year due to factors including the timing of clinical trials, any litigation that we may file or that may be filed against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

We expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates, if approved, or, in the future, establish and operate a manufacturing facility;
- continue our development, research and discovery activities;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- change or add contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;

- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- incur costs associated with becoming a public company;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause the share price of Ordinary Shares to decline.

As of December 31, 2022, we had cash and cash equivalents of CHF 19.8 million. We believe that these cash and cash equivalents will be sufficient to enable us to fund our current operations for at least the next twelve months period.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, if ever.

Our ability to generate revenue, alone or with strategic collaboration, and achieve profitability depends significantly on many factors, including:

- successfully completing research, preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in other countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates from third-party payors;

- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or non-U.S. regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more debt or equity financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable could decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of Ordinary Shares, all or any of which may adversely affect our viability.

Our operating and financial results are subject to concentration risk.

Our operational and financial results are subject to concentration risk. Our success will depend significantly on the development of OCS-01, OCS-02 and OCS-05, their regulatory approval in a limited number of jurisdictions and their commercialization by a limited number of commercial partners. Even if we are successful in developing and commercializing all of these products, our revenue will be dependent on a limited number of products that would account for a significant majority of our revenues. This concentration risk would increase to the extent we are successful in developing and commercializing fewer products as we would be dependent on a lower number of products for the significant majority of our revenues. Unfavorable changes or the non-occurrence of certain anticipated events with respect to any of these limited number of products, jurisdictions or commercial partners may disproportionately affect our global results.

If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the sale of equity securities. Developing our product candidates is expensive, and we expect to substantially increase our spending as we advance our product candidates in clinical trials. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding.

As of December 31, 2022, we had CHF 19.8 million in cash and cash equivalents. Although we believe that our existing cash and cash equivalents will be sufficient to fund our projected operations through at least the next 12 months, our estimate as to how long we expect our existing cash and cash equivalents to be available to fund our

operations is based on assumptions that may prove inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of Ordinary Shares to decline.

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

We are highly dependent on the research and development, clinical and business development expertise of our chief executive officer as well as other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Laws and regulations on executive compensation, including legislation in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. In Switzerland, legislation affecting public companies is in force that, among other things, (i) imposes an annual binding shareholders' "say on pay" vote with respect to the compensation of our executive committee and board of directors, (ii) generally prohibits severance, advances, transaction premiums and similar payments to members of our executive committee and board of directors, and (iii) requires companies to specify certain compensation-related matters in their articles of association, thus requiring them to be approved by a shareholders' vote.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees 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. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We will incur significant expenses and devote other significant resources and management time as a result of being a public company, which may negatively impact our financial performance and could cause our results of operations and financial condition to suffer.

We will incur significant legal, accounting, insurance and other expenses as a result of being a public company. The rules implemented by the SEC, and by the Nasdaq and Swiss corporate law require changes in corporate governance practices of public companies. We expect that compliance with these laws, rules and regulations and the move from a private to a public company will substantially increase our expenses, including our legal, accounting and information technology costs and expenses, and make some activities more time consuming and costly, and these new obligations will require attention from our executive officers and senior management and could divert their attention away from the day-to-day management of our business. We also expect these laws, rules and regulations and the move from a private to a public company to make it more expensive for us to obtain director and officer liability insurance, and we

may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Due to increased risks and exposure it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as officers. As a result of the foregoing, we expect a substantial increase in legal, accounting, insurance and certain other expenses in the future, which will negatively impact our financial performance and could cause our results of operations and financial condition to suffer. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of Ordinary Shares, fines, sanctions and other regulatory action and potentially civil litigation, which could adversely impact our business, results of operation, financial condition and the price of Ordinary Shares.

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

As of December 31, 2022, we had 28 employees. Additionally, we may rely on a number of temporary workers and contractors from time-to-time as needed. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. In addition, our success depends on our ability to attract and retain a talented workforce with a specialized set of skills. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We have identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future or fail to maintain effective internal control over financial reporting. If we are unable to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely affected, which could hurt our business, lessen investor confidence and depress the market price of our securities.

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2021 and 2020, we identified material weaknesses in our internal control over financial reporting. One material weakness identified was related to a lack of sufficient internal accounting personnel to support an efficient and structured financial statement close process and allow for the appropriate monitoring of financial reporting matters. During the preparation of our consolidated financial statements for the year ended December 31, 2022, we continued to identify control deficiencies in the process. While none of the identified control deficiencies resulted in a material misstatement to the Company's financial statements, as each of these control deficiencies could potentially result in a misstatement of our accounts or disclosures that might result in a material misstatement of our annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute a material weakness.

Status of Remediation Efforts for the Un-remediated Material Weakness

Until recently, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We are progressing with the activities necessary to implement the appropriate accounting policies, processes and controls required to comply with Section 404 of the Sarbanes-Oxley Act. We intend and have taken steps to remediate the material weakness described above through hiring additional qualified accounting and financial reporting personnel, and further enhance our accounting policies, procedures, and controls. In particular, in 2022, the Company has undertaken considerable efforts to strengthen the organization, systems and processes of our accounting and finance department, including additions of internal accounting personnel and strengthening of external resources to support

the Company's financial statement preparation reporting and reporting processes. Furthermore, the company continues to implement remediation actions to address the material weakness in 2023. These steps include addition of accounting personnel to support an efficient and structured financial statement close process and allow for the appropriate monitoring of financial reporting matters, enhancement of financial statements review procedures, and utilization of ERP system controls where applicable.

Remediation of Previously-Identified Material Weakness

The second material weakness identified in connection with the preparation of our consolidated financial statements for the years ended December 31, 2021 and 2020 was related to the maintenance of effective controls over information technology general controls for IT accounting and financial reporting systems. Specifically, IT systems and related operations are outsourced to third parties and therefore, we were not in a position to maintain user access controls, program change management controls, and testing and approval controls. As of December 31, 2022, we believe that we have remediated the material weakness through the implementation and controls testing of a new ERP system, as well as implementation of ERP system controls and manual controls. We have concluded that the material weakness has been remediated since each component for which management had identified a material weakness has been operating effectively during sufficient period of time as confirmed by the tests of operational effectiveness performed. However, there can be no assurance that we will not identify additional material weaknesses in the future.

In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

We cannot provide assurance that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weakness in our internal control over financial reporting nor that they will prevent or avoid potential future material weaknesses. If we are unable to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely affected, which could hurt our business, lessen investor confidence and depress the market price of our securities.

Economic, financial, geopolitical, epidemiological, or other conditions could result in business disruptions which could seriously harm our future revenue and financial condition and increase our costs and expenses.

Concerns over inflation, geopolitical issues, the U.S. financial markets, foreign exchange rates, capital and exchange controls, unstable global credit markets and financial conditions, COVID-19 pandemic, supply chain disruptions and economic issues, have led to periods of significant economic instability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, and increased unemployment rates. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive. In addition, there is a risk that one or more of our current or future service providers, manufacturers, suppliers and other partners could be negatively affected by difficult economic times, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

Our operations, and those of our contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), suppliers, and other third-party contractors and consultants upon which we rely, could be subject to wildfires, earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war (including trade wars), political instability or other conflicts, and other natural or man-made disasters or other events outside of our control that could disrupt our business. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the United States and other countries, following Russia's invasion of Ukraine, against Russia to date include restrictions on selling or importing goods, services or technology in or from affected regions and travel bans and asset freezes impacting

connected individuals and political, military, business and financial organizations in Russia. The United States and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact our business, financial condition and results of operations.

In addition, our available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of cash in our operating accounts and cash invested in money market funds. At any point in time, the funds in our U.S. operating accounts may exceed the Federal Deposit Insurance Corporation insurance limits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail. Our active treasury strategy is to minimize risk through natural hedging of currencies, bank diversification and cash preservation. To date, we have experienced no loss or lack of access to cash in our operating accounts or our invested cash or cash equivalents; however, we can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For example, we rely on third-party manufacturers to produce our product candidates. Our ability to obtain supplies of our product candidates, or other necessary supplies, could be disrupted if the operations of our suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay the marketing or development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage, our business, financial condition, and results of operations may be seriously harmed should the losses we suffer as a result of such property damage and/or business interruption substantially exceed our insurance coverage and we are required to make up for this shortfall.

Our business, financial condition and results of operations would suffer in the event of computer system failures, security breaches or other disruptions to our information technology systems.

In the ordinary course of our business, we collect, store and transmit sensitive data, including protected health information (“PHI”), intellectual property, proprietary business information and other personal information. We rely on information technology systems, networks and services, some of which are managed, hosted or provided by third parties, to assist in conducting our business. While we have not previously experienced a security breach or computer failure resulting in destruction, theft, or other loss of this information, and we and our service providers have implemented a number of security measures designed to protect against security breaches, these measures could fail or may be insufficient, resulting in the unauthorized disclosure, modification, misuse, unavailability, destruction, or loss of confidential information or personal information we collect, store and transmit. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to attack, damage or interruption from computer viruses, unauthorized access, cyberattacks, employee theft or misuse, human error, hacking, fraud, natural disasters, fire, terrorism, war and telecommunication and electrical failures.

Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, “phishing attacks”, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The use of cloud-based computing also creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers’ systems, portable media or storage devices. Furthermore, as a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption

of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Despite our efforts to ensure the security, privacy, integrity, confidentiality, availability, and authenticity of our information technology networks and systems, processing and information, we may not be able to anticipate or to implement effective preventive and remedial measures against all data security and privacy threats. We cannot guarantee that the recovery systems, security protocols, network protection mechanisms and other security measures that we or our third-party providers have integrated into our or their systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches will be adequate to prevent or detect service interruption, system failures, data loss or theft, or other material adverse consequences. No security solution, strategy, or measures can address all possible security threats or block all methods of penetrating a network or otherwise perpetrating a security incident. The risk of unauthorized circumvention of our security measures has been heightened by advances in computer and software capabilities and the increasing sophistication of hackers who employ complex techniques, including without limitation, the theft or misuse of personal and financial information, counterfeiting, “phishing” or social engineering, ransomware, extortion, publicly announcing security breaches, account takeover attacks, denial or degradation of service attacks, malware, fraudulent payment and identity theft. Furthermore, because the techniques used to sabotage, disrupt or to obtain unauthorized access to our systems, networks, or physical facilities in which data is stored or through which data is transmitted change frequently and often are not recognized until launched against a target, we or our third-party providers may be unable to implement adequate preventative measures or stop security breaches while they are occurring. We or our third-party providers may also experience security breaches that may remain undetected for an extended period. Even if identified, we or our third-party providers may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence, or we or our third-party providers may be unable to repair our or their systems in an efficient and timely manner. In addition, laws, regulations, government guidance, and industry standards and practices are rapidly evolving to combat these threats. We may face increased compliance burdens regarding such requirements from regulators and incur additional costs for oversight and monitoring of security risks relating to our own supply chain.

If we or our third-party providers were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. Unauthorized access to our systems, networks, or physical facilities could result in litigation with our customers or other relevant stakeholders, which may adversely affect our business. These proceedings could force us to spend money in defense or settlement, divert management’s time and attention, increase our costs of doing business, or adversely affect our reputation.

Further, we may not have adequate insurance coverage for security incidents or breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. Depending on the facts and circumstances of such an incident, the damages, penalties and costs could be significant and may not be covered by insurance or could exceed our applicable insurance coverage limits. If the impacts of a security incident or breach, or the successful assertion of one or more large claims against us, exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), it could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms, or at all, or that our insurers will not deny coverage as to all or part of any future claim or loss.

Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

We are subject to numerous laws, regulations, standards and other requirements related to personal information, privacy and data protection. Our actual or perceived failure to comply with such laws, regulations, standards and other requirements could negatively affect our business, financial condition or results of operations.

The global data protection landscape is rapidly evolving, and we are subject to numerous federal, state and foreign laws, regulations, standards and other requirements governing the collection, use, disclosure, retention and security of

personal information, such as information that we may collect in connection with clinical trials in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal or external policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations, enforcement actions, claims by third parties or damage to our reputation, any of which could have a material adverse effect on our business, results of operations and financial condition.

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations that govern the collection, processing, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, in the United States, the Health Insurance Portability and Accountability Act of 1996 (“*HIPAA*”) imposes among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by the U.S. Department of Health and Human Services, or HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission (the “*FTC*”) failing to take appropriate steps to keep consumers’ personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, (“*CCPA*”), which creates individual privacy rights for California consumers, including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households and may apply to us in the future. The CCPA provides for civil penalties for violations and also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act, or CPRA, significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., as other states or the federal government may follow California’s lead and increase protections for U.S. residents, which creates the potential for a patchwork of overlapping but different state laws and could increase our potential liability and adversely affect our business, financial condition and results of operations. For example, the Virginia Consumer Data Protection Act, a comprehensive privacy statute that shares similarities with the CCPA, CPRA and legislation proposed in other states, will take effect on January 1, 2023. Colorado enacted a similar law, the Colorado Privacy Act, which becomes effective on July 1, 2023. Similar laws have been passed and proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the

United States. The enactment of such laws could add layers of complexity to compliance in the U.S. market, increase our compliance costs and adversely affect our business, financial condition and results of operations.

Further, we are subject to international data protection laws and regulations, including the European Union General Data Protection Regulation and applicable national supplementing laws, or GDPR, which may apply to health-related and other personal information obtained outside of the United States. The GDPR imposes strict requirements for collection, control, sharing, disclosure, transfer, use and other processing of the personal data of individuals located in the European Economic Area (the “EEA”), including clinical trial data, as well as potential fines for noncompliant companies. The GDPR also imposes strict requirements relating to obtaining consent, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, taking certain measures when engaging third-party processors. Compliance with the GDPR may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our activities carried out in the context of our EEA operations.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the European Economic Area, or EEA, to the United States. On July 16, 2020, in a case known as Schrems II, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the Standard Contractual Clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. Additionally, new Standard Contractual Clauses that repealed the Standard Contractual Clauses adopted under the Data Protection Directive have been adopted on June 4, 2021 by the European Commission. As supervisory authorities issue further guidance on personal data export mechanisms, including on the new Standard Contractual Clauses, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we conduct clinical trials, it could affect our business. U.S. President Joseph Biden and the President of the European Commission announced on March 25, 2022 that they had reached an agreement in principle for a Trans-Atlantic Data Privacy Framework, which would allow personal data to flow freely and safely between the EU and participating U.S. companies. To that end, U.S. President Joseph Biden signed the Executive Order on Enhancing Safeguard for United States Signals Intelligence Activities, or EO, on October 7, 2022. The EO answers to certain shortcomings identified by the EU but it does not yet allow for the free transfers of personal data to the United States. Organizations must continue to implement a valid compliance mechanism for cross-border data transfers, such as the Standard Contractual Clauses, and conduct an assessment of the U.S. laws prior to transferring personal data to the United States. As the EO introduces safeguards for U.S. intelligence services’ access to European personal information, certain supplementary measures that have been implemented and are linked to these practices could be softened and the overall risk associated to the data transfer could be lowered. It is expected that a new EU-US data transfer framework will not be ready before Spring 2023.

Relatedly, following the United Kingdom’s withdrawal from the EEA and the EU, we are required to comply with both the GDPR and, separately, the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR sets out the UK-specific requirements related to data protection, including with respect to transfer of personal data outside of the UK, which increases our regulatory compliance burden. Further, in July 2022, the UK government published a Data Reform Bill that will amend the UK GPDR. This creates uncertainty with regard to the data protection regulatory regime in the United Kingdom and could result in the introduction of data privacy laws that materially deviate from the EU GDPR. This would expose us to two parallel regimes. Further, the entry into force of the US-UK Data Access Agreement on 3 October 2022 may put at risk the European Commission’s adequacy decision granted to the UK. If such adequacy decision were to be withdrawn, personal data would not flow freely between the UK and the EU and additional safeguards would need to be adopted, which could result in additional costs for us.

Any failure or perceived failure by us to comply with our legal obligations concerning privacy, data protection or information security could result in claims by data subjects, governmental investigations and enforcement action

against us, including fines, enforcement orders, imprisonment of company officials and public censure, (individual and collective) claims for damages by affected individuals and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, and operating results. Companies that must comply with the GDPR and UK GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, litigation (including private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests), regulatory investigations, enforcement actions that require us to change the way we use personal data, and/or prohibitions on the use of personal data. Such penalties may be in addition to any civil litigation claims by data subjects. We may not be successful in avoiding potential liability or disruption of business resulting from the failure to comply with these laws and, even if we comply with laws, we may be subject to liability because of a security incident. Further, complying with the applicable notification requirements in the event of a security breach could result in significant costs. Furthermore, future interpretations of existing data protection laws or regulations could be inconsistent with our current interpretations, increase our compliance burden, make it more difficult to comply, and/or increase our risk of regulatory investigations and fines.

EU data protection laws also require opt-in consent to send marketing emails or use cookies and similar technologies for advertising, analytics and other purposes – activities on which our marketing strategies may rely. Enforcement of these requirements has increased and a new regulation that has been proposed in the EU, known as the Privacy Regulation, may make these requirements more stringent and increase the penalties for violating them. Such restrictions could increase our exposure to regulatory enforcement action, increase our compliance costs, and adversely affect our business. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision and remains under review by the European Commission during this period.

Additionally, we contract with, and are accountable for, third-party service providers we engage to process personal data on our behalf, including our CROs. We cannot assure you that our service providers with access to our or our customers', suppliers', trial patients' and employees' personal information, including health data and other sensitive or confidential information, will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof. If they were to breach their contractual obligations or experience a security incident, such event could have an adverse effect on our business, including putting us in breach of our obligations under privacy laws and regulations, which could in turn adversely affect our business, financial conditions and results of operations. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

The Swiss Federal Act on Data Protection, or DPA, also applies to the collection and processing of personal data by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The DPA has been revised and adopted by the Swiss Parliament, and the revised version and its revised ordinances will enter into force on September 1, 2023. This revised law may lead to an increase in our costs of compliance, risk of noncompliance and penalties for noncompliance.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Compliance with applicable United States and foreign data protection, privacy and security laws, regulations and standards could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our ability, or our

that of our partners or suppliers, to operate in certain jurisdictions. Each of these constantly evolving laws can also be subject to varying interpretations. Any failure or perceived failure to comply could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity, and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We may not realize the benefits of acquired assets or other strategic transactions.

We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or product candidates, intellectual property, or technologies as well as pursue joint ventures or investments in complementary businesses. The success of any future strategic transaction depends on various risks and uncertainties, including:

- unanticipated liabilities related to investee companies or joint ventures;
- conflicts in economic or business interests with our joint ventures or investee companies;
- difficulties integrating acquired personnel, technologies, and operations into our existing business;
- retention of key employees;
- diversion of management's time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in or termination of our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to investee companies or joint ventures.

Foreign acquisitions and joint ventures are subject to additional risks, including those related to regulatory or compliance issues, integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations, and the particular economic, political, and regulatory risks associated with specific countries.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We could also incur losses resulting from undiscovered liabilities that are not covered by the indemnification we may obtain from the seller.

If we in-license product candidates or products or acquire businesses, we may not be able to realize the benefit of those transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies the transaction. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

The COVID-19 pandemic, which began in late 2019, may continue to affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019, caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

Our business, operations and clinical development timelines and plans had been and could in the future be adversely affected by COVID-19, and could be adversely impacted by other health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom we rely. The COVID-19 pandemic has affected multiple countries worldwide, including those where we have planned and ongoing preclinical studies and clinical trials. In addition, in response to the COVID-19 pandemic, many state, local and foreign governments put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, and the perception that such orders or restrictions could continue or, after being lifted, be reinstated for a period of time, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt our business and operations. While some of the orders and restrictions have been lifted, we cannot be certain that such orders and restrictions will not be reinstated in the future, particularly with the emergence of new variant strains of the COVID-19 virus. We may take further actions that alter our operations as may be required by federal, state or local authorities, or which we determine are in the best interests of our employees.

Moreover, our clinical development timelines and plans could be affected by the COVID-19 pandemic as we and the third-party manufacturers and clinical research organizations that we engage may face disruptions. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the COVID-19 pandemic or patients not having a desire to enroll in clinical trials due to concerns regarding COVID-19. We cannot be certain that we will not experience future delays in enrollment. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding COVID-19 or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak.

We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 could be adversely impacted.

We may experience disruptions that could severely impact our business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required IND or similar approval to initiate clinical trials from regulatory bodies in other jurisdictions;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- manufacturing disruptions;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- delays in the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak;
- interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays in the operations of the FDA or non-U.S. regulators which may impact review and approval timelines;
- delays in regulatory approvals for our product candidates due to the FDA or non-U.S. regulators focusing on clinical trials related to therapies and vaccines targeting COVID-19;
- refusal of the FDA or non-U.S. regulators to accept data, including from clinical trials in affected geographies or failure to comply with updated guidance and expectations of the FDA or non-U.S. regulators related to the conduct of clinical trials during the COVID-19 pandemic; and
- interruption or delays to our sourced discovery and clinical activities.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.

Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which the COVID-19 pandemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent government orders and mandates are lifted and normal economic and operating activities can resume. Further, while the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the COVID-19 pandemic has resulted in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent the

COVID-19 pandemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described herein.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Risks related to development and regulatory approval of our investigational therapies

The success of our product candidates, and our ability to generate revenue in the future, will depend upon a number of factors, many of which are beyond our control.

The success of our business, including our ability to finance and generate revenue in the future, primarily depends on the successful development, regulatory approval and commercialization of OCS-01, OCS-02, and OCS-05. The clinical and commercial success of our product candidates depend on a number of factors, including the following:

We are a clinical-stage biopharmaceutical company with no approved products. We have not yet successfully completed any Phase 3 clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.

- Our innovations to the treatments of retinal diseases, dry eye and glaucoma are unproven, and we do not know whether we will be able to successfully develop these products.
- Drug development is a lengthy, highly uncertain undertaking and involves a substantial degree of risk. The outcome of preclinical testing and earlier clinical trials may not be predictive of the success of later clinical trials. In addition, the regulatory approval processes of the Food and Drug Administration ("FDA"), and non-U.S. regulatory authorities are highly complex, lengthy, and inherently unpredictable, and the results of our clinical trials may not satisfy the requirements of the FDA or other regulatory authorities.
- Our business depends on the successful development and commercialization of OCS-01, OCS-02, OCS-05 and our other product candidates. To the extent the pipeline products are not commercially successful, our business, financial condition, and results of operations may be adversely affected.
- Our products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for these products may be smaller than we estimated.
- We have no experience manufacturing any of our product candidates at a commercial scale. We, or our CMOs, may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.
- The manufacturing of OCS-02, a biologic, and certain of our other product candidates are complex and highly regulated, and there are particular risks associated with manufacturing the products to commercial scale, including our reliance on third parties and the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair the commercialization or development efforts.
- If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business.

- If we fail to comply with our obligations under any license, collaboration or other agreements, including our license agreements with Novartis Technology LLC (“Novartis”) and Accure Therapeutics SL (“Accure”), such agreements may be terminated, we may be required to pay damages and we could lose intellectual property rights that are necessary for the development and protection of our product candidates.
- We will need substantial additional funding to support our operations and pursue our growth strategy. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate future commercialization efforts or one or more of our research and development programs. In addition, raising additional capital may cause dilution to our shareholders or restrict our operations.
- We have a limited operating history and have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur losses for the foreseeable future, which may make it difficult for investors to evaluate our current business and predict our future success and viability.
- We qualify as an “emerging growth company” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make Ordinary Shares less attractive to investors.
- We may from time to time report the results of clinical trials and some of those results may not meet our or market expectations. For instance, we expect to receive readouts from OCS-01 trials as soon as in mid-2023. Any results that we report that do not meet our or market expectations may negatively affect the trading price of Ordinary Shares.

The sizes of the market opportunities for our product candidates have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.

Our assessment of the potential market opportunity the product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal epidemiology and market research studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. The potential market opportunities of our product candidates are difficult to precisely estimate. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and our own epidemiology studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for our product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets where we lack familiarity with local regulations, environment and procedures and for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in other foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of

such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- imposition of restrictions on currency conversion or the transfer of funds;
- anti-competitive policies or anti-competitive practices which are condoned and the imposition of restrictions on investments and other measures that may be taken to protect the local industry in these foreign markets; and
- actions by non-U.S. regulators, governments, companies, or other entities which prevent us from entering into or benefiting from licensing agreements or other collaborations with non-U.S. companies, universities, research institutes, or other entities.

Our approach to the treatment of retinal disease with OCS-01 is unproven, and we do not know whether we will be able to successfully develop OCS-01.

OCS-01 is designed to deliver therapeutic drug levels to the retinal tissue by a topical route of administration as an eye drop formulation. There are currently no FDA-approved therapies that treat retinal diseases by a topical route of administration. Our future success partially depends on the successful development of OCS-01 which is based on this novel therapeutic approach. We have not yet demonstrated efficacy and safety for OCS-01 or any other product candidates in a pivotal trial or obtained marketing approval of any product candidate. OCS-01 may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. If we are unsuccessful in our development efforts, we may not be able to advance the development and commercialization of OCS-01.

Our potential approach to use OCS-02 for the treatment of dry eye disease in patients identified with a biomarker is unproven, and we do not know whether we will be able to successfully confirm the role of the biomarker and successfully develop OCS-02.

OCS-02 is in development for treating ophthalmic diseases including dry eye disease. One of our potential strategies for OCS-02 is also to develop it for patients identified with a biomarker to predict patients that may respond well to

OCS-02 treatment. There are currently no FDA-approved therapies that treat dry eye disease in this “precision medicine” way. If we choose to utilize this biomarker strategy, then our future success partially depends on the successful development of both OCS-02 and a companion diagnostic for the biomarker and our ability to demonstrate that patients with that biomarker are likely to respond well to OCS-02 treatment. We have not yet demonstrated efficacy and safety for OCS-02 or any other product candidates in patients with or without a biomarker in a pivotal trial or obtained marketing approval of any of our product candidates. OCS-02 may not demonstrate in patients with or without the biomarker any or all of the pharmacological benefits we believe it may possess. If we are unsuccessful in our development efforts, we may not be able to advance the development and commercialization of OCS-02.

Our approach to the treatment of ophthalmic disease with OCS-05 is unproven, and we do not know whether we will be able to successfully develop OCS-05.

OCS-05 is intended to prevent or reverse nerve damage (“neuroprotection”) in ophthalmic diseases in which patients lose vision due to nerve damage. There are currently no FDA-approved therapies that treat ophthalmic diseases in this “neuroprotective” way. Our future success partially depends on the successful development of OCS-05 which is based on this novel therapeutic approach. We have not yet demonstrated efficacy and safety for OCS-05 or any other product candidates in a pivotal trial or obtained marketing approval of any product candidate. OCS-05 may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. If we are unsuccessful in our development efforts, we may not be able to advance the development and commercialization of OCS-05.

We in-licensed OCS-05 from Accure in 2022. Accure was previously unable to establish a no-observed-adverse-effect-level (“NOAEL”) for the product candidate. We have engaged Toxicodynamix International LLC to manage toxicology studies relating to OCS-05. If our studies do not satisfy the FDA’s requirements, OCS-05 may not receive clearance from the FDA to proceed with human clinical trials, may never receive clearance from the FDA to proceed with human clinical trials and may never receive regulatory approval from the FDA, and we may be unable to market and commercialize OCS-05 in the United States.

We have not yet successfully completed any Phase 3 clinical trials, received any marketing approvals or commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.

Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research as well as Phase 1 and Phase 2 clinical trials for our product candidates. We have not yet demonstrated an ability to successfully complete Phase 3 clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We depend significantly on our product candidates, OCS-01, OCS-02, and OCS-05, which we are developing for treatment of multiple diseases. If we are unable to complete the clinical development of any of these product candidates, if we are unable to obtain marketing approvals for any of these product candidates, or if any of these product candidates are approved and we fail to successfully commercialize the product candidate or experience significant delays in doing so, our business will be materially harmed.

We depend significantly on the success of our lead product candidate, OCS-01, which we are developing for the treatment of patients with diabetic macular edema, and also for the treatment of patients with pain or inflammation following ocular surgery. In addition, we also depend on the success of OCS-02, which we are developing for the treatment of dry eye disease and non-infectious anterior uveitis and on the success of OCS-05, which we are initially developing for the treatment of Acute Optic Neuropathy.

We have invested a significant portion of our efforts and financial resources in the development of OCS-01 for the treatment of patients with diabetic macular edema as well as for the treatment of patients with pain or inflammation

following ocular surgery. There remains a significant risk that we will fail to successfully develop OCS-01 in one or both of these indications. The results of our Phase 2 clinical trials in each indication may not be predictive of the results of our Phase 3 clinical programs due, in part, to the fact that (i) we have no clinical data on OCS-01 therapy in diabetic macular edema in any clinical trial with treatment longer than 12 weeks, (ii) we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trial as compared to our Phase 2 clinical trial, (iii) we have no clinical data from a trial of similar size to that anticipated for our Phase 3 clinical trial, and (iv) we plan to conduct our Phase 3 clinical trials at many clinical centers that were not included in our Phase 2 clinical trial. The results of our Phase 2 clinical trials for inflammation and pain following ocular surgery may not be predictive of the results of the planned Phase 3 clinical study, due, in part, to the fact that we plan to conduct our Phase 3 clinical trial at clinical centers that were not included in our Phase 2 clinical trial. Furthermore, despite consultation with regulatory authorities, no assurance can be provided that the FDA or non-U.S. regulatory authorities would consider the planned Phase 3 clinical trials to be sufficient to serve as the basis for approval in either indication, or that the Phase 2 study for inflammation and pain following ocular surgery may be considered as one of the two required adequate and well-controlled trials to support a New Drug Application (NDA) submission, with such a final determination only made by the FDA or non-U.S. regulatory authorities following review of the NDA.

We cannot accurately predict when or if any of our product candidates will prove effective or safe in humans or whether these product candidates will receive marketing approval. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our obtaining marketing approval for and commercializing OCS-01, OCS-02, or OCS-05.

The success of OCS-01, OCS-02, OCS-05 and other product candidates will depend on many factors, including:

- successfully and timely completing preclinical studies and clinical trials that demonstrate to the satisfaction of the FDA, the European Medicines Agency, or EMA, or comparable non-U.S. regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the scope of the label that may be approved by applicable regulatory authorities, including the specific indication for which the product may be approved;
- whether we are required by the FDA or similar non-U.S. regulatory agency to conduct additional studies beyond those planned to support the approval and commercialization of OCS-01, OCS-02 and OCS-05;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors, including relative to alternative and competing treatments;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of our products both prior to and following any marketing approval of our product candidates;
- demonstrating consistent therapeutic efficacy of our products following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to our product candidates;
- scaling up our manufacturing processes and capabilities to support additional or larger clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;

- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices;
- developing and expanding our sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- minimizing and managing any delay or disruption to our ongoing or planned clinical trials, and any adverse impacts to the U.S. and global market for pharmaceutical products, as a result of the ongoing COVID-19 pandemic;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity; and
- protecting and enforcing our rights in our intellectual property portfolio.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business, financial condition, results of operations and growth prospects.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

The results from the prior preclinical studies and clinical trials for OCS-01, OCS-02, and OCS-05 may not necessarily be predictive of the results of future preclinical studies or clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timelines, the results from our prior clinical trials of our product candidates may not be replicated in these future trials. Many companies in the pharmaceutical and biotechnology industries (including those with greater resources and experience than us) have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain FDA or non-U.S.-regulatory authority approval. If we fail to produce positive results in our clinical trials of any of our product candidates, the development timelines, regulatory approvals and commercialization prospects for our product candidates, as well as our business and financial prospects, would be adversely affected. Further, our product candidates may not be approved even if they achieve their respective primary endpoints in Phase 3 registration trials. The FDA or non-U.S. regulatory authorities may disagree with our trial designs or our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. Furthermore, any of these regulatory authorities may also approve our product candidates for fewer or more limited indications than it requests or may grant approval contingent on the performance of costly post-marketing clinical trials.

Some of our clinical data results come from previous trials of less than 100 patients each, including a Phase 2a clinical trial of OCS-02 for the treatment of dry eye disease, a Phase 2a clinical trial of OCS-02 for the treatment of non-infectious anterior uveitis, and a Phase 1 dose-ranging study of OCS-05 in healthy volunteers, making it difficult to predict whether the favorable results from such trials will be repeatable in larger, more advanced clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We cannot assure you that the FDA or non-U.S. regulatory authorities would consider our completed and planned clinical trials used for an NDA submission to be sufficient to serve as the basis for approval of our product candidates for any indication. Even if the results of future Phase 3 clinical trials are positive, the FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that our product candidates are safe and effective. If we are required to conduct clinical trials of our

product candidates in addition to those we have planned prior to approval, we will need substantial additional funds, and cannot assure you that the results of any such outcomes trial or other clinical trials will be sufficient for approval.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidate that we may develop, including:

- clinical trials of our product candidates may not produce statistically significant, conclusive, or anticipated results, and we may decide, or regulators may require us, to conduct additional clinical trials or amend product development programs, or abandon product development programs entirely;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- Regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators, IRBs, or ethics committees may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our clinical trial material or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these trials or other tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining or unable to obtain marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

We may be required, or choose, to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, the trials are not well-designed, or research participants experience adverse safety outcomes.

Regulatory agencies, IRBs, or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with GCPs and other applicable non-U.S. regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, non-U.S. regulatory authorities and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current good manufacturing practices. Clinical trials may be placed on a full or partial clinical hold by the FDA, non-U.S. regulatory authorities, or us for various reasons, including, but not limited to: deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; deficiencies in the clinical trial operations or trial sites; deficiencies in the trial designs necessary to demonstrate efficacy; fatalities or other adverse effects arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments; the product candidates may not appear to be more effective than current therapies; or the quality or stability of the product candidates may fall below acceptable standards.

If we elect or are forced to suspend or terminate a clinical trial of any of our current or future product candidates, the commercial prospects for that product may be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

Any additional SAEs could result in the FDA delaying our clinical trials or denying or delaying clearance or approval of a product. Even though an adverse effect may not be the result of the failure of our drug candidate, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse effect is reviewed, and likely would do so in the event of multiple such events. Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse effects during the trials, may cause an increase in costs and delays in the submission of any New Drug Applications, or NDAs, to the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, financial condition, results of operations and growth prospects. Lengthy delays in the completion of clinical trials of our products would adversely affect our business and prospects and could cause us to cease operations.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate. Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Our product candidates may cause undesirable side effects, such as an increase in intraocular pressure caused by OCS-01, or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action. OCS-05 was placed on a clinical hold with the FDA in 2016. If we are unable to establish a NOAEL, or if our studies otherwise do not satisfy the FDA's requirements, OCS-05 may not receive clearance from the FDA to proceed with human clinical trials, may never receive regulatory approval from the FDA, and we may not be able to market and commercialize OCS-05 in the United States, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Unforeseen side effects varying in severity (from minor reactions to death) and frequency (infrequent or prevalent) from OCS-01, OCS-02, or OCS-05 could arise either during clinical development or, if approved, after marketing. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to

interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to subjects on a commercial scale after approval.

If OCS-01, OCS-02 or OCS-05 or any of our other product candidates are associated with serious adverse events, or SAEs, or other undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the SAEs, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

In addition, OCS-05 was placed on a clinical hold by the FDA in 2016. We licensed OCS-05 from Accure in 2022. Accure had conducted a limited set of animal regulatory toxicology studies in 2016 and submitted them to the FDA in an IND requesting the initiation of human testing. Upon review, the FDA found the data insufficient and asked for more animal toxicology data to be generated prior to human studies, thereby placing OCS-05 on the regulatory status of "clinical hold" pending the availability of the requested data. In response, Accure chose to withdraw the IND in 2017 rather than invest in further toxicology studies to address the FDA's request. Upon our license of OCS-05 from Accure in 2022, we reactivated the IND and plan to meet with the FDA in the first half of 2023 to agree on a comprehensive toxicology plan to satisfy the FDA's request. Other health authorities where clinical studies have been proposed, including the UK and France, have authorized us to commence clinical studies of selected doses and reinforced safety measures as in our European Phase 1 trial in Acute Optic Neuritis ("AON"). We have engaged Toxicodynamix International LLC to manage toxicology studies relating to OCS-05. If our studies do not satisfy the FDA's requirements, OCS-05 may not receive clearance from the FDA to proceed with human clinical trials, may never receive regulatory approval from the FDA, and we may be unable to market and commercialize OCS-05 in the United States, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable non-U.S. regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such adverse event findings also could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which would harm our business, financial condition, results of operations and growth prospects. In such an event, we could be required by the FDA or other comparable regulatory authorities to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable regulatory authorities could order us to cease further development of or deny, vary, or withdraw approval of our product candidates for any and all intended indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any comparable regulatory agency in a timely manner, if ever, and any of these occurrences may harm our business, financial condition, results of operations and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining U.S. or non-U.S. regulatory approval, a number of potentially negative consequences could result, including but not limited to, regulatory authorities suspending, withdrawing or varying approvals of such product, regulatory authorities requiring additional warnings on the label or otherwise requiring labeling to be updated or narrowed, us becoming liable for harm caused to patients and the diminution of our reputation, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product candidate, if approved, and could substantially increase the costs of commercializing such product, which would have a material adverse effect on our business, results of operation, financial condition and prospects.

If any of our product candidates receives approval, regulatory agencies including the FDA and other non-U.S. regulatory agencies will require that we regularly report certain information, including information about adverse events that may have caused or contributed by those products. The timing of adverse event reporting obligations would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other regulatory agencies could take action that may include criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or suspension of market approval, and delay in approval or clearance of future products.

Interim, topline and preliminary data from our clinical trials may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions may be subject to change following a more comprehensive review of the data. We also may use assumptions and estimates as part of our preliminary analyses of the data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Topline data also remain subject to audit and verification procedures before they can be finalized. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. For example, we may report interim analyses of only certain of the endpoints of the clinical trial, rather than all of the endpoints. Additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of Ordinary Shares. Further, investors may not agree with what we determine is the material or otherwise appropriate information to include in our public disclosures, and any information we determine not to disclose may ultimately be deemed significant by us or, if subsequently disclosed, by investors, with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Further, others, including regulatory agencies and investors may not accept our conclusions regarding such preliminary or interim analyses, which could impact the value of a particular program or the approvability or commercialization of the particular product candidate, or result in volatility in the price of Ordinary Shares.

The topline results that we report may differ significantly from the final results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. As a result, topline and interim data from clinical trials are subject to the risk that one or more of the reported clinical outcomes may materially change, and should be viewed with caution until the final data are available. If the preliminary or topline data that we report differ from the final results, or if others, including regulatory authorities, disagree with our conclusions, then our ability to obtain approval for, and to successfully commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects.

We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an investigational new drug application, or IND, or a clinical trial application, or CTA, will result in the FDA or comparable non-U.S. regulatory authorities, or any other regulatory authority as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful.

Any difficulties we experience relating to the initiation or completion of patient visits in clinical trials, including as a result of the SARS-CoV-2 virus, could delay regulatory approval for our product candidates. Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of clinical trials depends on our ability to recruit subjects to participate, as well as the completion of required follow-up periods. Patients may be unwilling to participate in clinical trials because of negative publicity from adverse events related to the biotechnology or pharmaceutical fields, competitive clinical trials for similar patient populations, the existence of current treatments or for other reasons. The timeline for recruiting patients, conducting studies and

obtaining regulatory approval of our product candidates may be delayed, which could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. Patient enrollment for any of our future clinical trials may be affected by other factors, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- the determination by the reviewing regulatory authority to require more costly or lengthy clinical trials than we currently anticipate;
- delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB, or ethics committee approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments on trials conducted by competitors for related technology that raises FDA, or comparable non-U.S. regulatory authorities, or any other regulatory authority concerns about risk to patients of the technology broadly; or if the FDA, EMA, National Medical Products Administration, or NMPA, or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- perceived risks and benefits of the product candidate under study;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, or cGCPs, requirements, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- availability of competing treatments and clinical trials;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate, including as a result of volatility in currency exchange rates;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, or comparable non-U.S. regulatory authorities, or any other regulatory authority, or if the IRBs or ethics committees of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, or comparable non-U.S. regulatory authorities, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the commencement or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We do, and may in the future, conduct clinical trials for our product candidates outside the United States, and the FDA and applicable non-U.S. regulatory authorities may not accept data from such trials.

We and investigator sponsors have conducted clinical trials, are conducting clinical trials, and may in the future choose to conduct one or more clinical trials outside of the United States. Although the FDA or applicable non-U.S. regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable non-U.S. regulatory authority may be subject to certain conditions or exclusions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many non-U.S. regulatory bodies have similar requirements. In addition, such non-U.S. studies would be subject to the applicable local laws of the jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable non-U.S. regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable non-U.S. regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

We rely on and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

We rely on, and expect to continue to rely on, third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also expect to rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and applicable regulatory requirements, including the FDA's regulations and good clinical practice, or GCP requirements, and equivalent non-U.S. and international standards, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and national, supranational, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties are expected to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We expect to rely heavily on these parties for the execution of our clinical trials and preclinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA and comparable non-U.S. regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other comparable non-U.S. regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine whether or not any of our clinical or preclinical trials comply with applicable GCP and GLP requirements. In addition, our clinical trials generally must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process, and adversely affect our operations.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to it from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA and comparable non-U.S. regulatory authorities, which could delay the regulatory approval process and adversely affect our operations.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to continuous subsequent regulatory obligations and scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for pharmacovigilance, manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies (if any) and submission of other post-market information, including both federal and state requirements in the United States and equivalent requirements of comparable regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP regulations and adherence to commitments made in any marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved conditions of use for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional data generation, including clinical trials. We will be

required to report certain adverse reactions and production problems, if any, to the FDA and comparable regulatory authorities, and to conduct surveillance to monitor the safety and efficacy of the product candidate. Any new legislation addressing drug safety or biologics issues could result in delays in product development or commercialization or increased costs to assure compliance.

We will have to comply with requirements concerning advertising and promotion for our product candidates, if approved. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions that vary throughout the world and must be consistent with the information in the product's approved label. As such, we may promote our products in ways that are not consistent with FDA-approved labeling, e.g., for indications or uses for which they do not have approval.

If a regulatory authority discovers previously unknown problems with one of our products such as adverse events of unanticipated severity or frequency, or if there are problems with the facility where the product is manufactured or the regulatory authority disagrees with the advertising, promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us. If we fail to comply with applicable regulatory requirements, a regulatory authority such as FDA may, among other things:

- issue warning or untitled letters;
- refer a case to the U.S. Department of Justice to impose civil or criminal penalties;
- begin proceedings to suspend or withdraw regulatory approval;
- issue an import alert;
- suspend our ongoing clinical studies;
- refuse to approve pending applications (including supplements to approved applications) submitted by us;
- ask us to initiate a product recall; or
- refer a case to the U.S. Department of Justice to seize and forfeit products or obtain an injunction imposing restrictions on our operations.

Any government investigation of alleged violations of law or regulations could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of us and our operating results will be adversely affected.

If we are not successful in discovering, developing, and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop, and potentially commercialize additional product candidates beyond our current portfolio to treat various conditions in a variety of therapeutic areas. We intend to do so by investing in our own drug discovery efforts, exploring potential strategic alliances for the development of new products, and in-licensing technologies. Identifying new product candidates requires substantial technical, financial, and human resources. We may fail to identify promising product candidates and, even if we do identify such product candidates, we may fail to successfully develop and commercialize such product candidates for many reasons, including:

- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may be covered by third parties' patents or other intellectual property and proprietary rights;

- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- we may be incapable of producing a product candidate in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by patients, the medical community or third-party payors.

We have several early-stage programs in preclinical development as we seek to expand our pipeline. Preclinical development programs in the biotechnology industry carry high risk of failure. If any of these programs fails due to, among others, adverse formulation, pharmacokinetic, pharmacodynamics, or safety, we may need to terminate the program. If we are unsuccessful in identifying and developing additional product candidates and progressing those into clinical development, our potential for growth may be impaired.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. As a result of the foregoing, our business, operations and prospects could be materially adversely affected.

We may choose to discontinue developing or commercializing any of our product candidates, or may choose to not commercialize product candidates in approved indications, at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from a competing product, cost concerns, manufacturing challenges, analysis of preclinical and clinical trial results or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. As a result, our business, financial condition, results of operations and growth prospects may be adversely affected.

Risks related to our manufacturing activities

We have no experience manufacturing any of our product candidates at a commercial scale. If we or any of our third-party manufacturers encounter difficulties in production, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to establish a commercially viable cost structure.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we need to manufacture them in small and large quantities. The manufacturing processes for OCS-02 and OCS-05 have never been tested at commercial scale, and the process validation requirement (the requirement to consistently produce the active pharmaceutical ingredient used in these drug candidates in commercial quantities and of specified quality on a repeated basis and document our ability to do so) for each of OCS-01, OCS-02, and OCS-05 has not yet been satisfied. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in

sufficient quality and quantity, the development, testing and clinical trials of our product candidates may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity.

In addition, the manufacturing process for any products that we may develop is subject to FDA, European Commission, NMPA and other non-U.S. regulatory authority approval processes and continuous oversight. We will need to contract with manufacturers who can meet all applicable FDA, European Commission, EMA, NMPA and other non-U.S. regulatory authority requirements, including complying with current good manufacturing practices, or cGMPs, regulations on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, European Commission, EMA, NMPA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, NMPA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture of OCS-02, a biologic, is highly complex, costly and requires substantial lead time to produce.

Manufacturing OCS-02, a biologic, involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells, and harvesting and purifying the biologic produced by them. These processes require specialized facilities, highly specific raw materials and other production constraints. As a result, the cost to manufacture a biologic is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Because of the complex nature of this product candidate, we need to oversee manufacture of multiple components that require a diverse knowledge base and specialized personnel.

Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as OCS-02 generally cannot be adequately characterized prior to manufacturing the final product. As a result, an assay of the finished product is not sufficient to ensure that the product will perform in the intended manner. Accordingly, we expect to employ multiple steps to attempt to control our manufacturing process to assure that the process works and the product or product candidate is made strictly and consistently in compliance with the process.

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, improper storage or transfer, inconsistency in yields and variability in product characteristics. Even minor deviations from normal manufacturing, distribution or storage processes could result in reduced production yields, product defects and other supply disruptions. Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt commercialization. Production of additional drug substance and drug product for OCS-02 may require substantial lead time. In the event of significant product loss and materials shortages, we may be unable to produce adequate amounts of our product candidates or products for our operational needs, which would materially adversely affect our business, financial condition and results of operations.

Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. We and our third-party manufacturing partner are engaged in efforts to reduce the expected costs for OCS-02. In the future, if the proposed manufacturing plans to reduce OCS-02 costs does not succeed when producing OCS-02 at commercial scale, we may not be able to proceed with OCS-02 commercialization, if approved.

Any of the foregoing could potentially materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks related to our future commercialization activities

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial successes of OCS-01, OCS-02, or OCS-05, if approved, will depend significantly on attaining broad adoption and use of the products by physicians and patients for approved indications, and any of these product candidates may not be commercially successful even if shown to be effective in clinical trials. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which they are approved;
- efficacy and potential advantages compared to alternative treatments, including the existing standard of care;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration by physicians or patients;
- patient satisfaction with the results, administration and overall treatment experience;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA-approved, or comparable non-U.S. regulatory authorities-approved labeling for the applicable product;
- any FDA or comparable non-U.S. regulatory authority's requirement to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

Even if we receive marketing approval for OCS-01, OCS-02, OCS-05, or any future product candidate, we may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that

a product will be paid for in all cases or at a rate that covers costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Pricing and reimbursement outside of the United States vary widely and are constantly evolving, with requirements and limitations becoming increasingly strict.

Coverage and reimbursement by a third-party payor or competent foreign authority may depend upon a number of factors, including the third-party payor's or competent foreign authority's determination that use of a product is:

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

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors or competent foreign authorities to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness

of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved, which would materially adversely affect our business, results of operations, financial condition and growth prospects.

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

The development and commercialization of new drug products are highly competitive. We face competition with respect to our product candidates that we may seek to develop or commercialize, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors may

also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

The diabetic macular edema market is already served by multiple approved products, such as ranimizumab, aflibercept, brolucizumab, faricimab VEGF inhibitors as well as dexamethasone and fluocinolone acetonide intravitreal implants. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to OCS-01. Companies that we are aware are commercializing or are developing therapeutics for diabetic macular edema include large companies with significant financial resources, such as Roche (Genentech), Novartis, Bayer, Regeneron, Abbvie (Allergan), and Alimera Sciences. In addition, OCS-01 will compete with the current status quo practice of treating diabetic macular edema, which is often observing and not treating milder patients before they often progress to invasive treatments.

The post-operative inflammation and pain market is already served by multiple approved steroid products, such as difluprednate ophthalmic emulsion, loteprednol etabonate ophthalmic gel and suspension, prednisolone acetate ophthalmic suspension, among others. These drugs are well established therapies with multiple generics in the market and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to OCS-01. Companies that we are aware are commercializing or are developing therapeutics for post-operative inflammation and pain include large companies with significant financial resources, such as Bausch + Lomb, Kala Pharmaceuticals, Alcon Laboratories, Abbvie (Allergan), TEVA Pharmaceuticals and Novartis.

The dry eye disease market is already served by multiple approved products, such as Cyclosporine ophthalmic emulsion and solution, lifitegrast ophthalmic solution, loteprednol etabonate ophthalmic suspension, varenicline solution. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to OCS-02. Companies that we are aware are developing therapeutics for dry eye disease include large companies with significant financial resources, such as Abbvie (Allergan), Sun Pharmaceuticals, Novartis, Alcon and Viartis. In addition, over the counter products are currently available for the treatment of dry eye disease which may impact sales of our products.

The non-infectious anterior uveitis market is already served by multiple approved steroid products indicated to treat inflammation of the eyes, such as prednisolone acetate suspension, loteprednol etabonate ophthalmic formulations, dexamethasone sodium phosphate formulations, fluorometholone ophthalmic suspension, among others. These drugs are well established therapies with multiple generics in the market and are widely accepted by physicians, patients and third-party payors, which may make it difficult to convince these parties to switch to OCS-02. Companies that we are aware are commercializing or are developing therapeutics for non-infectious anterior uveitis include large companies with significant financial resources, such as Abbvie (Allergan), Bausch and Lomb, Novartis, among others.

The glaucoma market is already served by multiple approved drug classes to reduce elevated intraocular pressure, such as Alpha Agonists, Beta Blockers Carbonic Anhydrase Inhibitors, Cholinergic (Myotic), Prostaglandin Analogs, Rho Kinase Inhibitors and combination products, however no drug for neuro protection has been approved so far. These drugs are well established therapies with multiple generics in the market and are widely accepted by physicians, patients and third-party payors. OCS-05 is not meant to replace IOP lowering but rather be an add-on to IOP lowering to tackle neuroprotection. Companies that we are aware are commercializing or are developing therapeutics for glaucoma include large companies with significant financial resources, such as Novartis, Abbvie (Allergan), Bausch and Lomb, Akorn, Teva Pharmaceuticals, Pfizer, Merck, Sun Ophthalmics among others.

In addition to competition from other companies targeting the diseases which we target, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies or drug delivery devices. Our commercial opportunity for any of our product candidates could also be reduced or eliminated if our competitors develop and commercialize new products that are safer, more effective, are more convenient, or are less expensive than our products. The competitors also may obtain FDA or other non-U.S. regulatory approval for their products more rapidly than we may obtain approval for our candidates, which could result in competitors establishing a strong market position before we are able to enter the market for a new product candidate. If our product candidates are not perceived as more effective, safe, cost-effective, or otherwise medically beneficial than current practices or products in their respective target market segments, then our commercial opportunities will be negatively impacted. If we are unable to demonstrate the value of our product candidates based on our clinical data, patient experience, or real-world evidence, future successful commercialization of such product candidates could be adversely affected.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, including Medicare and equivalent foreign health insurance programs, seeking to encourage the use of generic products. For example, a generic version of Restasis® to treat dry eye disease received FDA approval in February 2022. Generic products are generally offered at lower prices than branded products, and consequently, after the introduction of a generic competitor, a significant percentage of the sales of any branded product may be lost to the generic product. Accordingly, competition from generic products could have a material adverse impact on our ability to successfully commercialize OCS-02 for dry eye disease or any other product candidate or indication, if approved, or negatively impact sales or pricing of our products or our ability to gain market acceptance or market share.

Many of our current and future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in clinical trials. We face an even greater risk for any products we develop and sell commercially. Off-label use or misuse of our products if and when commercialized may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- significant costs to defend the related litigation;
- significant delays in product launch;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We may need to purchase insurance coverage as we expand our clinical trials and should we eventually realize sales of any product candidate for which we obtain marketing approval. Insurance coverage is increasingly expensive, restrictive and narrow. We may not be able to maintain insurance coverage at a reasonable cost, upon adequate terms or in a sufficient amount necessary to protect us against losses due to product liability or other similar legal actions that may arise. A successful product liability claim or series of claims brought against us which substantially exceeds

our insurance coverage will require us to make up the shortfall, which may in turn require us to drawdown on our cash reserve, and harm our business, financial condition, results of operations and growth prospects.

Risks related to our reliance on third parties

We may enter into collaborations with third parties for the development and commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may enter into a combination of exclusive and non-exclusive collaboration arrangements with third parties to develop or commercialize some or all of our product candidates. We also may enter into arrangements with third parties to perform these services in the United States and other jurisdictions if we do not establish our own sales, marketing and distribution capabilities in the United States and other jurisdictions for our product candidates or if we determine that such arrangements are otherwise beneficial. We also may seek collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. While we are not currently party to any such arrangement, our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in the future in these arrangements.

Collaborations that we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property or proprietary rights or may use our intellectual property or proprietary rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary rights or expose us to potential litigation and liability;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments, or be able to recover any costs and expenses incurred by us under the collaboration arrangement. If we do not receive the funding we expect, or recover any costs and expenses incurred under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receives regulatory approval and for any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain the active pharmaceutical ingredients, or APIs, and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, and if we are unable to seek suitable replacements in a timely manner or at all, we may face delays or be unable to continue to develop or commercialize our products and product candidates.

We do not have direct control over whether or not our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with APIs and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP regulations for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result.

We may be unable to establish any further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party or us;

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible early termination of the agreement by us at a time that requires us to pay a cancellation fee;
- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting; and
- the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business, financial condition, results of operations, and prospects.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing our products or product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

By relying on third-party manufacturers for outsourced, custom manufacturing, we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of manufacturing capabilities. If we, or our CMOs, encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or halted, or we may be unable to maintain a commercially viable cost structure, which would materially adversely affect our business, results of operations and financial condition.

If third-party suppliers on which we rely fail to successfully scale up their production of our product candidates, we may face delays and lost opportunities with our development or future commercialization efforts.

In order to conduct larger or late-stage clinical trials for a product candidate and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities more cost-effectively and, in certain cases, at higher yields than they currently achieve. If our third-party contractors are unable to scale up the manufacture of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of

the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries.

We rely on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our reliance on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Our rights to develop and commercialize our technology are subject, in part, to the terms and conditions of licenses granted to us by others. In particular, we depend on licenses for development and commercialization rights to OCS-02 and OCS-05. If these rights are terminated or we fail to comply with our obligations under these agreements or any other license, collaboration or other agreement, we may be required to pay damages and we could lose intellectual property rights that are necessary for the development and protection of our product candidates.

We currently and may in the future license from third parties certain intellectual property relating to current and future product candidates. For example, we are party to various license agreements, including with Novartis and Accure, that we depend on for rights to OCS-02 and OCS-05, respectively. These agreements impose, and other potential agreements we may enter into with third parties may impose, diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under the Novartis Agreement (as defined below) and Accure Agreement (as defined below), for example, we are obligated to make payments to the counterparty upon us achieving certain development or commercialization milestones and to make royalty payments to Novartis and Accure on net product sales of OCS-02 and OCS-05, respectively.

We also have diligence and development obligations under the Novartis Agreement and Accure Agreement. Generally, these diligence obligations require us to use commercially reasonable efforts to develop, manufacture, seek regulatory approval for and commercialize the licensed products. If we fail to comply with our obligations under current or future license agreements, use the licensed intellectual property in an unauthorized manner or otherwise breach a license agreement, our counterparties may have the right to terminate these agreements, in which event we might not have the rights or the financial resources to develop, manufacture or market any licensed product that is covered by these agreements. Future counterparties also may have the right to convert an exclusive license to non-exclusive in the territory in which we fail to satisfy our diligence obligations, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of 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, seek alternative sources of financing or cause us to lose our rights under these agreements, including our rights to OCS-02, OCS-05 or other important intellectual property or technology. Any of the foregoing could prevent us from commercializing OCS-02 or OCS-05 or cause a competitor to gain access to the licensed technology, which could have a material adverse effect on our operating results and overall financial condition.

Our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could 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 prospects. Disputes may arise between us and our licensors or future licensors, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;

- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to transfer or assign the license, or to sublicense patents and other intellectual property rights to third parties;
- our diligence obligations 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 any of our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Additionally, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. Some of our in-licensed patent rights are sublicensed to us pursuant to parent license agreements we are not a party to. If any such parent licenses terminate, whether due to our licensor's breach of the parent license agreement or for other reasons outside of our control, we could lose our rights to such sublicensed patent rights. Furthermore, if other third parties have ownership rights to our in-licensed patents, the license granted to us in jurisdictions where the consent of a co-owner is necessary to grant such a license may not be valid, in any case, and such co-owners may be able to license such patents to our competitors, and our competitors could market competing products and technology. In addition, certain of our in-licensed patent rights are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patent rights. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patent rights may be adversely affected. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses. Some of our in-licensed patent rights are subject to pre-existing rights granted by the licensor to third parties and our acquired technologies and current or future licensed technology may also be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, certain of our current or future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. If we are limited in our ability to utilize acquired technologies or current or future licensed technologies, or if we lose our rights to critical acquired or in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and current or future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

For more information on our license agreements with third parties, please see the section entitled “*Business Overview—Material Licenses, Partnerships and Collaborations.*”

Risks related to our intellectual property

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

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. These legal measures afford only limited protection, and competitors or others may gain access to our intellectual property and proprietary information. Our success depends in part on our ability to obtain, maintain, expand, enforce and defend the scope of our intellectual property protection in the United States and other countries with respect to our product candidates.

We have sought and will continue to seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. However, the patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents or patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Additionally, in some instances, we have submitted and expect to submit provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with competitive advantage. Any failure to obtain or maintain patent and other intellectual property protection with respect to our product candidates could harm our business, financial condition and results of operations. Additionally, although we seek to enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

As of December 31, 2022, our owned and exclusively in-licensed patent portfolio included 11 issued U.S. patents, five issued European patents validated in multiple jurisdictions, and 45 issued patents in other foreign jurisdictions, as well as six pending non-provisional U.S. patent applications, 65 foreign pending patent applications, including five pending European patent applications, and one pending PCT application related to our different product candidates, namely, OCS-01, OCS-02, OCS-03, OCS-04 and OCS-05. Please see the section entitled “*Business Overview – Intellectual Property*” for further details on our intellectual property portfolio. The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our licensors will be successful in protecting our product candidates by obtaining, maintaining, enforcing and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our products and product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

We may also choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. PCT applications do not issue directly as patents, and national phases of such PCT application must be filed within 30 months after the earliest priority date of such PCT application. There can be no assurance that any national phases of such PCT application will result in an issued patent, or that the claims in national phases of such PCT application will not be narrowed during prosecution or, even if issued, be broad enough to adequately cover OCS-03. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date.

Moreover, we are, and could become in the future, a licensee of a third party's patents or patent applications and we may not have the right to control the preparation, filing or prosecution of such patent applications, or to maintain, enforce or protect the patents in-licensed from those third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents or patent applications may not be prosecuted, maintained, enforced or protected in a manner consistent with the best interests of our business. We also cannot be certain that patent prosecution and maintenance activities by any of our licensors will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If any of our licensors fail to do so, this could cause us to lose rights in any applicable intellectual property, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications under a license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution. If our current or future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If disputes over intellectual property that we license prevents or impairs our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we own, license, or may own or license in the future with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade other companies from collaborating with

us to develop product candidates, and threaten our ability to commercialize our product candidates, if approved. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, there is a risk that we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are highly uncertain. Our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned and in-licensed patents or narrow the scope of patent protection for our product candidates.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or in-licensed patent rights or the patent rights of others. In particular, the costs of defending patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or in-licensed patents and patent applications is threatened, it could dissuade companies from collaborating to license, develop or commercialize current or future product candidates. We may not be aware of all third-party intellectual property rights potentially relating to our products, product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our owned and in-licensed patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. We cannot ensure that we do not infringe, misappropriate or otherwise violate any patents or other intellectual property or proprietary rights held by others or that we will not infringe, misappropriate or otherwise violate intellectual property or proprietary rights held by others in the future. If our products were found to infringe, misappropriate or otherwise violate any proprietary intellectual property or right of another party, we could be required to pay significant damages or license fees to such party and/or cease production, marketing and distribution of those products. Litigation may also be necessary to defend infringement, misappropriation or other violation claims of third parties or to enforce patent or other intellectual property rights we hold or protect trade secrets or techniques or other intellectual property we own. Further, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents or other intellectual property, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our owned or in-licensed patents invalid, unenforceable, or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and patents in which we or our licensors have an interest may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent terms can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment). The scope of patent protection may also be limited. In addition, the laws of foreign

jurisdictions may not protect our rights to the same extent as the laws of the U.S. For example, certain countries outside of the U.S. do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the U.S. having similar scope to those we have obtained or may obtain in the future in the U.S.

It is possible that defects of form in the preparation or filing of our owned or in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary, and our competitors could market competing products and technology. Our competitors may have a competitive advantage due to their size, capital resources and greater development and commercialization capabilities. In addition, companies may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product, and our customers may be forced to stop using the relevant products. If we or our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our own.

Depending upon the timing, duration and specifics of FDA marketing approval of future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval. This extension is based on the first approved use of a product and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch our product earlier than might otherwise be the case.

Obtaining and maintaining intellectual property, including patent protection, depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental agencies, and our intellectual property, including patent protection, could be reduced or eliminated for noncompliance with these requirements.

The patent prosecution process is expensive, time-consuming and complex. Periodic maintenance, renewal, annuity and various other fees on any issued patent are due to be paid to the USPTO and other foreign governmental agencies in several stages over the lifetime of the intellectual property. The USPTO and various national or international agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in

abandonment or lapse of the intellectual property, resulting in partial or complete loss of rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or any of our licensors fail to maintain the intellectual property covering our product candidates, our competitors may be able to enter the market, which would have an adverse effect on our business, financial condition and results of operations.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates, if approved. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe, misappropriate or otherwise violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments.

We may become subject to third-party claims or litigation alleging infringement, misappropriation or other violation of such third party's patents or other intellectual property or proprietary rights, or seeking to invalidate our patents or other intellectual property or proprietary rights, which could be costly, time consuming, and, if successfully asserted against us, may delay or prevent the development and commercialization of any of our product candidates.

Our commercial success depends in part on us and our licensors avoiding infringement, misappropriation and other violations of the patents and other intellectual property or proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment, or limit the duration of the patent protection of our technology. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing, misappropriating or otherwise violating their patents or other intellectual property or proprietary rights or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents or other intellectual property or proprietary rights do not exist which might be enforced against our product candidates, resulting in either an injunction prohibiting sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Accordingly, the market price of Ordinary Shares may decline. Such announcements could also harm our reputation or the market for future products, which could have a material adverse effect on our business.

Lawsuits or other proceedings to protect or enforce our patents, the patents of any licensors or our other intellectual property rights could be expensive, time consuming, and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use or misappropriations, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more patents of us or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counterclaims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant

proceedings such as ex parte reexaminations, inter partes review, post-grant review or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, for any patents and patent applications that we license from third parties, we may have limited or no right to participate in the defense of such licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

Furthermore, even if our patents or other intellectual property or proprietary rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead award us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our current or future owned or in-licensed patents, any patents that may be issued as a result of our current or future owned or in-licensed patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of us or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms or at all, our customers may be forced to stop using our products.

We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property or other proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms or at all. Any litigation or other proceedings to enforce our intellectual property or proprietary rights may fail, and even if successful, may result in substantial costs and distract the management and other employees.

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

Changes in U.S. or foreign patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States government has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

In 2011, the Leahy-Smith America Invents Act (the “*Leahy-Smith Act*”) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. These also include provisions that switched the U.S. from a “first-to-invent” system to a “first-to-file” system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. A third-party that files a patent application in the USPTO after March 2013, but before the Company could therefore be awarded a patent covering an invention even if the Company had made the invention before it was made by such third-party. This will require the Company to be cognizant of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, the Company cannot be certain that it was the first to file any patent application related to its products or invent any of the inventions claimed in its patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate the Company’s patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of the Company’s patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on the Company’s business, financial condition, and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering our product candidates throughout the world would be prohibitively expensive. Furthermore, the requirements for patentability and obtaining other intellectual property protection may differ in certain countries, particularly developing countries. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the

United States. Competitors may use our technologies in jurisdictions where we have not obtained patent or other intellectual property protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent or other intellectual property protection, but where patent or other intellectual property enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents or other intellectual property protection and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties for a wide variety of services, including the manufacture and continuing development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our trade secrets in part by entering into agreements containing confidentiality and use restrictions and obligations prior to disclosing

proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and may have an adverse effect on business and results of operations.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of agreements with third parties, independent development or publication of information by any of the third-party collaborators. A competitor's discovery of our trade secrets could impair our competitive position and have an adverse impact on our business.

If we fail to protect the confidentiality of our trade secrets and other proprietary information, the value of our product candidates and our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how or other proprietary information that is not patentable or that we elect not to patent. Trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes and we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property rights. In addition, monitoring unauthorized use and disclosure of our intellectual property rights by employees, consultants and other third parties who have access to such intellectual property or other proprietary rights is difficult. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors or third parties, despite the existence generally of these confidentiality restrictions. There can be no assurance that such employees, consultants, advisors or third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by third parties, including our competitors.

We may be subject to claims that our employees, consultants or independent contractors have infringed, misappropriated or otherwise violated the intellectual property of a third party, including trade secrets or know-how of their former employers or other third parties.

We may be subject to claims that our employees or consultants have wrongfully used for our benefit or disclosed to us confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, or at research institutions. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us and seek to protect our ownership of intellectual property rights by ensuring that our agreements with employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. To the extent that our employees, consultants or contractors use intellectual property rights or proprietary information owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents or other intellectual property or proprietary rights. Litigation may be necessary to defend against any of these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

If we fail to validly execute invention assignment agreements with our employees and contractors involved in the development of intellectual property, the value of our products, business and competitive position may be harmed. Our patent rights and other intellectual property may also be subject to priority, ownership or inventorship disputes, interferences, and similar proceedings.

To maintain the confidentiality of our trade secrets, proprietary information and other intellectual property rights, we generally have confidentiality and invention assignment provisions in place with our employees, consultants, suppliers, contract manufacturers, collaborators, and others upon the commencement of a relationship. However, we may not enter into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or who conceives or develops intellectual property rights that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, 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. There can be no assurance that such agreements will be upheld in the face of a potential challenge or that third parties will not breach their agreements with us, or that we will have adequate remedies for any breach.

We may also be subject to claims that former employees, collaborators, or other third parties have an interest in our current or future patents and patent applications or other intellectual property rights, including as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents and patent applications, such co-owners rights may be subject, or in the future subject, to assignment or license to other third parties, including competitors. In addition, we may need the cooperation of any such co-owners to enforce any such patents and any patents issuing from such patent applications against third parties, and such cooperation may not be provided. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property rights to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity, despite the inclusion of valid, present-tense intellectual property assignment obligations. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim.

If we or our licensors are unsuccessful in any priority, validity (including any patent oppositions), ownership or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, 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 the product candidates we may develop. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we are successful in priority, inventorship or ownership disputes, such disputes could result in substantial costs and be a distraction to management and other employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

Intellectual property rights do not necessarily address 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 products that are similar to our current and future product candidates we intend to commercialize that are not covered by the patents that we exclusively licensed and have the right to enforce;

- we or any of our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or any of our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or in-licensed intellectual property rights;
- others may have access to the same intellectual property rights licensed to us on a nonexclusive basis;
- it is possible that our future patent applications will not lead to issued patents;
- issued patents that we own or in-license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may choose not to seek patent protection for some of our proprietary technology to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how; and
- we may not develop additional proprietary technologies that are patentable.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our current and future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets and markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. At times, competitors may adopt trade names or trademarks similar to us, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how trademarks and trade names may be used, a breach of these agreements or misuse of such trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, growth prospects, operating results and financial condition.

Risks related to government regulation

The regulatory approval processes of the FDA and non-U.S. regulatory authorities are highly complex, lengthy, and inherently unpredictable. If we are unable to obtain regulatory approval for our product candidates, or to do so in a timely manner, we will be unable to generate product revenue and our business will be substantially harmed.

The processes that must be followed to obtain approval by the FDA and non-U.S. regulatory authorities to market a pharmaceutical product are highly complex and unpredictable, and typically take many years following the commencement of clinical trials. A company's ability to obtain such an approval, and the time necessary to obtain it, depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and non-U.S. regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested.

Further, development of a company's product candidates and/or regulatory approval may be impacted or delayed by events beyond our control. For example, events such as a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or the FDA's diversion of resources to handle the SARS-CoV-2 virus public health emergency and pandemic, may result in significant reductions to the FDA's budget, employees and operations, and could lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. In addition, the impact of SARS-CoV-2 virus pandemic may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for our product candidates. Moreover, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs or biologics license applications, or BLAs.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or non-U.S. regulatory authorities may disagree with the design, implementation, or results of our clinical trials;
- the FDA or non-U.S. regulatory authorities may determine that our product candidates are not safe and effective, are insufficiently effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission to obtain regulatory approval;
- we may be unable to demonstrate to the FDA or non-U.S. regulatory authorities that a product candidate's risk-benefit ratio for our proposed indication is acceptable;

- the FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This complex and lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, or a failure to obtain such approval in a timely manner, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may face difficulties in commercializing and achieving reimbursement of our products from changes to current regulations and future legislation.

In the United States, the European Union and other jurisdictions there have been a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may be unable to successfully commercialize our products, and may not achieve or sustain profitability.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively, the “ACA”), substantially affects the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that can reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. There have been extensive judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as efforts and proposals to revise or repeal the law and its application, to control the prices at which pharmaceutical products are sold, and to implement other healthcare reform measures. Such efforts can be expected to continue in the future, but it is unclear what measures will be enacted or implemented, or how they might affect our business.

In addition, other legislative and administrative changes have been adopted in the United States in recent years, and others continue to be proposed. These changes include reductions to payments made under the Medicare program. In addition, during 2021, the Biden administration proposed additional potential legislative and administrative actions to, among other things, reform drug pricing. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles.

These recent laws, administrative decisions and proposals, and any new ones that follow, may result in additional reductions in Medicare payments and other healthcare funding, which could have a material adverse effect on customers for our products and product candidates, if approved, and accordingly, on our results of operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that have been adopted, or may be adopted in the future, could result in more rigorous healthcare insurance coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other

government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

In the European Union and other countries, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In most EU member states, healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. Moreover, in the European Union, some EU member states may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product to currently available therapies. This Health Technology Assessment, or HTA, which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal product will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU member states. On December 15, 2021, the Health Technology Regulation, or HTA Regulation, was adopted. The HTA Regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA, European Union, or other jurisdictions' regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by, for example, United States Congress of the FDA approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

If the FDA does not conclude that OCS-01 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for OCS-01 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We plan to seek FDA approval through the Section 505(b)(2) regulatory pathway for OCS-01. The Hatch-Waxman Amendments added Section 505(b)(2) (“Section 505(b)(2)”) to the Federal Food, Drug and Cosmetic Act (the “FDCA”). Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA to rely in part on data in the public domain or the FDA’s prior conclusions regarding the safety and effectiveness of approved drug products, which could expedite the development program for OCS-01 by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval.

If we cannot pursue the Section 505(b)(2) regulatory pathway for OCS-01, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for OCS-01, and complications and risks associated with OCS-01, would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than OCS-01, which would likely adversely impact our competitive position and prospects. Even if we can pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that OCS-01 will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to thirty (30) months or longer depending on the outcome of any litigation. It is not uncommon for the owner of the NDA of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions could significantly delay, or even prevent, the approval of a new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to earlier approval.

Moreover, even if OCS-01 is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

The U.S. Government and non-U.S. regulatory authorities actively enforce laws and regulations regarding the promotion of pharmaceutical products.

The FDA and other U.S. Government agencies and non-U.S. regulatory authorities strictly regulate the manner in which prescription products may be marketed. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. In addition, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. Such laws, and the application of those laws, are complex and evolving.

If we are found to have improperly promoted the sale of any of our product candidates, if approved, such as through the promotion of the off-label use of those products, or through kickbacks or fraud, or through any other conduct or activity deemed to be unlawful, then we may become subject to significant liability. For example, if we receive marketing approval for a product as a treatment for a disease, physicians may nevertheless choose to prescribe the product for their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, growth prospects, operating results and financial condition.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in individual EU member states and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in all EU member states. The competent regulatory authorities in the EU actively enforce the laws and regulations governing promotion of medicinal products. If we are found to have undertaken improper promotional activities we may be subject to significant civil, criminal and administrative penalties, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

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

We are exposed to the risk that our employees, independent contractors, consultants, principal investigators, CROs, suppliers, vendors and other third parties with which we do business may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with federal and state health care fraud and abuse laws and regulations and equivalent foreign laws, FDA regulations and equivalent regulation of foreign authorities, requirements to provide accurate information to the FDA or equivalent foreign authorities, data privacy and security laws and requirements to accurately report financial information or data or to disclose unauthorized activities to us. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics with respect to our employees, agents and contractors, it is not always possible to identify and deter misconduct by these parties, 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid and equivalent foreign health insurance programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. The FDA and non-U.S. regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA approves a drug candidate for an indication in the U.S., comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product in those countries. In addition, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the U.S., including additional preclinical studies or clinical trials, since clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining non-U.S. regulatory approvals and establishing and maintaining compliance with non-U.S. regulatory requirements could result in significant difficulties and costs for us and could delay or prevent the introduction of our product candidates, if approved, in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, then our target market will be reduced and our ability to realize the full market potential of our product candidates, if approved, will be harmed.

Our business operations and current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare

professionals, including physicians, clinical investigators, CROs, third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Food Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require biotechnology companies to report information on the pricing of certain drug products, state and local laws that require the registration of pharmaceutical sales representatives;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on “covered entities,” including certain healthcare providers, health plans, healthcare clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Some state laws require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products. Certain state and local jurisdictions require the registration of pharmaceutical sales representatives. State, federal and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including the provision of compensation for consulting services to physicians and other healthcare providers, some of whom may be in a position to recommend, purchase and/or prescribe our product candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against it, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could have an adverse effect on our business and reputation.

Our business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We may conduct clinical trials in countries other than the United States. In addition, we have entered into a license agreement with Accure, a biotechnology company headquartered in Barcelona, Spain. Our business activities are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of Switzerland and other countries in which we operate. Anti-corruption laws, including the FCPA, generally prohibit offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, potentially including officials of foreign governments. Additionally, although none of our product candidates is yet approved for sale in any country, in many countries other than the U.S., the healthcare providers who prescribe pharmaceuticals like our product candidates are employed by their government, and the purchasers of pharmaceuticals are government entities. Therefore, any future dealings by us with these prescribers and purchasers may be subject to regulation under the FCPA and other applicable anti-corruption laws.

The SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable anti-corruption laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, cessation of business activities in certain countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products, if approved, in one or more countries and could materially damage our reputation, our brand, international activities, our ability to attract and retain employees and our business, growth prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, export control laws and economic sanctions may prohibit the shipment of certain products and services to specified countries, governments, and persons. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products could adversely affect our business.

Disruptions at the FDA, the SEC and other government agencies and comparable non-U.S. regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable non-U.S. regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, our ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the ability of the FDA and comparable non-U.S. regulatory authorities to perform routine functions. Average review times at the FDA and comparable non-U.S. regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other agencies, and comparable non-U.S. regulatory authorities may slow the time necessary for new drugs to be reviewed or approved, which could adversely affect our business. For example, in recent years, including in 2013, 2018 and 2019, the U.S. government shut down several times, and in 2020 and 2021 the FDA diverted significant resources to handle the SARS-CoV-2 virus public health emergency and pandemic. Certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees for a time, and to stop critical activities in response to such events, and may be required to do so again in the future.

If such disruptions recur, or if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and comparable non-U.S. regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government disruptions or shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and waste; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also may produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or waste. 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 hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not currently maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with storage or disposal of hazardous and flammable materials, including chemicals and biological materials. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on business, financial condition, results of operations and growth prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions that could have a material adverse effect on our business, reputation and growth prospects.

Risks related to domicile in Switzerland and being foreign private issuer

We are a Swiss stock corporation. The rights of its shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Swiss stock corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies, including listed companies, incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the laws of the United States. In the performance of its duties, our board of directors is required by Swiss law to consider the interests of the Company, and may also have regard to the interests of our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. Swiss corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court.

Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by the our board of directors, but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought to the competent courts at our registered office, currently in Zug, Switzerland. In addition, under Swiss law, any claims by shareholders against the Company must be brought exclusively to the competent courts at our registered office, currently in Zug, Switzerland. U.S.-style class actions and derivative actions are not available under Swiss law. There can be no assurance that Swiss law will not change in the future, which could adversely affect the rights of our shareholders, or that Swiss law will protect our shareholders in a similar fashion as under U.S. corporate law principles.

The shareholders' resolutions regarding the ordinary and conditional share capital increases and the introduction of a capital band may still be challenged.

Immediately prior to the completion of the Business Combination, our shareholders approved an ordinary share capital increase and the introduction of a capital band as well as conditional share capital. The execution of the share capital increases by our board of directors and the related filings were made prior to the completion of the Business Combination. As with all share capital increases in Switzerland, the shareholders' resolutions regarding such share capital increases may be challenged in court within two months after such shareholders' meeting which could prevent or delay the completion of this offering. However, only the holders of Oculis Holding AG shares before the Closing of the Business Combination Agreement may challenge the resolution, making such challenge unlikely. In addition, it is unclear under Swiss law, whether a successful challenge would have an impact on the issued shares after such capital increases have already been registered with the commercial register.

The Ordinary Shares are not listed in Switzerland, our home jurisdiction. As a result, certain Swiss law provisions designed to protect shareholders in the event of a public takeover offer or change of control transaction will not apply.

The Swiss rules that require investors to disclose their interest in a company if they reach, exceed or fall below certain ownership thresholds only applies to issuers that have a listing (including a secondary listing) for their equity securities in Switzerland. Since the Ordinary Shares are listed exclusively on The Nasdaq Global Market, a U.S. market, the disclosure obligations regarding major shareholdings according to art. 120 of the Swiss Financial Markets Infrastructure Act and its implementing provisions do not apply to us. Likewise, the Swiss takeover regime does not apply to us. In particular, the duty to make a mandatory bid offer for all outstanding listed equity securities of a company by any person or group of persons that acquires more than one third of a company's voting rights does not apply to us. In addition, the Swiss takeover regime imposes certain restrictions and obligations on bidders in a voluntary public takeover offer that are designed to protect shareholders. However, these protections are applicable only to issuers that list their equity securities in Switzerland and, because the Ordinary Shares are listed exclusively on The Nasdaq Global Market, are not applicable to us. Furthermore, since Swiss law restricts our ability to implement rights plans or U.S.-style "poison pills," Our ability to resist an unsolicited takeover attempt or to protect minority shareholders in the event of a change of control transaction may be limited. Therefore, our shareholders may not be protected in the same degree in a public takeover offer or a change-of-control transaction as are shareholders in a Swiss company listed in Switzerland.

U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

We are a corporation organized and incorporated under the laws of Switzerland with registered office and domicile in Zug, Switzerland, and the majority of its assets are located within Switzerland. Moreover, a number of our directors and executive officers are not residents of the United States, and all or a substantial portion of the assets of such persons are or may be located outside the United States. As a result, investors may not be able to effect service of process within the United States upon us or upon such persons, or to enforce judgments obtained against us or such persons in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. There is doubt that a lawsuit based upon United States federal or state securities laws could be brought in an original action in Switzerland and that a judgment of a U.S. court based upon United States securities laws would be enforced in Switzerland.

The United States and Switzerland currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, may not be enforceable in Switzerland, please see the section entitled "*Enforcement of Civil Liabilities.*"

Our status as a Swiss stock corporation means that our shareholders enjoy certain rights that may limit its flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and the cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize its board of directors to, increase our share capital. While its shareholders may introduce a capital band pursuant to which share capital that can be issued by its board of directors without additional shareholder approval, Swiss law limits this capital band to 50% of the share capital registered in the commercial register at the time of the introduction

of the capital band. The capital band, furthermore, has a limited duration of up to five years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants pre-emptive rights to existing shareholders to subscribe for new issuances of shares, which may be limited or withdrawn under certain conditions. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different classes of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise where greater flexibility would have provided benefits to its shareholders.

Shareholders outside of the United States may not be able to exercise pre-emptive rights in future issuances of equity or other securities that are convertible into equity.

Under Swiss corporate law, shareholders may receive certain pre-emptive rights to subscribe on a pro-rata basis for issuances of equity securities or other securities that are convertible into equity securities. Due to the laws and regulations in certain jurisdictions, however, shareholders who are not residents of the United States may not be able to exercise such rights unless we take action to register or otherwise qualify the rights offering, including, for example, by complying with prospectus requirements under the laws of that jurisdiction. There can be no assurance that we will take any action to register or otherwise qualify an offering of subscription rights or shares under the laws of any jurisdiction other than the United States where the offering of such rights is restricted. If shareholders in such jurisdictions were unable to exercise their subscription rights, their ownership interest in the Company will be diluted.

Anti-takeover provisions in our Articles of Association could make an acquisition of the Company, which may be beneficial to its shareholders, more difficult.

Our Articles of Association contain provisions that may have the effect of discouraging, delaying or preventing a change in control of the Company that shareholders may consider favorable, including transactions in which its shareholders may receive a premium for their shares. Our Articles of Association include provisions that:

- in certain cases, allow our board of directors to place such number of new ordinary shares corresponding to up to 17,841,084 Ordinary Shares (capital band) and to place rights to acquire such number of new shares corresponding to up to an additional 5,000,000 of new Ordinary Shares (conditional capital for bonds and similar debt instruments) respectively, of the expected outstanding share capital, with affiliates or third parties, without existing shareholders having statutory pre-emptive rights in relation to this share placement;
- allow our board of directors not to record any acquirer of ordinary shares, or several acquirers acting in concert, in our share register as a shareholder with voting rights with respect to more than 15% of our share capital registered in the commercial register;
- restrict shareholders from exercising voting rights with respect to own or represented shares in excess of 15% of our share capital registered in the commercial register;
- limit the size of our board of directors to nine members; and
- require two-thirds of the votes represented at a general meeting of shareholders for amending or repealing the above-mentioned registration and voting restrictions, the provision setting a maximum board size, and the provision for indemnification of the members of our board of directors and our executive committee as set forth in our articles of association, and for dismissing the chairman or any member of the our board of directors or any member of our remuneration committee before the end of his or her term of office.

These and other provisions of our articles of association, alone or together, could delay or prevent takeovers and changes in control. Please see the sections entitled “*Description of Securities*” and “*Comparison of Shareholder Rights*.” Any provision of the Articles of Association that has the effect of delaying or preventing a change in control could limit the opportunity for shareholders to receive a premium for their shares of our share capital and could also affect the price that some investors are willing to pay for Ordinary Shares.

We are a foreign private issuer and, as a result, not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we have the option to follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we may choose, and have chosen, to comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of the Nasdaq.

Swiss law does not require that a majority of our board of directors consist of independent directors. Its board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.

Although Swiss law also requires that we set up a remuneration committee, we may follow home country requirements with respect to such committee. Among other things, Swiss law does not require that all or a majority of the remuneration committee consist of independent directors.

Our articles of association provide for an independent proxy elected by its shareholders, who may represent its shareholders of record at a general meeting of shareholders, and it must provide shareholders of record with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies, thus our practice may vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. Furthermore, in accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

For an overview of our corporate governance principles, please see the section entitled “*Corporate Governance*.” As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status, which would then require us to comply with the domestic reporting requirements of the Exchange Act and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our status as a foreign private issuer, either (i) a majority of its ordinary shares must be either directly or indirectly owned of record by non-residents of the United States; or (ii) (a) a majority of its executive officers or directors may not be United States citizens or residents, (b) more than 50% of its assets cannot be located in the United States and (c) its business

must be administered principally outside the United States. If it lost this status, it would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. Among other things, we would be required under current SEC rules to prepare its financial statements in accordance with generally accepted accounting principles in the United States, rather than IFRS, which would involve significant time and cost and could result in variations, which could be material, between historical financial results reported under IFRS and as reported under US GAAP. It may also be required to make changes in its corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost it would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time-consuming and costly. If it loses its foreign private issuer status and is unable to devote adequate funding and the resources needed to maintain compliance with U.S. securities laws, while continuing its operations, we could be forced to deregister with the SEC. A deregistration would substantially reduce or effectively terminate the trading of its securities in the United States. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for it to obtain director and officer liability insurance, and it may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

Tax authorities may challenge EBAC's tax residency, which could adversely affect our tax burden and financial position.

EBAC has registered as a resident of Switzerland for Swiss tax purposes as of October 2022 and has deregistered as a taxpayer for Dutch corporate income tax and Dutch dividend withholding tax purposes, but no confirmation has been obtained from the Dutch tax authorities that EBAC is no longer considered a Dutch tax resident. EBAC's tax residency primarily depends upon EBAC's place of effective management, which is a question of fact based on all circumstances. Because the determination of EBAC's residency is highly fact sensitive, no assurance can be given regarding the definitive determination of EBAC's tax residency. If the Dutch tax authorities were to assert that EBAC continues to be a tax resident of the Netherlands, the Dutch tax authorities may seek to impose Dutch corporate income tax in respect of any income or gains realized by EBAC and/or Dutch dividend withholding tax in respect of any distributions made by or on behalf of EBAC (including the payment of the EBAC Share Redemption Amount to the extent that it exceeds the aggregate recognized paid-in capital per redeemed share). If the Dutch tax authorities would be successful in such assertion, this could affect EBAC's tax burden and financial position and following the Acquisition Closing, our tax burden and financial position.

We urge our shareholders to consult with their legal and tax advisors with respect to the potential tax consequences of investing in or holding Ordinary Shares.

As a result of changes in tax laws, treaties, rulings, regulations or agreements, or their interpretation, of Switzerland or any other country in which we operate, the loss of a major tax dispute or a successful challenge to our operating structure, intercompany pricing policies or the taxable presence of our key subsidiaries in certain countries, or other factors, our effective income tax rates may increase in the future, which could adversely affect our net income and cash flows.

We operate in multiple jurisdictions and our profits are taxed pursuant to the tax laws of these jurisdictions. The tax laws applicable to our business activities, however, are subject to changes in interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our effective income tax rate may be affected by changes in or interpretations of tax laws, treaties, rulings, regulations or agreements in any given jurisdiction, the resolution of issues arising from any future tax audits with various tax authorities, utilization of net operating loss and tax credit carryforwards, changes in geographical allocation of income and expense, and changes in management's assessment of matters such as the realizability of deferred tax assets. In the past, we have experienced fluctuations in our effective income tax rate. Our actual tax rate may vary from our expectation and that variance may be material. Our effective income tax rate in a given fiscal year reflects a variety of factors that may not be present in the succeeding fiscal year or years. There is no assurance that our effective income tax rate will not change in future periods.

We file Swiss and non-Swiss tax returns. We are subject to tax audits, examinations and assessments in various jurisdictions. If any tax authority successfully challenges our operational structure, allocation of income by tax jurisdiction, or amounts paid between our affiliated companies pursuant to our intercompany arrangements or transfer pricing policies, if any tax authority successfully asserts that we are subject to income, withholding or other taxes in a jurisdiction by reason of our activities and operations or our other taxable presence in such jurisdiction, if the terms of certain income tax treaties are interpreted in a manner that is adverse to our structure, or if we lose a material tax dispute in any country, our effective income tax rate could increase. A tax authority may take the position that material income or other tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, which could adversely affect our profitability. If our effective income tax rate increases in future periods, our net income and cash flows could be adversely affected, including in future tax years.

Due to the Swiss corporate tax law reform that took effect on January 1, 2020, all Swiss cantons, including the Canton of Vaud, have abolished the cantonal tax privileges. Therefore, since January 1, 2020, we are subject to standard cantonal taxation. The standard effective corporate tax rate in Lausanne, Canton of Vaud, can change from time to time. The standard combined (federal, cantonal, communal) effective corporate income tax rate, except for dividend income for which we could claim a participation exemption, for 2022 in Vaud will be approximately 13.79%. The Federal Council of Switzerland has submitted on 23 June 2022 a proposal for a minimum tax of 15 percent for groups of companies with annual sales of at least 750 million euros on the basis of an internationally standardized assessment base. This proposal would implement the so-called GloBE rules (Global Anti-Base Erosion Rules) of the OECD. The minimum tax rate must be achieved in each country. Switzerland plans to implement these rules with a supplementary direct tax to become effective on January 1, 2024, which - if adopted - will result in a minimum tax rate of 15 percent on large corporate groups that achieve a worldwide turnover of at least 750 million euros.

We urge our shareholders to consult with their legal and tax advisors with respect to the potential tax consequences of investing in or holding the Ordinary Shares.

Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly regarding U.S. dollars, euros, British pounds and Swiss francs. Our functional currency is the Swiss franc and the majority of our operating expenses are paid in Swiss francs, but we also may receive payments from our business partners, including Amgen and AbbVie, in U.S. dollars or euros and we regularly acquire services, consumables and materials in U.S. dollars and Swiss francs. Further, potential future revenue may be derived from abroad, particularly from the United States and the European Union. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the Swiss franc, the euro, the U.S. dollar and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Besides our natural hedging, currently, we do not have any exchange rate hedging arrangements in place.

In addition, the possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the European Union to provide funding to certain European Union member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more European Union member states, or in more extreme circumstances, the abandonment of the euro or the dissolution of the European Union. The effects on our business of a potential dissolution of the European Union, the exit of one or more European Union member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Ownership of our Ordinary Shares and Warrants and our Status as a Public Company

We have and will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

We have and will incur significant legal, accounting and other expenses that it did not incur as a private company, and these expenses may increase even more if and when we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs have and will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board advisors or as executive officers.

Our management has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage the transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal securities laws. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities. This in turn may result in less time being devoted to our management and growth. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the United States. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the United States may require costs greater than expected. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company, which will increase our operating costs in future periods.

The market price and trading volume of our Ordinary Shares and Warrants may be volatile and could decline significantly.

The stock markets, including Nasdaq, on which Ordinary Shares and Warrants are listed under the symbols OCS and OCSAW, respectively, have from time to time experienced significant price and volume fluctuations. The market price of Ordinary Shares and Warrants may be volatile and could decline significantly. In addition, the trading volume in Ordinary Shares and Warrants may fluctuate and cause significant price variations to occur. Additionally, any substantial amount of trading or sales in Ordinary Shares could make it difficult for us to raise capital through the issuance of debt or equity securities in the future. Generally, securities of biopharmaceutical companies tend to be volatile and experience significant price and volume fluctuations. We cannot assure you that the market price of the Ordinary Shares and Warrants will not fluctuate widely or decline significantly in the future in response to a number of factors, including, among others, the following:

- the realization of any of the risk factors presented in this annual report;
- actual or anticipated differences in our estimates, or in the estimates of analysts, for our revenues, results of operations, liquidity or financial condition;
- additions and departures of key personnel;
- failure to comply with the requirements of Nasdaq;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations;

- future issuances, sales or resales, or anticipated issuances, sales or resales, of Ordinary Shares;
- publication of research reports about us;
- the performance and market valuations of other similar companies;
- broad disruptions in the financial markets, including sudden disruptions in the credit markets;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- speculation in the press or investment community;
- actual, potential or perceived control, accounting or reporting problems; and
- changes in accounting principles, policies and guidelines.

In the past, securities class-action litigation has often been instituted against companies following periods of volatility in the market price of their shares. This type of litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on us.

We expect to issue additional Ordinary Shares, including under our management incentive plan. Any such issuances would dilute the interest of our shareholders and likely present other risks.

We expect to issue a substantial number of Ordinary Shares, including under the Stock Option and Incentive Plan Regulation 2023.

Ordinary Shares reserved for future issuance under our management incentive plan will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. The aggregate number of Ordinary Shares initially reserved for issuance under the 2023 Plan is 7,835,544 Ordinary Shares.

Any such issuances of additional Ordinary Shares or securities convertible into Ordinary Shares:

- may significantly dilute the equity interests of our investors;
- may subordinate the rights of holders of Ordinary Shares if securities are issued with rights senior to those afforded Ordinary Shares; and
- may adversely affect prevailing market prices for Ordinary Shares.

Our Warrants are exercisable for Ordinary Shares, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our shareholders.

As a result of the Business Combination being consummated, outstanding warrants to purchase an aggregate of 4,403,294 Ordinary Shares became exercisable in accordance with the terms of the Warrant Agreement. These warrants became exercisable on April 2, 2023. The exercise price of these warrants is \$11.50 per share, or approximately \$50.6 million, assuming none of the warrants are exercised through "cashless" exercise. To the extent such warrants are exercised, additional ordinary shares will be issued, which will result in dilution to the holders of Ordinary Shares and increase the number of shares eligible for resale in the public market. We believe the likelihood that warrant holders will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our ordinary shares. If the trading price for our ordinary shares is less than \$11.50 per share, we believe holders of our Public Warrants and Private Placement Warrants will be unlikely to exercise their warrants. On March 2, 2023, the last reported sales price of our ordinary shares was \$11.19 per share and the last reported sales price of our Public Warrants was \$0.52 per warrant. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of ordinary shares. However, there is no guarantee that the Public Warrants will ever be in the money prior to their expiration,

and as such, the warrants may expire worthless. See “—The warrants may never be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment.”

The Warrants may never be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment.

The exercise price for our Warrants is \$11.50 per Ordinary Share. We believe the likelihood that warrant holders will exercise their Public Warrants and Private Placement Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe warrant holders will be unlikely to exercise their Warrants. There is no guarantee that the Warrants will be in the money following the time they become exercisable and prior to their expiration, and as such, the Warrants may expire worthless.

The Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and EBAC, and were assumed at the time of the Closing by us, pursuant to a warrant assignment, assumption and amendment agreement by and between us, EBAC, and Continental Stock Transfer & Trust Company. Continental Stock Transfer & Trust Company is currently the warrant agent. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity, correct any defective provision or correct any mistake, amend the definition of “Ordinary Cash Dividend” or add or change any provisions with respect to matters or questions arising under the warrant as the parties may deem necessary or desirable and that the parties deem shall not adversely affect the rights of the warrant holders, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment and, solely with respect to any amendment to the terms of the Private Placement Warrants or any provision of the warrant agreement with respect to the private placement warrants, 50% of the number of the then outstanding Private Placement Warrants. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, convert the warrants into cash, shorten the exercise period or decrease the number of Ordinary Shares purchasable upon exercise of a warrant.

We may redeem the Public Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless.

We may redeem the Public Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless. We will have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the closing price of the Ordinary Shares equals or exceeds \$18.00 per share (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending on the third trading day prior to the date on which a notice of redemption is sent to the warrant holders. We will not redeem the warrants as described above unless a registration statement under the Securities Act covering the Ordinary Shares issuable upon exercise of such warrants is effective and a current prospectus relating to those Ordinary Shares is available throughout the 30-day redemption period. If and when the Public Warrants become redeemable by us, it may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force holders (i) to exercise the Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous to do so, (ii) to sell the Public Warrants at the then-current market price when holders might otherwise wish to hold the Public Warrants, or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of the Public Warrants.

In addition, we will have the ability to redeem the outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.10 per warrant if, among other things, the closing price of the Ordinary Shares equals or exceeds \$10.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on the trading day prior to the date on which a notice of redemption is sent to the warrant holders. Recent trading prices for the Ordinary Shares have not exceeded

the \$10.00 per share threshold at which the Public Warrants would become redeemable. In such a case, the holders will be able to exercise their Public Warrants prior to redemption for a number of Ordinary Shares determined based on the redemption date and the fair market value of the Ordinary Shares.

The value received upon exercise of the Public Warrants (1) may be less than the value the holders would have received if they had exercised their Public Warrants at a later time when the underlying share price is higher and (2) may not compensate the holders for the value of the Public Warrants.

Risks Related to Taxation

If we are treated as a “passive foreign investment company” for any taxable year, U.S. investors could be subject to adverse U.S. federal income tax consequences.

A non-U.S. corporation generally will be treated as a “passive foreign investment company” (“PFIC”) for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (ii) at least 50% of its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business), and gains from the disposition of passive assets.

Assuming that the First Merger and the Second Merger, taken together, qualified as an F-reorganization for U.S. federal income tax purposes, we will be treated as the successor to EBAC for U.S. federal income tax purposes, including for purposes of the PFIC rules. Since EBAC was a blank-check company with no current active business, based upon the composition of EBAC’s income and assets, we believe that EBAC was a PFIC for the taxable year ended December 31, 2022. However, the determination of whether a non-U.S. corporation is a PFIC is a must be made on an annual basis. As a result, our actual PFIC status for any taxable year will not be determinable until after the end of such year. Therefore, there can be no assurance with respect to our status as a PFIC for the current or any future taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for the current or any future taxable year.

If we are treated as a PFIC, U.S. investors may be subject to certain adverse U.S. federal income tax consequences, including additional reporting requirements. See “Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Rules” for a more detailed discussion of the PFIC rules. U.S. investors should consult their tax advisors regarding the application of the PFIC rules in their particular circumstances.

Changes to tax laws in any of the jurisdictions in which we operate, including new proposals on taxing digital companies and the ongoing work by the Organization for Economic Cooperation and Development (the “OECD”), could have a material adverse effect on our business, operating results, and financial condition.

Tax laws, including tax rates, in the jurisdictions in which we operate may change as a result of macroeconomic or other factors outside of our control. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings.

Our tax treatment may also be impacted by tax policy initiatives and reforms such as the Organisation for Economic Co-Operation and Development’s (“OECD”) Base Erosion and Profit Shifting (“BEPS”) Project (including “BEPS 2.0”), and the European Commission’s state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or, in the specific context of withholding tax dividends paid. The OECD has published a package of measures for reform as a product of BEPS, which include the reallocation of global profits of large multinational companies to market jurisdictions based on customer location as well as the introduction of a global minimum tax. Many of the package’s proposed measures require amendments to the domestic tax legislation of various jurisdictions.

Changes in tax laws, treaties, or regulations or their interpretation or enforcement are unpredictable. Any of these occurrences could have a material adverse effect on our business, operating results, and financial condition, including changing the amount and recognition of our deferred tax assets and liabilities.

Item 4. Information on the Company.

A. History and Development of the Company

We are a stock corporation (*Aktiengesellschaft*) that was incorporated under the laws of Switzerland on October 31, 2022. We are registered with the commercial register of the Canton of Zug under company registration number CHE-396.695.611. The mailing address of our principal executive office after the Acquisition Closing is Oculis Holding AG, Bahnhofstrasse 7, CH-6300, Zug, Switzerland. Neither our articles of association nor the operation of law limit our duration.

Certain additional information about the Company is included in Item 4.B “*Business Overview*” and is incorporated herein by reference. The material terms of the Business Combination are described in Item 10 of this Report. The Company is subject to certain of the informational filing requirements of the Exchange Act. Since the Company is a “foreign private issuer”, it is exempt from the rules and regulations under the Exchange Act prescribing the furnishing and content of proxy statements, and the officers, directors and principal shareholders of the Company are exempt from the reporting and “short-swing” profit recovery provisions contained in Section 16 of the Exchange Act with respect to their purchase and sale of Ordinary Shares. In addition, the Company is not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. public companies whose securities are registered under the Exchange Act. However, the Company is required to file with the SEC an Annual Report on Form 20-F containing financial statements audited by an independent accounting firm. The SEC also maintains a website at <http://www.sec.gov> that contains reports and other information that the Company files with or furnishes electronically to the SEC.

Our telephone number is +41-58-810-0182 and its website is www.oculis.com.

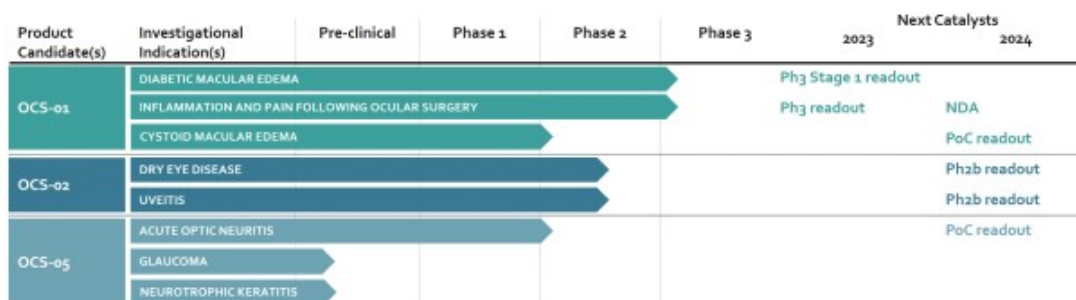
B. Business Overview

Company Overview

We are a clinical-stage biopharmaceutical company, based in Switzerland, with substantial expertise in therapeutics used to treat ocular diseases, and engaged in the development of innovative drug candidates which have the potential to address many currently eye-related conditions. Our mission and vision is to improve the health and quality of life of patients around the world by developing medicines that save sight and improve eye care for patients. To realize this vision, we intend to become a global leader in ocular therapeutics.

Our focus is on advancing therapeutic candidates intended to treat significant ophthalmic diseases which result in vision loss, blindness or reduced quality of life, and for which prevalence is growing and there are currently inadequate, limited or no treatment options. Our clinical portfolio currently consists of three therapeutic candidates: OCS-01, OCS-02 and OCS-05. Our lead product candidate, OCS-01, is currently being evaluated in two ongoing Phase 3 clinical trials: for the treatment of diabetic macular edema (“*DME*”), and for the treatment of inflammation and pain following cataract surgery. Our second product candidate is OCS-02, for which we anticipate initiating two Phase 2b clinical trials in 2023, evaluating: its use as a potential treatment for keratoconjunctivitis sicca, or dry eye disease (“*DED*”), and its use as a potential treatment for non-infectious anterior uveitis. Our third product candidate is OCS-05, which is a novel neuroprotective agent with potential application in multiple indications, including glaucoma, geographic atrophy (“*GA*”), diabetic retinopathy (“*DR*”), and neurotrophic keratitis. We are initially evaluating OCS-05 as a potential treatment for acute optic neuritis (“*AON*”) for which there are no currently approved therapeutic treatments.

Summary of Our Clinical Product Candidates Portfolio



OCS-01 is based on the OPTIREACH technology, OCS-02 is a single chain antibody fragment (ScFv) against TNF alpha and OCS-05 is a SGK-2 activator peptidomimetic small molecule with novel MoA targeting the activation of the trophic factor pathways. The Company's additional earlier stage development candidates are discussed in the section under the header "Our clinical development candidates" below.

Utilizing our internal core competency in formulation discovery and drug development capabilities, together with extensive licensing, collaboration and acquisition activities, we have assembled a pipeline of attractive development candidates that include both late-stage clinical candidates as well as earlier stage preclinical initiatives. Our clinical candidate portfolio includes:

OCS-01

Our lead candidate is OCS-01, a novel formulation (ophthalmic suspension) of dexamethasone at high concentration, designed to enhance drug penetration into both the anterior and posterior segments of the eye with enhanced persistence following topical application. We are evaluating OCS-01 for use as a potential treatment for DME and also a potential treatment for inflammation and pain following ocular surgery, we are also exploring the benefit of OCS-01 in treating cystoid macular edema ("CME"). A CME IIT study, a severe complication following ocular surgery, is ongoing and the related readout is expected in 2024. Using our proprietary Optireach® technology, OCS-01 was developed to be an eye drop drug capable of treating diseases affecting the retina, which is at the back of the eye. This approach is in contrast to currently available therapies, which require the use of more invasive treatments such as ocular implants or intravitreal injections to deliver medication to the retina. Furthermore, current treatment of DME often involves multiple intravitreal injections. Given the burden of therapy, FDA-approved therapeutics are not widely used for early disease intervention, despite the deterioration in visual acuity in 19% of patients within two years. We estimate that treatment might be further complicated by a suboptimal response at 12 weeks in approximately 40% of patients.

OCS-01 is a topical dexamethasone formulation which we believe is capable of delivering therapeutic levels of drug to the retina via eye drop, a route of administration for DME treatment that may enable earlier treatment intervention and thereby significantly increase the proportion of patients being treated as well as increase the prescribing physician base by providing a treatment option to general ophthalmologists. We are currently not aware of the existence of any other eye drop treatment for DME which is in a similar or more advanced stage of active clinical development; however, we cannot guarantee that OCS-01 will receive regulatory approval. Our Phase 2 clinical trial in DME met the key efficacy endpoints of central macular thickness ("CMT") and best-corrected visual acuity ("BCVA") with statistical significance based on the pre-specified alpha level. Our Phase 2 clinical trial in inflammation and pain after cataract surgery met its primary endpoint with statistical significance in the OCS-01 once-daily cohort and key secondary efficacy endpoints. Ocular tolerability was not significantly different between the OCS-01 and vehicle groups across clinical trials with the exception of change in intraocular pressure ("IOP"), consistent with known effects of topical steroids, including dexamethasone. We have concluded an affirming End-of-Phase 2 meeting with the FDA. We have initiated Phase 3 clinical evaluations in both indications and expect the results from the Stage One portion of our Phase 3 DME clinical trial and the Phase 3 clinical trial for the treatment of inflammation and pain related to cataract surgery to be available in mid-2023.

The total U.S. prevalence of DME in 2022 is estimated at 2.96 million, with the diagnosed U.S. prevalence estimated at 1.75 million by the Decision Resources Group DME Landscape November 2020 report. The same report estimates that 875 thousand U.S. DME patients were treated with drugs in 2022, leaving 879 thousand U.S. patients diagnosed

but untreated. These 879 thousand patients are a key addressable market segment for OCS-01. Additionally, OCS-01 is also intended to address the market segment of patients with suboptimal response to anti-VEGF therapy. A study published in the American Journal of Ophthalmology in 2016 found that nearly 40% of patients treated with anti-VEGF therapy had suboptimal responses at 12 weeks. By applying this figure to the number of treated U.S. patients, we estimate that suboptimal response occurs in 350 thousand patients. In total, we estimate that 1.2 million DME patients in the United States are addressable by OCS-01.

The Informa Meddevicetracker Ophthalmic Surgical Products Market October 2017 report projected that nearly 6.5 million ocular surgeries (which typically require inflammation and pain management post-surgery) were performed in 2019 in the United States. A study published in Investigative Ophthalmology and Visual Science, an Association for Research in Vision and Ophthalmology journal in 2021 observed that approximately 30% of patients who received cataract surgery from 2012 through 2019 had diabetes, a known risk factor for CME following cataract surgery. Given our observations in clinical studies that OCS-01 treatment led to improvements in visual acuity and macular thickness in patients with DME, we believe OCS-01, if approved for inflammation and pain following ocular surgery, would mainly be used in patients with higher risk of developing CME, a patient segment which is estimated to be approximately 2 million per year in the United States. An exploratory trial is ongoing in the US to assess its benefits in treating CME.

OCS-02

We are also advancing the clinical development of OCS-02, a next-generation biologic treatment for both DED and non-infectious chronic anterior uveitis. Differentiating OCS-02 is its use of a single chain antibody fragment formulation directed against the cytokine human tumor necrosis factor alpha (“TNF α ”), to enable the topical delivery of an anti-TNF α construct at increased concentrations. The anti-inflammatory and anti-necrotic properties of therapeutics inhibiting TNF α activity are well established with anti-TNF pharmaceuticals already approved as systemic treatments for ocular disease. In addition, we are advancing the development of OCS-02 in conjunction with the development of a potentially novel genetic biomarker intended to identify patients who may have a greater response to OCS-02 therapy. Two Phase 2 clinical trials in patients with symptoms of DED were conducted (the first with the predecessor of OCS-02, and the second with OCS-02), as well one Phase 2 clinical trial in acute anterior uveitis. Topical ocular administration of OCS-02 was associated with improvements in the global ocular discomfort score versus vehicle in patients with DED, and with reaching a pre-specified responder rate in patients with non-infectious anterior uveitis, as well as being well tolerated in all three studies. We plan to commence two Phase 2b trials for OCS-02 (one in DED in signs, and one in chronic anterior uveitis) and expect results of these trials to be available in 2024.

We estimate the segment of DED patients in the United States addressable by OCS-02 (patients with moderate or severe DED) to be approximately 10 million patients. This comprises an estimated 8.1 million patients with moderate DED and 1.5 million patients with severe DED (based on the rates of 42% moderate and 8% severe patients as reported in a study published in the American Journal of Ophthalmology in 2017 of a total of approximately 19.4 million diagnosed prevalent cases of DED in the U.S. as estimated by Decision Resources Group Dry Eye Disease Landscape and Forecast, December 2020).

We also estimate OCS-02 could help address a medical need in patients suffering from either chronic or recurring non-infectious anterior uveitis. This addressable patient population is estimated to be approximately 130,000 in the United States based on a prevalence rate of non-infectious uveitis of 121 per 100,000, applied to the U.S. population and the fact that anterior uveitis is the most prevalent form representing 81% of all cases, as found in a study published in the Journal of the American Medical Association Ophthalmology in 2016, and based on a prevalence of recurrent and chronic disease being estimated at 51%, as found in a study published in the Journal of the American Medical Association Ophthalmology in 2013.

OCS-05

Our third clinical candidate is OCS-05, a novel serum/glucocorticoid-regulated protein kinase 2 (“SGK2”) activator peptidomimetic small molecule, in development as a potential disease modifying neuroprotective agent against neurological damage to the optic nerve. We are initially developing OCS-05 as a potential therapeutic to treat AON, a rare disease with high unmet need as currently, there is no treatment which is approved by the FDA or European Commission for AON. OCS-05 has been granted Orphan Drug Designation by both the FDA and the European

Commission for this indication. OCS-05 has been studied in preclinical studies suggesting efficacious neuroprotective and remyelinating activity, as well as in a European Phase 1 clinical trial in healthy volunteers in which OCS-05 was observed to be well tolerated. We are currently conducting a First-in-Patient clinical trial of OCS-05 in AON in France to test the candidate's safety and tolerability, and we also plan to conduct IND-enabling activities for OCS-05 in the United States. Should the clinical results of our AON trial prove sufficiently compelling, we intend to evaluate the promise of OCS-05 to treat other neuro-ophthalmic disorders such as geographic atrophy, glaucoma, diabetic retinopathy and neurotrophic keratitis.

Additional development initiatives

In addition to these five clinical development programs involving the three clinical candidates, we also are engaged in a number of earlier preclinical development initiatives, including:

- The LEOPARD study is an investigator-initiated trial (IIT) to investigate the safety and efficacy of OCS-01 in Uveitic (UME) and Post-surgical (PSME) Macular Edema. LEOPARD is sponsored by Global Ophthalmic Research Center (GORC) and is being coordinated by Quan Nguyen, MD, MSc of the Byers Eye Institute at Stanford University in Palo Alto, California. Across 5 sites in the US, approximately twenty-four patients will be treated (12 with UME and 12 with PSME) for up to 24 weeks.
- The evaluation of OCS-03 as a possible treatment for corneal neovascularization, a common disorder caused by the aberrant development of new blood vessels into the cornea and pterygium, a pink colored growth that originates in the conjunctiva.
- OCS-04 is an innovative topical ophthalmic formulation project preliminarily intended for corneal graft rejection prevention and possibly other inflammatory related conditions targeting the ocular surface.

Our Executive Management Team

We are led by an experienced management team, composed of individuals who have extensive backgrounds in drug discovery and development, clinical trial design and operations, regulatory affairs, business development and commercial and general management at both large pharmaceutical companies and emerging biopharmaceutical organizations. Collectively, our management team has a track record of advancing new drug candidates through regulatory approval and successful commercialization. The expertise of our management team is complemented by our board of directors, which includes many accomplished industry veterans with significant capabilities in guiding the success of emerging biopharmaceutical companies such as ours. Since our inception we have raised approximately CHF 200 million from leading North American, European and Asian life science venture capital investors including Brunnur Ventures (Brunnur vaxtarsjodur slhf.), BVCF Management (BEYEOTECH), Novartis Bioventures Ltd., LSP 7 Coöperatief, Earlybird Growth, Novartis Bioventures, Pivotal bioVenture Partners, funds managed by Tekla Capital Management LLC, and VI Partners, among others. Please note that prospective investors should not rely on these named investors' investment decisions, as each of such investor's risk tolerance and investment strategy and goal may be different those of other prospective investors.

Our Strategy

We intend to become a leader in developing therapeutics to address ocular diseases characterized by significant medical needs with large market opportunities. To accomplish this objective, we plan to focus on successful completion of our key strategic initiatives, which include:

- *Executing the Phase 3 development of OCS-01 for DME.*

Based on results achieved in the Phase 2 trial, we have progressed to a Phase 3 trial of OCS-01 in DME which is currently ongoing. We believe the use of OCS-01 formulated as a non-invasive, self-administered eye drop, could, if approved, promote a shift in the current treatment paradigm to allow earlier intervention and increase both the treated patient population and the prescribing physician base.

- *Advancing the ongoing Phase 3 clinical trial of OCS-01 as a potential therapeutic for inflammation and pain following ocular surgery with potential further differentiating benefit for patients with elevated risk of CME; IIT on CME ongoing in the U.S. with readout planned in the second half of 2024.*

We are currently conducting a Phase 3 clinical trial of OCS-01, a novel formulation of dexamethasone which incorporates our proprietary Optireach technology, to evaluate its efficacy in treating inflammation and pain following ocular surgery. OCS-01 is differentiated in this indication by its potential ability to deliver therapeutic drug levels to the back of the eye. A proof-of-concept trial is currently ongoing to explore further the efficacy of OCS-01 in treating edema in CME. We believe this distinction of benefit in CME, if supported by this study and further studies, and if OCS-01 is approved, may enable us to achieve enhanced market access.

- *Pursuing the late-stage clinical development of OCS-02, our next-generation anti-TNF α biologic.*

Based on results achieved in three Phase 2 clinical trials, we intend to advance OCS-02 into Phase 2b clinical trials to assess its clinical benefit in treating both DED and non-infectious chronic anterior uveitis. OCS-02 is differentiated by its use of single-chain antibody fragment formulation technology, which enables the topical delivery of an anti-TNF α agent. We are advancing the development of OCS-02 in conjunction with further validation of a potential novel genetic biomarker intended to identify patients who may demonstrate an enhanced response to OCS-02 therapy and believe this precision medicine approach may allow the candidate to deliver superior outcomes in this patient group, if approved.

- *Evaluating OCS-05 in AON and additional indications to potentially access larger market opportunities.*

The differentiated mechanism of action of OCS-05, coupled with its potential disease modifying neuroprotective properties, suggests potential benefits across many of the more pervasive neurological pathologies of the eye including geographic atrophy, diabetic retinopathy, glaucoma and neurotrophic keratitis. We initially intend to assess the safety of OCS-05 as a treatment for AON and are currently evaluating OCS-05 in a First-in-Patient study called the ACUITY (as defined below) trial in France. There is currently no approved therapy for treatment of AON. OCS-05 has been granted Orphan Drug Designation by both the FDA and the European Commission. We believe that demonstration of therapeutic benefits in AON may provide compelling support for the exploration of OCS-05 in larger market opportunities.

- *Leveraging our internal formulation discovery and strengthening our development pipeline through robust licensing and acquisition activities.*

We intend to complement our ongoing development programs by accessing additional innovative product candidates and technologies through in-licensing, strategic collaborations and acquisitions. We believe that the depth of our formulation discovery and drug development expertise specific to ocular therapeutics, coupled with the industry network of our executive management, board of directors and advisors, provide us with the differentiated set of capabilities necessary to identify and advance products candidates successfully in this therapeutic category.

- *Evaluating and selectively entering into strategic collaborations to maximize the potential of our pipeline and the scope of our product portfolio.*

We have retained rights globally to all of our indications, including our lead product candidate OCS-01, for the potential treatment of DME and inflammation and pain following ocular surgery; OCS-02 for the potential treatment of DED and non-infectious anterior uveitis; and OCS-05 as a neuroprotective agent. Given the potential to treat patients worldwide, we may opportunistically enter into strategic collaborations around certain product candidates, diseases or geographic regions.

Diseases and disorders of the eye

Numerous diseases and disorders, many of which represent significant medical needs, are associated with the human eye. Ocular diseases which may result in significant visual impairment or blindness include retinal diseases such as DME, macular degeneration (including Geographic Atrophy), Diabetic Retinopathy, and retinal vein occlusion (“RVO”); disorders caused by swelling and inflammation such as DED, corneal keratitis and uveitis; and glaucoma, among other disease states. The global market for therapeutics used to treat eye disease is estimated to have exceeded \$22 billion in 2020. We employ our substantial expertise in the development of therapeutics, in particular pharmaceuticals used to treat ocular diseases, to potentially address many currently intractable eye-related conditions. Our focus is on developing innovative drug candidates to address significant and growing ophthalmic diseases, which result in vision loss, blindness or reduced quality of life, for which there are currently limited treatment options.

Our clinical development candidates

Utilizing our internal formulation discovery and drug development capabilities, together with extensive licensing, collaboration and acquisition activities, we have assembled a pipeline of attractive development candidates that include both late-stage clinical candidates as well as earlier stage preclinical initiatives. Our clinical portfolio is made up of (i) OCS-01, currently in two ongoing Phase 3 clinical trials, one Phase 3 trial (in Stage One of two stages) evaluating its use as a treatment for DME and the other Phase 3 trial assessing its utility to treat inflammation and pain following ocular surgery; (ii) OCS-02, which we anticipate entering two Phase 2b clinical trials, the first evaluating its use as a potential treatment for keratoconjunctivitis sicca, or DED, the second trial evaluating its potential use as a therapy for the treatment of non-infectious anterior uveitis; and (iii) OCS-05, a novel neuroprotective agent with potential application in multiple indications, including glaucoma, GA, and DR, which we are initially evaluating as a potential treatment for AON. A detailed assessment of each of these clinical candidates is contained in the descriptions provided below.

OCS-01

Key program highlights:

- Use of proprietary Optireach® technology enables enhanced drug penetration and residence time.
- Topically delivered formulation design to allow non-invasive self-administration for front and back of the eye.
- May enable earlier disease intervention if approved, potentially attracting an expanded patient population and expanded prescribing physician base.
- Phase 2 trial in DME met pre-specified efficacy endpoints for reduction in CMT and improvement in BCVA, and the Phase 2 trial in ocular surgery met reduction in inflammation and pain endpoints (statistical significance on those endpoints reached in both trials).
- Data readouts for the Stage One portion of the Phase 3 DME clinical trial and topline data from the Phase 3 clinical trial in ocular surgery are expected in mid-2023.
- Estimated 1.2 million total addressable U.S. DME patients; estimated 2 million total addressable U.S. patients with inflammation and pain after ocular surgery.

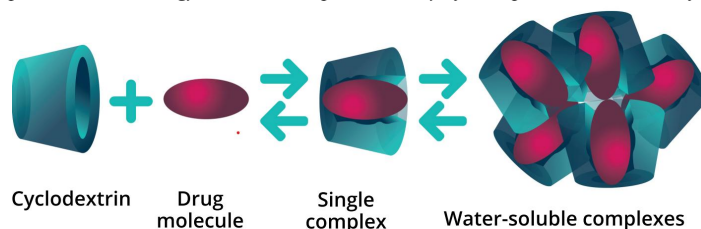
Our lead development candidate OCS-01 is a 1.5% suspension of the anti-inflammatory corticosteroid dexamethasone for use as a potential treatment for DME and for inflammation and pain following ocular surgery with potential benefit for patients at high risk for CME following ocular surgery. In contrast to currently available formulations of dexamethasone, which require the use of more invasive treatments such as an implant or intravitreal injection to deliver the medication to the retina, differentiating OCS-01 is our use of the proprietary Optireach® technology, which enables the topical delivery, as an eye drop, of dexamethasone to the back of the eye for the treatment of diseases affecting the retina. OCS-01 is a topical dexamethasone formulation which we have observed in clinical trials to be capable of delivering therapeutic levels of drug to the retina via eye drop, a route of administration for DME treatment that may enable earlier treatment intervention and thereby significantly increase the proportion of patients being treated as well as increase the prescribing physician base by providing a treatment option to general ophthalmologists. We are currently not aware of the existence of any other eye drop treatment for DME which is in a similar or more advanced stage of active clinical development; however, we cannot guarantee that OCS-01 will receive regulatory approval.

We completed Phase 2 clinical trials in which we observed: in DME, a statistically significant improvement in both BCVA and CMT based on a pre-specified Alpha, and in inflammation and pain following ocular surgery, a statistically significant increase in the proportion of subjects with absence of inflammation and pain under OCS-01 treatment versus vehicle and have concluded an affirming End-of-Phase 2 meeting with the FDA. We have initiated Phase 3 clinical evaluations in both indications. We expect the results from the Stage One portion of our Phase 3 DME clinical trial and the Phase 3 clinical trial evaluating the potential of OCS-01 to treat inflammation and pain related to ocular surgery to be available in mid-2023.

Dexamethasone is a widely studied and well characterized pharmaceutical commonly used to treat a range of inflammatory conditions and is currently included on the World Health Organization’s List of Essential Medicines. It may be administered orally, by injection, or topically. Specific to ocular disorders, dexamethasone intravitreal implants have been approved by the FDA to treat DME, uveitis and macular edema caused by RVO. Dexamethasone is also used as an ophthalmic suspension for ocular inflammation though the required frequency of dosing in order to achieve a therapeutic effect often limits its utility.

We are developing OCS-01 as a γ cyclodextrin-based formulation of dexamethasone, using the Optireach® delivery technology, in order to enhance its residence time at the anterior segment and its penetration into the posterior segment of the eye following topical application. The increased drug residence time produced by the delivery vehicle, combined with enhanced drug penetration allows for increases in drug concentration of more than 15-fold over conventional dexamethasone. We are currently not aware of the existence of any other topically administered formulation of dexamethasone or other active pharmaceutical ingredient in development intended to deliver sustained therapeutic levels of drug to diseased tissue at the back of the eye.

The Optireach® technology enables the topical delivery of therapeutics to the back of the eye.



OCS-01 for DME

We are advancing OCS-01 as a treatment for DME, which is a complication of diabetes and is caused by the progressive growth of new blood vessels under the retina that leak fluid and lipids, leading to swelling of the macula, which can result in significant blurring of vision and contribute to the risk of blindness from DR. DME is strongly associated with uncontrolled blood sugar levels, high blood pressure and high cholesterol. An estimated 5.5% of diabetics worldwide are affected by the disease. It is a leading cause of blindness among the U.S. adult population. In the G7 countries (the United States, France, Germany, Italy, Spain, UK and Japan), the market for the treatment of DME is estimated to have totaled approximately \$3 billion in 2019.

DME is estimated to impact three million people in the United States alone. Of those three million, we estimate that 1.2 million patients in the United States are addressable by OCS-01.

We are currently conducting Stage One (of two stages) of our ongoing Phase 3 DIAMOND trial in study sites in the United States (pursuant to the protocol filed to the IND in 2021) and Hungary. The number of countries and sites for Stage Two of the study has not been determined as of December 2022.

Limitations of current treatments for DME

The DME disease onset may initially go unnoticed and as a result an estimated 46% of patients with DME may go undiagnosed. A study by the American Academy of Ophthalmology indicates that, among diagnosed patients, fewer than half are treated, with therapeutic intervention used most commonly in the one-third of patients who have moderate to severe visual impairment. Pharmacotherapy involves the invasive administration of a monoclonal antibody therapeutic targeting the vascular endothelial growth factor (“*VEGF*”) receptor to inhibit blood vessel growth. However, we estimate that approximately 40% of patients have a suboptimal response to therapy after 12 weeks of anti-VEGF treatment, according to the results of a study published in the American Journal of Ophthalmology in 2016. Moreover, multiple intravitreal injections are required to maintain a therapeutic effect, which necessitates an increased treatment burden on patients, their caregivers and healthcare providers. The utility of anti-VEGF therapy is further complicated by compliance issues, with patients in clinical practice estimated to receive only around 30% of the treatments given to participants in the clinical trials which led to these therapeutics’ approval for this indication.

Patients whose disease progresses while on anti-VEGF therapy may then receive a steroid implant, or laser photocoagulation of the retina.

Currently, physicians often do not treat patients who present with DME in its earlier stages of progression (patients with recent disease onset or mild visual impairment), a category that makes up approximately 67% of diagnosed patients with symptoms. We believe this decision to observe and not intervene is often driven by the significant burden current treatment options (laser photocoagulation, frequent intravitreal injections, intravitreal implants) place on the patient, as well as the expense and significant demands placed on healthcare resources. FDA approved therapeutics are not widely used for early disease intervention, despite the deterioration in visual acuity of approximately five letters, the equivalent of one line, or more in 19% of this patient population within two years.

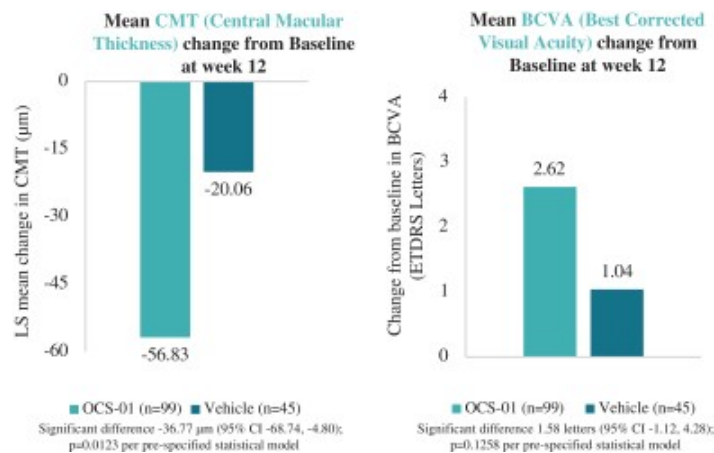
OCS-01's innovation and differentiation

OCS-01 is in development to be a topical treatment for DME, and we are currently not aware of the existence of any other eye drop treatment for DME which is in a similar or more advanced stage of active clinical development. In addition to this potential breakthrough advancement, we believe that an eye drop therapy would allow for easy, accessible, low-burden self-administration of treatment for DME and would therefore significantly address the limitations of current, invasive therapies for DME. We expect that OCS-01, if approved, could address patients who are diagnosed with DME, with recent onset of disease or mild visual impairment and who are therefore currently observed and untreated, as well as patients who are diagnosed with DME and who have a suboptimal response to anti-VEGF intravitreal injections. We estimate that this segment of patients in the United States alone totals 1.2 million.

OCS-01 has produced clinical trial results which support its continued development as a potential treatment for DME

In our DX-211 Phase 2 clinical trial which evaluated the use of OCS-01 as a treatment for DME, patients who received OCS-01 demonstrated a statistically significant improvement from baseline in key measurements of therapeutic efficacy. In this randomized, double masked trial of 144 DME patients with 2:1 randomization (OCS-01 vs. Vehicle), 99 of the trial participants self-administered OCS-01 eye drops three times per day over a 12-week period, with 45 participants administered vehicle only. As noted in the graphic presented below, OCS-01 demonstrated improvements in both CMT and BCVA, key metrics of clinical efficacy, with OCS-01 producing a 56.8 least squares mean (“LSM”) change in CMT from baseline as compared to a 20.1 change for the vehicle group and a 2.6 positive change in BCVA as compared to 1.0 for the vehicle group as measured using a standard 5 letter/line Early Treatment Diabetic Retinopathy Study (“ETDRS”) letters chart.

OCS-01 generated improvements in both CMT and BCVA measurements.

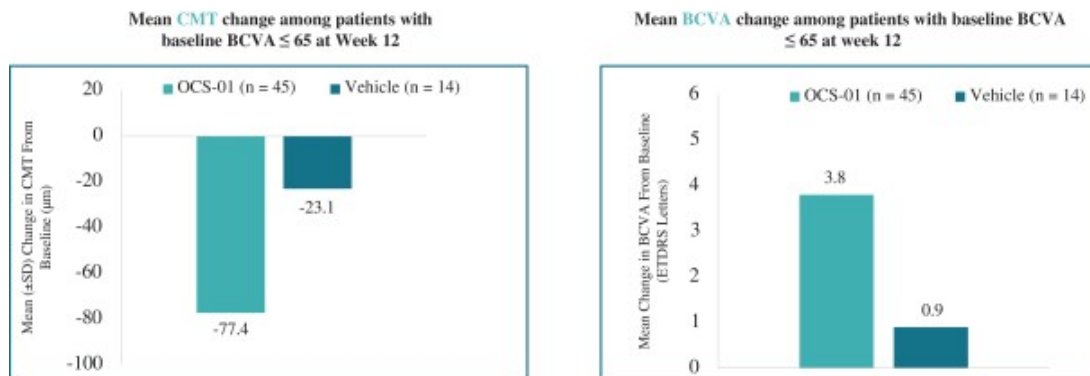


(According to Wasserstein RL, Lazar NA. The ASA's Statement on p-Values: Context, Process, and Purpose. *Am Stat.* 2016;70(2):129–33., p-value is “the probability under a specified statistical model that a statistical summary of the data (e.g., the sample mean difference between the 2 compared groups) would be equal to or more extreme than its observed value.” This

trial (DX211) was designed as a Phase 2 clinical study. Accordingly, the pre-specified alpha defined for the study was 0.15. The study met the above endpoints with statistical significance.)

More pronounced results were achieved among patients who entered the trial with worse visual acuity at baseline. As noted in the chart presented below, among participants whose baseline BCVA score as measured by an EDTRS letters test was less than or equal to 65, OCS-01 generated a mean improvement in BCVA of 3.8 letters and in CMT of 77.4 μm in contrast to the 0.9 letters and 23.1 μm improvement noted among trial participants who received vehicle. We have incorporated this appreciation of effect into our ongoing Phase 3 DIAMOND trial in which a baseline BCVA score of less than or equal to 65, but equal or greater than 24, are the inclusion criteria. The trial design of DIAMOND was reviewed by the FDA as part of our End-of-Phase 2 meeting with the agency.

Improvements in both CMT and BCVA were greater among patients with lower baseline visual acuity.



Treatment emergent adverse events (“AEs”) were noted in 32 of the 99 trial participants who received OCS-01, with the most prevalent AE being an increase in intraocular pressure (“IOP”), which was observed in 21 of the 99 patients in the active group. These findings of increased IOP were consistent with our expectations given glucocorticoids’ well-known ocular safety profiles, including the profile of an approved dexamethasone ocular implant. Patients who encountered IOP consistently noted the increase during the beginning phase of the trial and the increase reversed after discontinuation of drug candidate dosing. No patients discontinued the trial due to IOP increase. Overall, the IOP effects observed in our trial were consistent with what is generally expected given established ophthalmic use of dexamethasone. Other AEs observed during clinical trials included conjunctival hemorrhage and eye pain, which was not noted among patients who received OCS-01.

Aside from increased IOP, eye irritation and ocular hypertension were observed in three patients each, while individual instances of cataract subcapsular, eyelid erythema, ocular hyperaemia, and posterior capsule opacification were noted, as was a single instance of a decline in BCVA by 15 letters or more. Except for increased IOP, AEs of a similar nature and number were noted among trial participants who received vehicle. No AE led to trial discontinuation by any patient. While OCS-01 may contribute to a slightly accelerated onset of cataracts, we do not believe this issue is significant given the likelihood that the patient population expected to be treated with this drug, if approved, is more inclined to develop the condition independent of treatment with OCS-01.

The Phase 2 clinical trial results achieved with OCS-01 in treating DME follow outcomes achieved in two earlier small exploratory studies of DexNP (a previous formulation of OCS-01). In one of the studies, which was conducted in Japan, a 22-patient evaluation conducted in 2015 compared the use of a topically delivered g cyclodextrin-based formulation of dexamethasone to the posterior injection of 20 mg triamcinolone acetonide. Used at the time of the trial as an off-label treatment for DME, the g cyclodextrin-based formulation generated significant improvements in visual acuity and decreased macular thickness, comparable to the results achieved using triamcinolone acetonide. The results of this 2015 study confirmed similar findings achieved in another 19-person exploratory Japanese study conducted in 2011.

Phase 3 trial design for OCS-01

Our ongoing adaptive design Phase 3 clinical evaluation of OCS-01 in DME (DIAMOND) includes two stages. In Stage One, OCS-01 is compared to vehicle to evaluate the safety and efficacy of an alternate dosing regimen using a “loading dose” and a “maintenance dose” (each as defined below). The enrollment target for Stage One is 147 subjects. OCS-01 or vehicle is administered six times per day for six weeks (“loading dose”) and then three times per day for six weeks (“maintenance dose”). A previous Phase 3 study of dexamethasone ocular intravitreal implants in DME subjects (the “MEAD Study”) demonstrated a dose-response relationship, in which subjects who received the higher dose implant showed a greater BCVA gain compared to subjects who received the lower dose implant. In an earlier Oculis study, 11 subjects who received a previous formulation of OCS-01 (DexNP) six times per day for four weeks experienced a greater CMT reduction than eight subjects who received DexNP three times per day. In light of these findings, we believe that a “loading dose” may enhance the therapeutic effect of OCS-01. Key inclusion criteria of our DIAMOND study include: Diabetes mellitus 1 or 2, BCVA between 24 and 65 letters and macular thickness (Central Subfield Thickness or “CST”) of 310 μm or greater.

Upon completion of Stage One, we will evaluate whether to progress to Stage Two of the trial, and if so, using what dosing regimen and sample size. Currently, we intend to conduct two, 52-week pivotal Phase 3 trials. We anticipate that each of these global Phase 3 trials will enroll between an estimated 350 and 450 subjects. The primary endpoint of these studies will be the mean change from baseline in BCVA at 52 weeks. Key secondary endpoints are to include the mean change in macular thickness (“CST”), as assessed by spectral domain optical coherence tomography (“SD-OCT”) and the percentage of participants that exhibit ETDRS improvement of 15 letters or more from baseline. Key inclusion criteria are expected to be similar to those used in Stage One of the trial. The Phase 3 (“DIAMOND”) clinical trial protocol was reviewed by the FDA during an End-of-Phase 2 meeting.

OCS-01 has the potential to expand the number of treated patients and prescribing physicians.

OCS-01 was designed to address two sizeable treatment gaps pervasive among the DME patient population in early on-set and in severe segments. Furthermore, the sustained delivery of the drug to the back of the eye and non-invasive self-administration are unique differentiators to currently available treatments. Addressing the two existing treatment gaps may allow for increased early disease intervention with expanded treatment of retinal edema due to reduced treatment burden and improved access to care. Success in demonstrating therapeutic efficacy to treat the earlier-stages of DME disease progression may promote the use of OCS-01, if approved, among those DME patients whose treatment is currently restricted to observation. We believe that this potential expansion of the patient base to include earlier-stage DME patients may also increase the number of prescribing physicians, with general ophthalmologists, not just retina specialists, more likely to engage in disease management. If approved, OCS-01 may also be used as a non-invasive complement to currently approved therapeutic regimens, including anti-VEGF medications, potentially extending or enhancing the clinical benefit of those treatments particularly among those patients with more advanced diseases whose condition have not responded adequately to the current standard of care protocol.

OCS-01 for ocular surgery patients

We estimate that approximately six million cataract, glaucoma, refractive, and vitrectomy surgical procedures are performed annually in the United States. Inflammation and pain remain an expected consequence of ocular surgery. While steroids have proven to be an effective treatment, compliance and potency are major issues with topical steroids dosed several times per day.

An estimated 30% of the patients who undergo cataract surgery are at an elevated risk for CME. Clinically significant CME occurs in up to 5.8% of cataract surgeries. Similar to DME, CME involves an accumulation of excess fluid in the macula which distorts central vision. CME is the most significant cause of postoperative vision loss among patients who undergo ocular surgery. Although the specific causes of CME are not well understood, comorbidities including diabetes and uveitis, among other factors, are believed to be significant contributors to disease emergence. In addition to developing OCS-01 to treat DME, we are also developing OCS-01 to treat inflammation and pain following from ocular surgery and conducting a proof-of-concept study in CME to assess its potential in CME treatment. Prior to OCS-01’s commercial launch, if approved, we anticipate a proof-of-concept trial of OCS-01 (IIT) as a potential treatment for CME to be completed.

Limitations of current therapies for inflammation and pain post ocular surgery and OCS-01’s differentiation

Inexpensive steroids such as prednisone are currently widely prescribed after ocular surgery; but, since they are not formulated to reach the retina, their therapeutic benefit in treating or preventing complications related to CME has not been established. Given that OCS-01 has demonstrated the potential to treat macular edema, as evidenced by CMT reduction and BCVA gain in our Phase 2 DME trial, coupled with additional exploratory data that may be gained from the planned clinical evaluation of OCS-01 in CME, we envision OCS-01 as a well-differentiated potential treatment for inflammation and pain following ocular surgery in patients at higher risk of developing CME, rather than as an alternative to prednisone in the broader ocular surgery market. We believe that this distinction may enable OCS-01 to achieve enhanced pricing and market access, if approved. OCS-01, if approved, may further benefit from anticipated once daily dosing, in contrast to the multiple daily doses required of alternative treatments. A proof-of-concept (IIT) CME trial is planned to further evaluate the therapeutic efficacy of OCS-01 for this indication and we expect trial results by year-end 2024.

We expect that OCS-01, if approved, could address the segment of patients who have ocular surgery and are at higher risk for CME. We forecast this segment to total approximately 1.9 million patients per year in the United States.

OCS-01 has produced clinical trial results which support its continued development as a potential treatment for inflammation and pain post ocular surgery

We conducted the DX-216 trial, which enrolled 153 subjects in a vehicle-controlled, multi-center Phase 2 clinical trial in the United States, to assess the safety and efficacy of OCS-01, dosed once or twice daily, as a treatment for inflammation and pain following cataract surgery. After screening for an anterior chamber cell count of grade 2 or higher, an indication of intraocular inflammation, eligible trial participants were randomized into one of three cohorts, an active drug cohort administered OCS-01 once daily, another active drug cohort administered OCS-01 twice daily, and a third cohort which received vehicle beginning one day after surgery for 15 consecutive days followed by a one-week observation period. The primary endpoints of the trial were the absence of anterior chamber cells at Day 15 and the absence of pain at Day 4. The key secondary endpoints were the absence of anterior chamber cells at Day 4 and 8, and the absence of pain at Days 2, 8, and 15.

The trial met both its primary and secondary endpoints. OCS-01 achieved statistical significance in both primary endpoints for subjects who received once daily dosing of OCS-01 versus those who received vehicle. A single daily application of OCS-01 was shown to reduce anterior chamber cells at Day 15 to zero in 51% of trial participants on an intent to treat basis ($p < 0.001$), compared to 19.6% of subjects in the cohort that received vehicle alone. The elimination of pain at Day 4 was observed among 72.5% of subjects who received once daily dosing of OCS-01 ($p < 0.005$), as compared to 45.1% in the vehicle only cohort.

OCS-01 was also well tolerated in this trial. No serious ocular or systemic AEs were reported, and the rate of non-serious AEs noted during the trial appeared to be largely procedure related. Moreover, no subject displayed an IOP of greater than or equal to 30 mmHg at any time during the trial, nor did any participant experience a change in IOP from baseline of 10 mmHg or more.

The design of our Phase 3 trial follows the Phase 2 trial. Once daily administration of OCS-01 is compared with vehicle over a 15-day period following cataract surgery and the trial involves multiple trial sites throughout the United States. The study design was reviewed with the FDA during the End-of-Phase 2 meeting, and subject randomization for this trial began in July 2022 with trial results expected to be available in 2nd half of 2023.

OCS-02

Key Program Highlights:

- Next-generation biologic in development as a potential treatment for severe DED and non-infectious anterior uveitis using single chain antibody fragment technology targeting TNF α .
- Eye drop formulation enables localized self-administration, minimizing possible complexity and side effects associated with systemic anti-TNF α treatment.
- Results from three Phase 2 trials of OCS-02's predecessor and OCS-02 support moving into Phase 2b trials.

- Phase 2b trials are planned, with results expected to be available in 2024.
- Potential proprietary genetic biomarker may enable precision medicine guided patient stratification in DED.
- Total addressable U.S. DED patient population of approximately 10 million patients.

We are also developing OCS-02 as a next-generation biologic treatment for both DED and as a treatment for non-infectious anterior uveitis. OCS-02 is differentiated by its use of a single chain antibody fragment formulation directed against the cytokine human TNF α to enable the topical delivery of an anti-TNF α construct at increased concentrations. The anti-inflammatory and anti-necrotic properties of therapeutics inhibiting TNF α activity are well established with anti-TNF pharmaceuticals already approved as systemic treatments for ocular disease. In addition, we are advancing the development of OCS-02 in conjunction with the further validation of a potential genetic biomarker intended to identify patients who may have a greater response to OCS-02 therapy and believe this precision medicine approach may allow the candidate to deliver superior outcomes in these patients if approved. Two Phase 2 clinical trials in patients with symptoms of DED were conducted (the first with the predecessor of OCS-02, and the second with OCS-02), as well one Phase 2 clinical trial in acute anterior uveitis. Topical ocular administration of OCS-02 was associated with improvements in the global ocular discomfort score versus vehicle in patients with DED, and with reaching a pre-specified responder rate in patients with non-infectious anterior uveitis, as well as being well tolerated in all three studies. We plan to evaluate OCS-02 in two Phase 2b trials and expect results of the Phase 2b trials to be available in 2024.

TNF α performs important roles in the initiation and propagation of both normal and aberrant immune responses via mechanisms ranging from the stimulation of other cytokines to inflammatory cell recruitment to the alteration of vascular permeability. Inhibition of TNF α has demonstrated significant clinical benefit in the treatment of an array of diseases arising from dysfunctional immune system activity and anti TNF α therapeutics have become among the most widely prescribed biologics. Three anti-TNF α therapeutics (etanercept, sold under the brand name Enbrel[®], infliximab, sold under the brand name Remicade[®], and adalimumab, sold under the brand name Humira[®]), have each been studied for use in ocular disease. While the use of antagonists to TNF α have demonstrated favorable efficacy in the treatment of ocular inflammatory diseases, these drugs require intravenous infusion or subcutaneous injection and systemic anti-TNF α therapies are associated with a range of often serious adverse effects. Ocular diseases, such as DED and non-infectious anterior uveitis, involve a local TNF α driven inflammatory process which may not justify general, systemic TNF α -suppressive therapy. The novel design of OCS-02 embracing lower molecular weight single chain antibody fragment technology may enable it to be used in ocular disease as an eye drop for localized administration.

OCS-02 for the treatment of DED

Keratoconjunctivitis sicca, also referred to as DED results from inflammation related to tear gland damage. DED is a multifactorial disease of the tears and ocular surface characterized by ocular surface inflammation and increased osmolarity of the tear film that results in ocular discomfort, visual disturbance and tear film instability. The etiology of DED can involve several deficiencies of the tear film, including the aqueous layer, the lipid layer, mucin layer or a combination of the three layers. The disease often presents as a complication of other diseases, prominently autoimmune disorders such as rheumatoid arthritis, diabetes and Sjogren's syndrome, which may contribute to its manifestation. As such, DED may afflict individuals with differing severity of burning sensation, a feeling of dryness, and other symptoms of ocular discomfort. In severe cases, vision may be significantly impaired. Although the pathogenesis of DED includes a variety of causes, common consequences are a breakdown of corneal tear film with dehydration of the exposed outer corneal surfaces, ocular surface inflammation and subsequent damage to exposed tissues. Increased concentration of pro-inflammatory cytokines, such as TNF α , in patient tears or conjunctival tissue has been demonstrated to correlate with disease severity.

In 2020, the U.S. DED patient population was estimated to be approximately 37.9 million people and is expected to rise to 41.3 million patients by 2029. The market for prescription medications to treat DED is forecasted to increase to \$7.3 billion in the G7 countries (the United States, France, Germany, Italy, Spain, UK and Japan) by 2029 from \$3.9 billion in 2019. We estimate the segment of DED patients in the United States addressable by OCS-02 (patients with moderate or severe DED) to be approximately 10 million patients.

Limitations of current therapies and potential for OCS-02 in DED

The DED patient population is significantly underpenetrated with only an estimated 9% of diagnosed patients receiving treatment. The vast majority of patients who do receive treatment are treated with anti-inflammatory drugs, yet among treated patients only 13% achieve lasting relief. Approved topical treatments for DED include Restasis® and Cequa®, which are both formulations of cyclosporine. These drugs act only to increase tear production and are not indicated to reduce DED symptoms. Further limiting cyclosporine’s therapeutic utility is a delayed onset of action necessitating a two to three month steroid bridge, and a stinging sensation on application in some patients. Topical steroids are also often used to treat DED but are contraindicated for long-term use because of their side effects including glaucoma and cataracts.

OCS-02’s differentiation as a potential treatment for DED

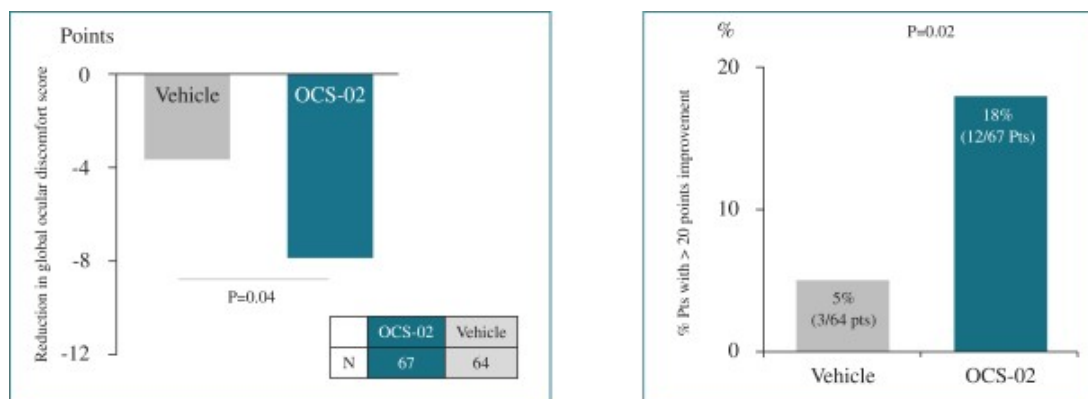
Given the central role of ocular inflammation in sustaining the pathology of DED and the utility of anti-TNF α as a highly effective anti-inflammatory agent, we believe the localized application of OCS-02 as an anti-TNF α therapeutic, if approved, may provide a differentiated DED treatment approach, which may avoid undesirable features of current therapies (such as stinging sensation, delayed onset of action, or steroid-related side effects), and which may provide benefit for many patients who do not receive lasting relief from current therapies.

We estimate the segment of DED patients in the United States addressable by OCS-02 (patients with moderate or severe DED) to be approximately 10 million patients.

OCS-02 has produced clinical trial results which support its continued development as a potential treatment for DED

Novartis, from whom we have obtained certain exclusive, worldwide rights to develop and commercialize OCS-02 through a December 19, 2018 licensing agreement (please see the section entitled “—Material Licenses, Partnerships and Collaborations” below), conducted a randomized, multi-center, double-masked, vehicle control Phase 2 clinical proof-of-concept trial designed to assess the safety and tolerability of OCS-02 and its efficacy in reducing DED symptoms. In the trial, patients were randomized on a 1:1 ratio into two cohorts. For a six-week period, the first trial cohort received a 60 mg/ml ophthalmic solution of OCS-02, while the second received vehicle. Participants in both cohorts self-administered one drop to each eye three times per day. The primary efficacy endpoint of the trial was improvement in the Global Ocular Discomfort Score as compared to vehicle. The Global ocular discomfort score is a composite of discomfort frequency and severity as assessed by a visual analog scale using an electronic patient reported outcome. Improvement results in a reduction of the discomfort frequency or severity, or both, translating into a reduction of the resulting Global Ocular Discomfort Score as compared to baseline. A negative change from baseline indicates improvement. The secondary efficacy endpoint was an assessment of the number of patients that achieved more than 20 points improvement in the global ocular discomfort score. The data generated in this trial, consisting of 67 participants in the active group and 64 in the control group, are presented in the charts below.

OCS-02 generated statistically significant improvement in ocular discomfort as compared to vehicle.

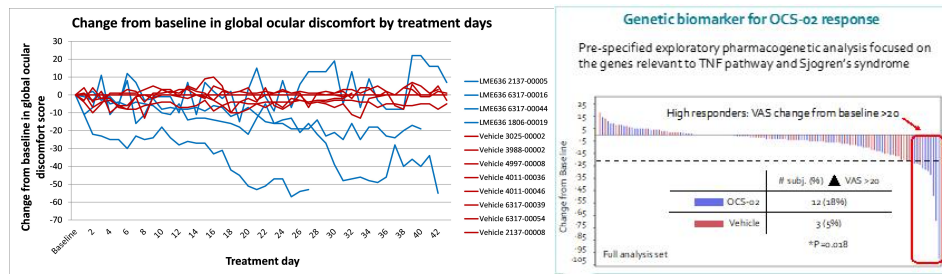


The trial met both primary and secondary endpoints. As is noted in the left chart above, administration of OCS-02 resulted in a statistically significant 7.9 mean point reduction in the global ocular discomfort score from baseline to treatment day 29 as compared to a 3.6 point mean reduction among patients that received vehicle only. In addition, as

is noted in the right chart above, OCS-02 generated an improvement in the global ocular discomfort score of greater than 20 points in 12 of the 67 patients, or 18% of total trial participants. A similar level of response was achieved in only 5%, or three of the 64, patients included in the vehicle control group. The results of exploratory endpoints, which included physician graded conjunctival hyperemia, corneal staining, Meibomian gland assessment and tear film osmolarity, were similar across treatment groups. OCS-02 demonstrated a statistically significant improvement in the Global Ocular Discomfort Score compared to vehicle in patients with severe DED. It was well tolerated, with no increase in IOP and minimal systemic drug exposure.

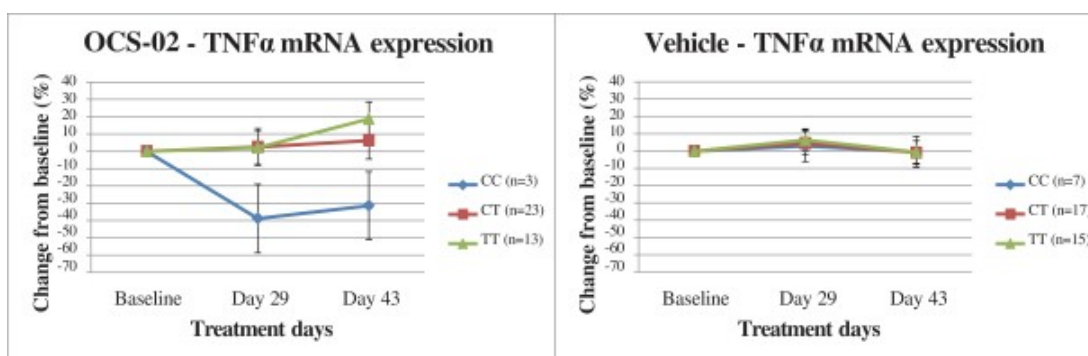
Proprietary genetic biomarker may enable a precision medicine approach to DED

We conducted an exploratory pharmacogenetic analysis focused on the genes relevant to the TNF pathway and Sjogren’s syndrome among those 12 out of 86 patients who displayed a CC genotype gene variance or SNIP. Among the gene variants analyzed, a correlation between one variant, designated the SNP rs1800693 CC genotype (“CC genotype”) in the TNFR1 gene, and a greater response ($p < 0.0001$) to OCS-02 was observed at Day 29. Below Figure shows individual patient profiles by study days for change from baseline Global Ocular Discomfort Score for participants with the CC genotype.



Patients with this variant displayed a significant reduction in inflammatory factors, including interleukin 1 beta (IL1B), interleukin 8 (IL8) and TNF α . This correlation is evidenced in the messenger RNA (“mRNA”) expression profiles of TNF α presented in the charts below which compared expression levels of patients with the various gene variants at Days 29 and 43 after dosing with either active drug candidate or vehicle. It was represented in 12 of 86 patients (14%) analyzed for the primary efficacy endpoint in this study, similar to the 13% of patients in the US study.

A specific gene variant may enable biomarker based response stratification



We believe that further validation of this genetic biomarker may enable us to identify a specific high response patient population which may allow us to enrich clinical trial enrollment and enhance our ability to evaluate the efficacy of OCS-02 in this indication and subpopulation. We intend to further evaluate the utility of this biomarker during our planned Phase 2b trial of OCS-02.

Phase 2b trial design

In light of the results generated by OCS-02 in its Phase 2 proof-of-concept trials, we plan to advance OCS-02 into a 2+6+2-week, estimated 120 subject Phase 2b clinical trial to evaluate the safety and efficacy of OCS-02 in treating the signs and symptoms of DED. This trial is designed to be a randomized, multi-center, double masked, vehicle-controlled trial. Following initial screening, trial participants will participate in a two-week run-in period during which time vehicle or artificial tears will be administered three times daily. Subjects that respond to treatment with artificial tears will be excluded from further participation. Subjects who continue with the trial will be randomized on a 1:1 basis into either the treatment cohort or the vehicle cohort and receive OCS-02 or vehicle three times daily for eight weeks. The efficacy measures and endpoints of the trial include a significant improvement in signs of DED, such as total corneal fluorescein staining, the percentage of patients with a 10 mm or greater increase in Schirmer's test, as well as symptoms of DED such as global ocular discomfort compared to vehicle. Biomarker analyses (from tear collection), as well as genotyping of subjects, are additional endpoints of the trial. We expect to commence the Phase 2b clinical trial in the second half of 2023.

OCS-02 for the treatment of non-infectious anterior uveitis

In addition to its potential use as a therapeutic to treat DED, we are also evaluating OCS-02 for use as a treatment option for patients with non-infectious anterior uveitis, including patients with chronic or recurrent non-infectious anterior uveitis who would benefit from a steroid-sparing option.

Uveitis is a condition characterized by the inflammation of the uveal tract but can also cause the inflammation of nearby tissues, such as the retina, the optic nerve, and the vitreous humor. Uveitis is caused by inflammatory responses inside the eye in response to an attack from the body's own immune system, infection, or trauma and injury to the eye. Uveitis is closely associated with various systemic diseases, including autoimmune disorders, and infectious diseases. However, a significant proportion of uveitis is idiopathic, with no identifiable cause for the disease. It primarily affects people between 20 and 60 years of age but can present at any age. If left untreated, uveitis can cause complications including macular edema, retina scarring, glaucoma, cataracts, optic nerve damage, retinal detachment and permanent vision loss. Uveitis, which can affect one or both eyes, accounts for between 10% to 15% of all cases of blindness in the United States and is the fourth leading cause of blindness in people aged 20-60 years in developed countries.

Loss of vision is correlated with the severity, frequency and duration of inflammatory episodes. Accordingly, the objective of treatment is fast and complete suppression of inflammation. Uveitis is categorized as either anterior, intermediate or posterior uveitis depending on the location of inflammation, or as panuveitis if present in multiple locations. Anterior uveitis is the most prevalent form of the disease and is associated with visual impairment. We estimate that that approximately 51% of patients in the United States who are diagnosed with anterior uveitis experience chronic or recurrent disease.

We estimate OCS-02 to address a patient segment of 129,000 patients with chronic or recurrent, anterior, non-infectious uveitis.

Limitations with the standard of care to treat anterior uveitis

The standard of care for uveitis is corticosteroids, which are administered as topical, intravitreal, periocular or oral depending on the location and severity of the disease. Active non-infectious uveitis is treated with topical corticosteroids. While topical corticosteroids have demonstrated clinical efficacy, their use is associated with a number of adverse ocular and systemic events. Topical ocular corticosteroid use is estimated to cause an increase in IOP of more than 15 mmHg among 4% and 6% of the general population and an increase of between 6 and 15 mmHg in up to one-third of users after daily application for four to six weeks. Persistent elevation in IOP may result in glaucoma, characterized by visual field loss and optic nerve damage, or the formation of cataracts. Incidence of cataract worsening or formation is related to total topical dose and duration. Based on multi-year studies with ocular corticosteroid implants, we estimate that approximately 31-47% more patients developed or experienced worsening of cataracts compared to control arms (sham implants or standard of care).

OCS-02 differentiated as a steroid-sparing treatment for anterior uveitis

Given the limitations related to longer-term steroid use in patients with recurrent or chronic uveitis, we believe OCS-02 has potential as a steroid-sparing treatment alternative. In November 2019, we commissioned a market research report which involved interviews with 14 key opinion leaders, high volume practitioners of uveitis treatment

(ophthalmologists and uveitis specialists) and payer experts. The results suggested that physicians are likely to be receptive to prescribing a topical, non-steroidal treatment after initial administration of a topical corticosteroid that may both shorten the duration of topical steroid use and obviate the potential need to advance patients to oral steroids. If approved, OCS-02 may also be appropriate for patients who demonstrate an inability to tolerate steroid treatment.

We estimate OCS-02 to address a patient segment of 129,000 patients with chronic or recurrent, anterior, non-infectious uveitis.

OCS-02 Phase 2 clinical trial results support its continued development as a potential treatment for non-infectious anterior uveitis

Novartis also conducted a Phase 2 clinical proof-of-concept trial to evaluate the use of OCS-02 as a potential treatment for acute anterior uveitis (“AAU”). This trial was a randomized, multi-center, double-masked, active controlled evaluation to assess the safety, tolerability and efficacy of OCS-02 administered for up to 21 days in resolving ocular inflammation in the anterior chamber associated with AAU. A 60 mg/ml ophthalmic solution of OCS-02 was administered to trial participants in the OCS-02 cohort and topical dexamethasone administered to patients in the active-control cohort. Trial participants received a maximum of eight drops daily per treated eye for the first two weeks with dosing tapered for the following two-week period. Response to treatment was defined as a reduction from baseline of 2 or more anterior chamber cell grades.

35 patients completed the trial, with 25 patients in the OCS-02 cohort and 10 patients in the active control cohort. OCS-02 achieved the primary endpoint established for the trial, which was a responder rate in excess of 30%. Among the 25 participants that completed the trial and were treated with OCS-02, 14 patients, or 56%, demonstrated a response to OCS-02 treatment at Day 22, specified as the proof-of-concept treatment period for the trial. In the trial, OCS-02 was observed to be well tolerated. No increase in IOP related to OCS-02 was observed, and no systemic adverse safety signals were observed.

OCS-02 as a treatment for non-infectious anterior uveitis is to be conducted into a Phase 2 trial

Given the encouraging results generated by OCS-02 in the Phase 2 clinical proof-of-concept trial, we intend to advance this clinical candidate into a Phase 2b trial for evaluation as a therapeutic for non-infectious chronic anterior uveitis with potential as a steroid-sparing alternative to the currently used drugs. Trial parameters to be incorporated into this clinical evaluation are in development.

OCS-05

Key Program Highlights:

- Potentially unique in treatment paradigm as disease modifying, neuroprotective drug, if approved.
- Evidence of clinical benefit in AON may support assessment as potential therapeutic for glaucoma, geographic atrophy and diabetic retinopathy, among other indications.
- Advancing candidate in an ongoing Phase 2 clinical proof-of-concept trial in France to evaluate its safety and to explore its use as a treatment for AON.
- Phase 1 study performed in the UK showing OCS-05 was well-tolerated in 48 healthy volunteers.
- Oculis to continue to work with FDA to obtain IND in the U.S.

In addition to development candidates intended to modulate inflammatory conditions associated with ocular disease pathologies, we are also advancing OCS-05, a small molecule in development as a potential disease modifying neuroprotective agent designed to address neurological damage to the optic nerve. We are initially developing OCS-05 as a potential therapeutic to treat AON. OCS-05 has been granted Orphan Drug Designation by both the FDA and the European Commission for this indication. OCS-05 has been studied in preclinical studies suggesting neuroprotective and remyelinating activity, as well as in a UK Phase 1 clinical trial (with 48 healthy volunteers) in which OCS-05 was well tolerated and showed pharmacokinetics (“PK”) with good correlation with its pre-clinical

animal studies. We are currently studying OCS-05 in a proof-of-concept trial in AON in France. Should the clinical results of our AON trials prove sufficiently compelling, we intend to evaluate OCS-05 to treat other more pervasive neurological pathologies of the eye such as geographic atrophy, neurotrophic keratitis and glaucoma. We obtained an exclusive license, worldwide to develop OCS-05 through a licensing agreement we entered into with Accure Therapeutics SL (“Accure”), dated as of January 29, 2022 (Please see the section entitled “—Material Licenses, Partnerships and Collaborations” below).

OCS-05 is a small molecule peptidomimetic that has a differentiated mechanism of action through the activation of SGK2 which is hypothesized as part of the neurotrophic factor signaling pathways that supports neuronal cell development, survival and repair, including oligodendrocyte precursor differentiation and myelination. Enzymes in the SGK2 family are recognized to regulate a range of fundamental cellular processes such as cellular proliferation and survival. SGK2 activation leads to an upregulation of signaling molecules forkhead box O3 (“FOXO3”), which reduces apoptosis, the downregulation of glycogen synthase kinase 3 beta (“GSK3B”), which improves anti-oxidation, and an upregulation of N-myc downstream-regulated gene 1 (“NDRG1”) involved in oligodendrocyte development and differentiation. The potential disease modulating activity of OCS-05 may distinguish it as a neuroprotective SGK2 activator.

OCS-05 was placed on a clinical hold by the FDA in 2016

Accure had conducted a limited set of animal regulatory toxicology studies in 2016 and submitted them to the FDA in an IND requesting the initiation of human testing. Upon review, the FDA found the data insufficient and asked for more animal toxicology data to be generated prior to human studies, thereby placing OCS-05 on the regulatory status of “clinical hold” pending the availability of the requested data. In response, Accure chose to withdraw the IND in 2017 rather than invest in further toxicology studies to address the FDA’s request and pursue the development in the UK and France. Upon our license of OCS-05 from Accure in 2022, we reactivated the IND and plan to meet with the FDA in the first half of 2023 to agree on a comprehensive toxicology plan to satisfy the FDA’s request. Other health authorities where clinical studies have been proposed, including the UK and France, have authorized us to commence clinical studies of selected doses and reinforced safety measures as in our European Phase 1 trial in AON.

OCS-05 for the treatment of acute optic neuritis

AON is an inflammation of the optic nerve that can cause the death of neurons, leading to vision impairment. A variety of infectious diseases, immune disorders, demyelinating disorders, non-inflammatory systemic disease or trauma can cause AON. AON is commonly associated with multiple sclerosis (“MS”) and shares similar physiopathology. AON is the presenting symptom of MS in 15-20% of patients and will impact over 50-65% of patients with MS at some time during their lifetime. However, the causes of AON are not always clear, as it can also arise in patients without MS.

The acute inflammation of the optic nerve causes the loss of myelin and oligodendrocytes, optic nerve conduction block and loss of vision. At the onset of AON, patients often suffer from ocular pain increasing with eye movement, associated with a variety of visual impairments. Deterioration of visual acuity, color vision or flashes of light are common. The loss of vision ranges considerably between patients from mild blurring to loss of perception of light. The condition tends to worsen over the first several days after the appearance of symptoms before starting to improve over the first two weeks. The recovery continues for as long as a year after onset. Even if high contrast visual acuity returns to near normal, patients often report that their vision has not completely recovered. There remains a persistent impairment of low contrast letter acuity and clinically meaningful reduction in vision-related quality of life.

When the inflammation recedes, remyelination often occurs but it is incomplete, the result of persistent demyelination and neuronal death. Without the myelin sheath which normally protects the axon, neurons located in demyelinated segments become fragile and prone to death. Thinning of the retinal neural fiber layer (“RNFL”), which is made up of unmyelinated axons originating from the retinal ganglion cell (“RGC”) bodies, indicates significant AON-induced axonal loss. RNFL thinning, most pronounced three to six months after an acute AON event, along with thinning of the ganglion cell bodies layer, correlates with diminished scores of visual acuity and visual field sensitivity.

No therapeutic is currently approved that preserves vision and ganglion/retinal nerve integrity after an acute episode of AON. Medication intended to treat the inflammation and related symptoms can be administered just after AON onset and patients often receive high doses of corticosteroids for a few days to alleviate disabling vision-related

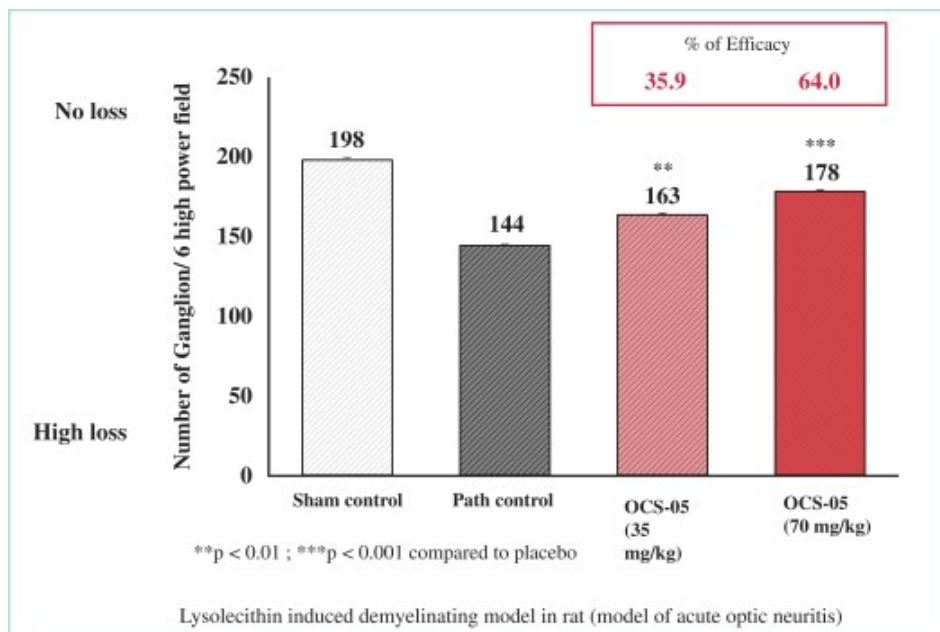
symptoms caused by the inflammation. Corticosteroids have become the current standard of care, as the therapy acts to shorten the attack and accelerate recovery of acute visual symptoms. However, vision loss persists in 10% to 20% of patients despite administration of IOP lowering therapy. We believe a neuroprotective therapeutic, such as OCS-05, if approved, could prevent long term axonal loss may promote enhanced clinical outcomes.

OCS-05 demonstrated compelling neuroprotective qualities in an animal model of AON

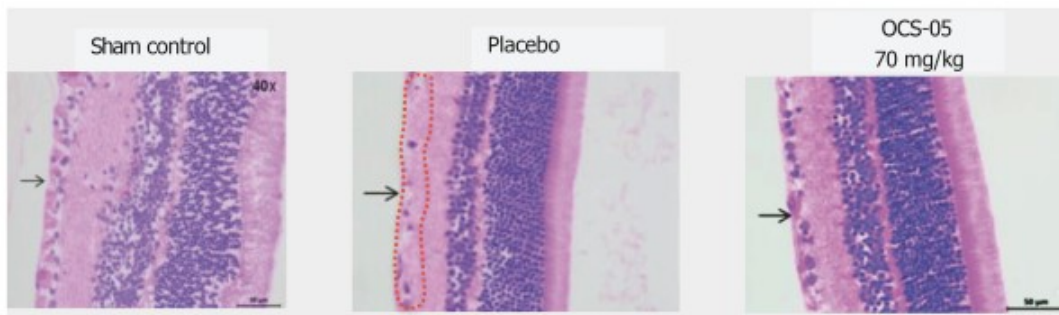
In a rat model of AON, animals were segregated into four groups. The first group of healthy animals represented a sham control. Three additional groups received lysolecithin via injection into the optic nerve of study animals to induce inflammation and demyelination. Rats in group two received no treatment and served as a pathological control group. Groups three and four were administered OCS-05 once daily over a five-day period. Animals in group three received a 35 mg/kg dose of OCS-05 while animals in the fourth group received a dose of 70 mg/kg. The animals were sacrificed on the sixth day and assessed for a decline in RGC count.

As is noted in the results presented below, both groups of animals that received OCS-05 generated a statistically significant reduction in RGC loss when administered following the lysolecithin challenge, with rats administered the 35 mg/kg dose of OCS-05 demonstrating a 35.9% mean reduction of RGC loss. Animals in the higher dose treatment group who received a 70 mg/kg dose of OCS-05 displayed a more profound benefit from OCS-05 dosing, with RGC loss declining 64.0%.

RGC loss in animals treated with OCS-05 was significantly reduced in an animal model of AON.



The reduction in RGC loss was also observed in a visual assessment of representative tissue samples collected from animals in three of the four study groups, the sham control group, the pathological control group and rats treated with the higher 70 mg/kg dose of OCS-05. As is depicted in the slides of the optic nerve presented below, normal ganglion cell density was observed in the evaluation of tissue taken from a healthy animal in the sham control group. In contrast, cell counts taken from samples of rats included the lysolecithin challenge group that made up the pathological control witnessed a prominent decrease. After completion of the five-day protocol, this decline was noted to have reversed, with rats who received the 70 mg/kg dose of OCS-05 observed to have retained a significantly higher number of ganglion cells. Similar results illustrating a reduction in axonal loss and demyelination, along with improvement in clinical function, have been achieved in animal models of AON.



OCS-05 was well tolerated in a trial involving healthy volunteers.

A randomized, double-masked, placebo controlled single-ascending dose and multiple-ascending dose trial was conducted in the United Kingdom to evaluate the safety, tolerability and PK and pharmacodynamics of OCS-05 dosing through the intravenous infusion of healthy volunteers with the drug candidate. This trial was designed to include four interlocking cohorts of eight adult subjects each to evaluate eight single ascending doses, with an additional two cohorts of eight adult subjects each included in the two multiple ascending dose trials. The single ascending dose cohorts were administered drug in doses ranging from .05 mg/kg to 3.2 mg/kg. The two cohorts in the multiple ascending dose trial received either a 2.4 mg/kg dose or a 3.0 mg/kg dose, once daily, for five consecutive days. In this trial, it was observed that OCS-05 was well tolerated with no serious AEs noted. Human PK data produced by this trial showed good correlation with data produced in animal studies of the compound. This trial was conducted under a clinical trial protocol approved by European regulatory authorities.

We are investigating OCS-05 as a treatment for AON in a First-in-Patient clinical trial

The results of prior clinical and preclinical trials of OCS-05 in promoting disease modifying effects, together with the safety and PK profile observed in this first-in-human clinical trial enabled us to advance the compound into a First-in-Patient clinical proof-of-concept trial. The Acute OptiC NeUrITis of DemYelinating Origin (“ACUITY”) trial, a randomized, double-masked, placebo controlled, multiple center trial, is a First-in-Patient trial enrolling patients diagnosed with AON within ten days of acute disease episode onset. The objective of this study is to assess the safety and tolerability of OCS-05 along with initial signs of efficacy. In addition to the trial’s primary safety endpoint, a key secondary endpoint will be the effect of OCS-05 on retinal layer thickness and other visual parameters in the affected eye. The study is currently being conducted in France under French regulatory guidance.

We believe that positive outcomes in this trial could support the compound’s possible development as a potential treatment in other ophthalmic conditions involving the posterior segment including glaucoma, geographic atrophy, DR as well as certain diseases of the anterior segment including corneal keratitis. The novel mechanism of action of OCS-05 may enable it to demonstrate benefit in treating these additional ocular conditions and may additionally allow its development in non-ocular neurological disorders involving neuronal inflammation such as MS.

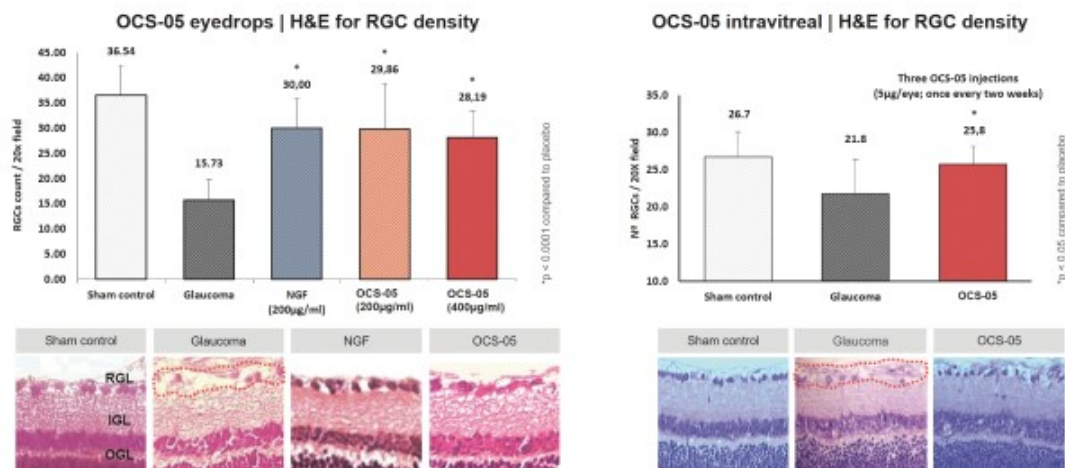
In 2016, the OCS-05 development program was placed on clinical hold by the FDA related to the absence of no observed adverse effects levels (“NOAEL”), in prior preclinical studies conducted by the sponsor at that time. After we licensed the asset from Accure, our strategy has included plans to work with DFS to complete the additional studies required to establish NOAEL, in order to enable our submission of an investigational new drug (“IND”) application with the FDA.

We are planning to investigate OCS-05’s potential as a treatment for Neurotrophic Keratitis and should the outcome of the AON trial be positive, we will also evaluate the potential as a treatment for neuro-ophthalmology diseases such as Glaucoma.

Preclinical studies of OCS-05 in a model of glaucoma in Sprague rats showed results which support its potential to be developed as a treatment for glaucoma. In these two experiments, high intraocular pressure was induced in rats by

injecting hypertonic saline solution into the episcleral vein of one eye of each rat, and then the rats were treated for six weeks. In one experiment, rats in the active group were treated with OCS-05 as an eye drop twice daily for six weeks, rats in the positive control group received nerve growth factor (“*NGF*”), and rats in the control group received placebo of saline 5% dimethyl sulfoxide (“*DMSO*”). In the other experiment, rats in the active group were treated with OCS-05 as an intravitreal injection once every two weeks, for six weeks, and rats in the control group received placebo of saline 5% *DMSO*. Retinal ganglion cells (“*RGCs*”) count was measured via haematoxylin and eosin stain (“*H & E*”) histological quantification, and IOP was also measured.

Sprague rats displayed significant loss of RGCs one month after the induction of ocular hypertension. In animals treated with OCS-05, either as eye drops or through intravitreal injection, there were statistically significant increases in RGCs surviving compared with those that received the placebo. In the experiment which included a positive control of NGF, OCS-05 treatment showed a similar effect to that seen with NGF. In addition, IOP did not significantly decrease with administration of OCS-05. We believe this data suggests that OCS-05 may promote neuronal survival in this animal model of glaucoma via neuroprotection (and not by reversing the induced ocular hypertension).



OCS-05 (eyedrops and intravitreal) prevents RGCs damage without reducing intraocular pressure

Given the results from these preclinical studies, we plan to further study OCS-05, and if results from our ACUIITY trial in AON further support OCS-05’s potential as a neuroprotective compound, we may prepare for and initiate clinical development of OCS-05 in glaucoma. Glaucoma represents a large market, and we are not currently aware of the existence of any other compound in a similar or more advanced stage of development as a neuroprotective drug for glaucoma.

Additionally, we also plan to further study OCS-05 for its potential to enter clinical development as a treatment for neurotrophic keratitis (“*NK*”). *NK* is a rare eye disorder which results from damage or loss of function of nerves which innervate the cornea, which can lead to corneal perforation, corneal scarring, corneal melting, loss of vision, or loss of the eye. In 2018, the FDA approved the NGF drug cenergermin (“*Oxervate*”) to treat *NK*. However, *Oxervate* may be cost prohibitive for patients and payors, as ASCRS Eyeworld estimated in 2020 that *Oxervate* costs \$11,000 per week for an 8-week treatment course for *NK*.

Given that preclinical studies of OCS-05 have shown data suggesting that the OCS-05 could provide neuroprotective benefits, we believe it may have potential to treat the nerve impairment underlying *NK*. If results from our ACUIITY trial in AON further support OCS-05’s potential as a neuroprotective compound, we may prepare for and initiate clinical development of OCS-05 in *NK*. We are currently not aware of the existence any other drugs except for *Oxervate* which are approved or in a similar or more advanced stage of development as a treatment for *NK*.

We are currently conducting formulation studies to develop a topical formulation of OCS-05 which can be used in further preclinical or in clinical development of OCS-05 in glaucoma or in *NK*.

Additional Discovery Initiatives

In addition to our five clinical development programs involving OCS-01, OCS-02 and OCS-05, we also are engaged in a number of earlier preclinical development initiatives, including the evaluation of OCS-03 as a possible treatment for corneal neovascularization, a common disorder caused by the aberrant development of new blood vessels into the cornea and pterygium, a pink colored growth that originates in the conjunctiva. We are also assessing the preclinical candidate OCS-04 as a potential therapeutic to prevent rejection in patients receiving corneal transplants.

Material Licenses, Partnerships and Collaborations

License Agreement with Novartis for OCS-02

Pursuant to a license agreement, dated as of December 19, 2018, as amended, by and between us and Novartis (the “*Novartis Agreement*”), we obtained an exclusive, royalty-bearing, sublicensable (subject to certain conditions), assignable (subject to certain conditions), worldwide license under certain patents, know-how and manufacturing platform technology to develop, manufacture and commercialize pharmaceutical, therapeutic or diagnostic products containing a specified single chain antibody fragment formulation as an active ingredient in the licensed field as defined in the Novartis Agreement. The license granted to us by Novartis includes sublicenses of rights granted to Novartis by certain third parties, and our license to such rights is expressly subject to the applicable terms and conditions of the agreements between Novartis and such third parties.

We are deemed the owner of any inventions that are (a) created solely by or on behalf of us pursuant to the Novartis Agreement and (b) severable from the licensed products, and grant Novartis a first right to negotiate a worldwide, royalty-bearing license under any patents directed at such inventions for purposes outside of the licensed field. We also grant Novartis a worldwide, non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up license back under any patents owned by us that (i) cover inventions arising from the Novartis Agreement, the practice of which would infringe the patents licensed to us by Novartis, or (ii) otherwise incorporate Novartis’ proprietary information, in each case, for certain uses outside of the licensed field.

We made an initial payment to Alcon of CHF 4.7 million (\$4.7 million at the exchange rate at the time of payment) in cash. We originally entered into the Novartis Agreement with Alcon Research, Ltd. (“*Alcon*”), which subsequently assigned its rights and obligations under the Novartis Agreement to Novartis in connection with Alcon's spin-off from Novartis. As of December 31, 2022, we were obligated to pay Novartis additional up to CHF 89.7 million (\$ 97.0 million at the December 31, 2022 exchange rate) in the aggregate upon the achievement of certain development, regulatory, sales and other milestones and tiered royalties ranging from a mid-single digit to a mid-teen percentage on net sales. In consideration for the exclusive sublicense from Novartis under certain third-party intellectual property rights, we are obligated to pay a low-single digit royalty on our net sales of the licensed product, however, such payments will be deducted from royalties payable to Novartis. Our royalty payment obligations are subject to certain reductions and expire with respect to any licensed product on a country-by-country basis upon the later of (a) the expiration of the last to expire valid claim of any licensed patent covering any such licensed product in such country; (b) the expiration of the period of data exclusivity in any country worldwide; or (c) twelve (12) years after first commercial sale of such licensed product in such country (“*Royalty Term*”).

Under the Novartis Agreement, we are obligated to use diligent efforts to develop, manufacture or have manufactured, and commercialize the licensed products in the licensed field worldwide. The Novartis Agreement will expire upon the last-to-expire Royalty Term. We may terminate the Novartis Agreement without cause at any time upon advance written notice to Novartis. Upon written notice to Novartis, we may terminate the Novartis Agreement for cause due to the following events: (a) an insolvency event occurs; (b) Novartis materially breaches its obligations under the Novartis Agreement and fails to cure such breach within a specified period of time; or (c) upon advance written notice for material scientific, technical or medical reasons or in case of a material adverse change that renders further continuation of the Novartis Agreement by us commercially unreasonable or otherwise not viable. Upon written notice to us, Novartis may terminate the Novartis Agreement for cause due to the following events: (i) we fail to pay any undisputed amount due under the Novartis Agreement and we fail to remedy such failure within a specified period of time; (ii) an insolvency event occurs; (iii) we materially breach our obligations under the Novartis Agreement and fail to cure such breach within a specified period of time; or (iv) following negative clinical trial results, we terminate development of the licensed product and do not pursue any further indications in the licensed field.

License Agreement with Accure for OCS-05

Pursuant to a license agreement, dated as of January 29, 2022, by and between us and Accure (the “*Accure Agreement*”), we obtained an exclusive, worldwide, sublicensable (subject to certain conditions) and transferable (subject to certain conditions) license under certain patents, know-how and inventory of Accure for any and all uses and purposes, including to perform research, development, manufacturing and commercialization activities in any manner and for any purpose. The licensed patents are co-owned by Accure with third parties who have reserved the right to use the licensed patents for education and research purposes pursuant to an inter-institutional agreement.

As of December 31, 2022, Legacy Oculis has paid the full contractual non-refundable up-front fee of CHF 3.0 million and reimbursed costs in the amount of approximately CHF 0.5 million. As of December 31, 2022, we were obligated to pay Accure (a) up to CHF 103.6 million (\$112.1 million at the December 31, 2022 exchange rate) in the aggregate upon the achievement of certain development, regulatory and sales milestones; (b) tiered royalties ranging from a mid-single digit to a low mid-teen percentage on net sales of licensed products; and (c) a percentage in the high teens on sublicensing revenues received any time after 36 months from the agreement effective date, and a higher percentage on sublicensing revenues received prior to such date, in all cases subject, in the case of this clause (c), to reduction for any amounts that were previously paid or are concurrently or later paid by us to Accure pursuant to our milestone payment obligations. Our royalty payment obligations are subject to certain reductions and expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of any licensed patent covering such licensed product in such country; (ii) the expiration of such licensed product’s Orphan Drug status, if any, in such country; or (iii) ten (10) years following the date of first commercial sale of such licensed product in such country (the “*Payment Period*”).

Under the Accure Agreement, we are obligated to use commercially reasonable efforts to develop and seek regulatory approval for a licensed product in major countries of the territory as defined in the Accure Agreement.

The Accure Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable Payment Period with respect to such licensed product in such country. We may terminate the Accure Agreement in whole or in part at any time upon advance written notice (a) for documented reasonable scientific, regulatory, commercial reasons related to the licensed product without incurring any penalty or liability to Accure and (b) for no reason. Each party may terminate the Accure Agreement with immediate effect upon written notice to the other party (i) in the event such other party commits a material breach of its obligations under the Accure Agreement and fails to cure that breach within a specified period of time or (ii) with certain exceptions, upon such other party’s bankruptcy. Accure may terminate the Accure Agreement with immediate effect upon written notice to us if we file any action to invalidate any of the licensed patents or fail to maintain the licensed patents in major countries of the territory as defined in the Accure Agreement, or, subject to certain exceptions, if we fail to meet certain development obligations and are unable to agree upon modifications to the development plan with Accure.

Manufacturing Strategy

We oversee and manage third-party contract manufacturing organizations (“*CMOs*”), to support development and manufacture of product candidates for our clinical trials, and, if any product candidates receive marketing approval, we expect to rely on such manufacturers to meet commercial demand. We expect this strategy will enable us to maintain a more efficient operating and cost infrastructure, avoiding dependence on our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise on the clinical development and future commercialization of our products, if approved. Currently, we rely on and have agreements with third-party contract manufacturers for developing and manufacturing API/drug substance/drug product for OCS-01, OCS-02 and OCS-05, and we expect to enter into commercial supply agreements with such manufacturers prior to any potential approval. We continue to develop and improve the manufacturing processes for OCS-02 and OCS-05 and to address the requirements in these highly regulated markets. Improvement of manufacturing processes may involve transferring the development and manufacturing to another CMO, taking into account technical, quality and economic aspects.

Each of OCS-01, OCS-02 and OCS-05 is manufactured via conventional pharmaceutical processing procedures, employing commercially available excipients and packaging materials. The procedures and equipment employed for manufacture and analysis are consistent with standard pharmaceutical production, and are transferable to a range of manufacturing facilities, if needed.

Competition

We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the treatment of ocular conditions.

In addition to the current standard of care treatments for patients with ocular diseases, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates.

Several large pharmaceutical and biopharmaceutical companies that have commercialized, or are developing treatments for ocular diseases, compete with us. Companies that compete with us directly on the level of the development of product candidates targeting DME include Abbvie, Alimera Sciences, Bayer, Novartis, Regeneron and Roche; companies that have commercialized or are developing drug candidates to treat inflammation and pain associated with ocular surgery include Abbvie, Alcon, Bausch + Lomb, Novartis and Teva Pharmaceuticals; companies that compete with us in the area of DED include Abbvie, EyePoint Pharmaceuticals, Aldeyra, Alcon, Novartis, Viatris and Sun Pharmaceuticals; and companies engaged in the commercialization or development of therapeutics to treat uveitis include Abbvie, Bausch + Lomb and Novartis, among others. We are also aware of an eye drop product candidate in clinical development by Ocuterra for the treatment of diabetic retinopathy and DME, an indication related to the indication for which we are developing OCS-01.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory approval process and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offerings. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by obtaining, maintaining, enforcing and defending intellectual property rights, including patent rights, whether owned or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally related to our novel drug targets, composition of matter, formulations and other inventions and improvements that are central to our R&D efforts. For our product candidates, our strategy is to pursue patent protection covering compositions of matter, formulations and methods of use. In addition, we seek to identify additional means of obtaining patent protection, including specific therapeutic indications and dosing regimen-related claims, which may enhance commercial success. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection.

As of December 31, 2022, we owned and exclusively in-licensed patent portfolio included 11 issued U.S. patents, five issued European patents validated in multiple jurisdictions, and 45 issued patents in other foreign jurisdictions, as well as six pending non-provisional U.S. patent applications, and 65 foreign pending patent applications, including five pending European patent applications, and one pending PCT application related to our different product candidates, namely, OCS-01, OCS-02, OCS-03, OCS-04 and OCS-05.

OCS-01

Regarding our OCS-01 product candidate, as of December 31, 2022, we owned a patent family that consisted of three issued U.S. patents and one granted European patent validated in 12 jurisdictions (Belgium, France, Germany, Great Britain, Iceland, Ireland, Italy, the Netherlands, Poland, Spain, Switzerland, Turkey) with claims covering the composition including dexamethasone. These patents will expire in 2026, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 31, 2022, we owned a second patent family that consisted of two issued U.S. patents, two pending non-provisional U.S. patent applications, one granted European patent validated in 41 jurisdictions (Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Germany, Great Britain, Greece, Finland, France, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Monaco, Montenegro, Morocco, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey), nine issued patents in other foreign jurisdictions (Columbia, Eurasia, India, Japan, Mexico, South Africa (two patents), Taiwan, Ukraine) and 17 pending foreign patent applications, including one pending European patent application, with claims covering the composition of matter of OCS-01. Patents (including any patents that issue from such patent applications) in this family will expire in 2037, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 31, 2022, we also owned a patent family that consisted of one U.S. non-provisional patent application and 21 additional foreign patent applications in other jurisdictions, including one European patent application, directed to specific formulations of OCS-01 and methods for stabilizing the composition for use as an eye drop. Patents, if issued from patent applications in this family, will expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

OCS-02

Regarding our OCS-02 product candidate, as of December 31, 2022, we exclusively licensed from Novartis under the Novartis Agreement, in the licensed field as defined in the Novartis Agreement, one patent family that consisted of three issued U.S. patents and two granted European patents (respectively one European patent validated in 36 jurisdictions (Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey) and another European patent validated in six jurisdictions (France, Germany, Great Britain, Italy, Spain, Switzerland), 28 issued patents in other foreign jurisdictions (Argentina, Australia (three patents), Brazil, Canada, Chile (two patents), China (two patents), India, Hong-Kong (two patents), Japan (two patents), Republic of Korea (two patents), Mexico (three patents), Philippines, Russia, South Africa, Taiwan (three patents), Ukraine, Uruguay) and five patent applications pending in other foreign jurisdictions, with claims covering composition of matter of OCS-02 or methods of use. Patents (including any patents that issue from such patent applications) will expire in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

In addition, as of December 31, 2022, we exclusively licensed from Novartis under the Novartis Agreement, in the licensed field as defined in the Novartis Agreement, six additional patent families covering composition of matter of OCS-02 or methods of use, including a biomarker for patient selection, which patents (including any patents that issue from patent applications in these families) will expire between 2023 and 2037, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal,

annuity or other governmental fees. Under the terms of the Novartis Agreement, Novartis is responsible for the prosecution and maintenance of these six patent families.

OCS-03

As of December 31, 2022, we also owned a pending PCT and US application with claims covering composition of matter of OCS-3 and its use. A European application claiming the benefit of such PCT application will be filed within the 31 months due date from the priority date of the PCT application. Patents, if issued from EP regional phases of such PCT application, will expire in 2041, assuming entering in European regional phases filings within the 31 months period, and without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

OCS-04

As of December 31, 2022, we also owned a priority European patent application with claims covering composition of matter of OCS-04 and manufacturing processes. In order for any future patent applications to claim the benefit of such priority application, they must be filed not later than 12 months after the filing date of such priority application. Patents, if issued from the patent applications claiming the benefit of such priority application, if issued, will expire in 2042 or 2043, assuming a filing within the 12-month priority period, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

OCS-05

Regarding our OCS-05 product candidate, as of December 31, 2022, we exclusively licensed from Accure under the Accure Agreement a patent family that consisted of three issued U.S. patents and one granted European patent validated in 24 jurisdictions (Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, Turkey), as well as 10 issued patents (Australia, Brazil, Canada, China, India, Israel, Japan, Republic of Korea, Mexico, Russia) in other foreign jurisdictions, with claims covering composition of matter of OCS-05. These patents (including any patents that issue from such patent applications) will expire in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 31, 2022, we also exclusively licensed from Accure under the Accure Agreement a patent family that consisted of one pending non-provisional U.S. patent application and 15 pending foreign patent applications, including one pending European patent application, directed to the method of use of the composition of OCS-05 in combination with active compounds. Patents, if issued from such patent applications, will expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 31, 2022, we also exclusively licensed from Accure under the Accure Agreement a patent family consisting of one pending non-provisional U.S. patent application and six pending foreign patent applications, including one pending European patent application, with claims directed to specific dosage regimen for administering the active pharmaceutical ingredient of OCS-05. Patents, if issued from such patent applications, will expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

As of December 31, 2022, we also owned a priority European patent application with claims covering a manufacturing process of OCS-05 and OCS-05's intermediate synthesis products. In order for any future patent applications to claim the benefit of such priority application, such future patent application must be filed no later than 12 months after the filing date of such priority application. Patents, if issued from the patent applications claiming the benefit of such priority application, will expire in 2042 or 2043, assuming a filing within the 12-month priority period, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Our commercial success will depend in part on obtaining, maintaining, protecting and enforcing patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges, enforcing such patents against third-party infringers, and operating without infringing on, misappropriating or otherwise violating the intellectual property or proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be issued with respect to any of our owned or in-licensed pending patent applications or with respect to any patent applications filed by us or our licensors in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see the section entitled “*Risk Factors—Risks Related to Our Intellectual Property.*”

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (“*USPTO*”), in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. U.S. patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see section entitled “*Risk Factors—Risks Related to Our Intellectual Property.*”

We file U.S. non-provisional applications and Patent Cooperation Treaty (“*PCT*”), applications that claim the benefit of the priority date of earlier filed priority applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application is not issued as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any product candidates, as well as all new applications and/or uses we discover for existing technologies and product candidates, assuming these are strategically valuable. We continuously reassess the number and type of patent applications in our portfolio, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes and compositions, given existing patent office rules and regulations. Further, claims may be narrowed during patent prosecution, to the extent allowed, to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we or our licensors may not obtain or maintain adequate patent protection for any of our future product candidates or for our Optireach® technology platform. We cannot predict whether the owned or in-licensed patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents we own or in-license will provide sufficient proprietary protection from competitors. Any patents that we own or in-license may be challenged, circumvented or invalidated by third parties.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to intellectual property or proprietary rights required to develop or commercialize our product candidates or future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see the section entitled “*Risk Factors—Risks Related to Intellectual Property.*”

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. As of December 31, 2022, we owned four registered U.S. trademarks (three of which being fractions of international registrations), four international trademark registrations (either granted or still under examination in several countries), 11 registered foreign trademarks as well as two pending foreign trademark applications. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee’s use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, please see the section entitled “*Risk Factors—Risks Related to Intellectual Property.*”

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property or proprietary rights related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, nonclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing. Generally, before a new drug or biologic can be marketed, considerable data must be generated, which demonstrate the product’s quality,

safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug and Biologic Development Process

In the United States, the FDA regulates drugs and biologics under the federal Food, Drug, and Cosmetic Act (“*FDCA*”), and its implementing regulations. Biologics are additionally subject to regulations under the Public Health Service Act. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a biopharmaceutical may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies, and formulation studies in accordance with FDA’s good laboratory requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (“*IRB*”) ethics committee, either centralized or with respect to each clinical site, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with cGCP requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or Biologics License Application (“*BLA*”) after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the biopharmaceutical is produced to assess compliance with cGMP regulations to ensure that the facilities, methods and controls are adequate to preserve the biopharmaceutical’s identity, strength, quality, and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which may review data and endpoints at designated check points, make recommendations and/or halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase One: Phase 1 clinical trials are designed to test a new therapy in a small group of people for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify adverse effects). It can include healthy participants or patients.

Phase Two: Phase 2 clinical trials are designed to study an investigational therapy in a larger group of people to determine efficacy and to further evaluate its safety. It is conducted in participants with the condition or disease under study and will determine common short-term adverse effects and risks.

Phase Three: Phase 3 clinical trials are designed to study the efficacy of the investigational therapy in large groups of patients by comparing the therapy to other standard or experimental therapies as well as to monitor adverse effects, and to collect information that will allow the therapy being studied to be used safely.

Post-approval clinical trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

During the development of a new biopharmaceutical, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP regulations. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final product. In addition, appropriate

packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AEs, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

NDA or BLA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees, although a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA has a goal of ten months from the date of "filing" of a standard NDA or BLA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA or BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs or BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP regulations and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the application identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the application does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the application with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP regulations and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP regulations and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase 4 clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

The FDA closely regulates the marketing, labeling, advertising, and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA") or an NDA submitted under Section 505(b)(2) ("505(b)(2) NDA"), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Section 505(b)(2) NDAs

A special type of NDA, commonly referred to as a Section 505(b)(2) NDA, enables the applicant in certain circumstances to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. A Section 505(b)(2) NDA may provide an alternate path to FDA approval for a new or improved formulation, a new route of administration, or a new use of a previously approved product. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is

scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. If we choose to rely on the 505(b)(2) process to seek approval for OCS-01, there can be no assurance that the FDA will agree with our use of that pathway.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's prior findings of safety or effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

FDA Approval and Regulation of Companion Diagnostics

A therapeutic product may rely upon an *in vitro* companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion diagnostics in conjunction with the review of our therapeutic product candidate OCS-02 will, therefore, likely involve coordination of review by the FDA's Center for Biologics Evaluation and Research and the FDA's Center for Devices and Radiological Health.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The three primary types of FDA marketing authorization applicable to a medical device include premarket notification, also called 510(k) clearance, premarket approval ("*PMA*"), and *de novo* classification requests.

EU/Rest of World Regulation

Conduct of Clinical Trials in the EU

In addition to regulations in the United States, there are a variety of regulations in other jurisdictions governing, among other things, clinical trials, commercial sales and distribution of medicinal products. Even if FDA approval of a particular product is obtained, it must still obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

In the EU, the Clinical Trials Regulation (EU) No 536/2014 entered into application on January 31, 2022. The Regulation is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase their transparency. Specifically, the new Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure via a single entry point, the "EU portal", the Clinical Trials Information System ("*CTIS*"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I is assessed by the competent authorities of a reference member state selected by the trial sponsor largely of the type of clinical trial, risk-benefit analysis, and compliance with technical requirements. This assessment is then submitted

to the competent authorities of all the concerned member states in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and ECs in each EU member state concerned. Individual EU Member States shall retain the power to authorize the conduct of clinical trials on their territory. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial. If a clinical trial continues for more than three years from January 31, 2022, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

Pathways to Obtain a Marketing Authorization in the EU

In the European Economic Area (“EEA”), which consists of the 27 Member States of the European Union, as well as Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after a related marketing authorization has been granted. A company may submit a marketing authorization application (“MAA”), either on the basis of the centralized, or decentralized procedure or mutual recognition procedure. Under the centralized procedure, MAAs are submitted to the EMA for scientific review by the EMA’s Committee for Medicinal Products for Human Use (“CHMP”). The CHMP issues an opinion concerning whether the quality, safety and efficacy of the product has been demonstrated. The opinion is considered by the European Commission which is responsible for granting a centralized marketing authorization in the form of a binding European Commission decision. If the application is approved, the European Commission C grants a single marketing authorization that is valid throughout the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National marketing authorizations, which are issued by the competent authorities of EEA countries and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EEA country, this national marketing authorization can be recognized in another EEA country through the mutual recognition procedure. The mutual recognition procedure provides for the EEA countries selected by the applicant to mutually recognize a national marketing authorization that has already been granted by the competent authority of another EEA country, referred to as the Reference Member State (“RMS”). The decentralized procedure is used when the product in question has yet to be granted a marketing authorization in any EEA country. Under this procedure the applicant can select the EEA country that will act as the RMS. In both the mutual recognition and decentralized procedures, the RMS reviews the application and submits its assessment of the application to the EEA countries for which marketing authorizations are being sought, referred to as Concerned Member States.

Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether to recognize the RMS assessment or reject it on the basis of potential serious risk to public health. If the disputed points cannot be resolved, the matter is first referred to the Heads of Medicines Agencies’ Coordination Group for Mutual Recognition and Decentralized Procedures for agreement. If the Heads of Medicines Agencies’ Coordination Group for Mutual Recognition and Decentralized Procedures cannot reach an agreement, a referral is made to the EMA. The CHMP will provide an opinion that will form the basis of a decision to be issued by the European Commission that is binding on all EEA countries. If the application is successful during the decentralized or mutual recognition procedure, national marketing authorizations will be granted by the competent authorities in each of the EEA countries chosen by the applicant.

In principle, a marketing authorization has an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EEA country in which the original marketing authorization was granted. To support the application, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up to date data concerning the quality, safety and efficacy of the product, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EEA countries may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be

valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EEA country within three years after authorization ceases to be valid (the so-called sunset clause).

In the EU, conditional marketing authorizations may be granted in the centralized procedure for a limited number of medicinal products for human use in cases where the related clinical dataset is not yet complete. A conditional marketing authorization may be granted for a medicinal product, if (i) the risk-benefit balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive data after the authorization, (iii) the medicinal product fulfills unmet medical needs and (iv) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. The authorization is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

A marketing authorization may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional marketing authorization, a marketing authorization granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard marketing authorization. However, unlike the conditional marketing authorization, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the marketing authorization “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization is withdrawn in case the risk-benefit ratio is no longer favorable.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (“PRIME”), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA’s support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In addition to an MAA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the Union. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. Marketing authorization holders and/or manufacturing and import authorization (MIA) holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states’ requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

In the EU, innovative medicinal products that are subject to marketing authorization on the basis of a full dossier and do not fall within the scope of the concept of global marketing authorization qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The concept of global marketing

authorization prevents the same marketing authorization holder or members of the same group, or companies that have concluded tacit or explicit agreements concerning the marketing of the same medicinal product, from obtaining separate data and market exclusivity periods for medicinal products that contain the same active substance. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. However, the generic product or biosimilar products cannot be marketed in the EU for a further two years thereafter. The overall ten-year period may be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate or SPC if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. For other countries outside of the European Union, such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Orphan Medicinal Products

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application, or grant a marketing authorization, or accept an application to extend a marketing authorization for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has

increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application; (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Requirements

Where a marketing authorization is granted in relation to a medicinal product in the EU, the holder of the marketing authorization is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EEA countries. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (“*PSURs*”).

All new marketing authorization applications must include a risk management plan (“*RMP*”), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of *PSURs*, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EEA countries laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics (“*SmPC*”), as approved by the competent authorities in connection with a marketing authorization. The *SmPC* is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the *SmPC* is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Regulation of Companion Diagnostics in the EU

In the EU, despite the absence of a legal definition, companion diagnostics are deemed to be *in vitro* diagnostic medical devices and are governed by Directive 98/79/EC (“*IVDD*”). The *IVDD* currently regulates the placing on the market, the CE-marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufacturers and devices as well as the vigilance procedure related to such products. *In vitro* diagnostic medical devices, including companion diagnostics, must comply with the requirements provided for in the *IVDD*, and with further requirements implemented at national level (as the case may be).

In vitro diagnostic medical devices (including companion diagnostics) are currently required to conform with the essential requirements of the *IVDD*. To demonstrate compliance with the essential requirements laid down in Annex I to the *IVDD*, the manufacturer must conduct a conformity assessment procedure.

For general *in vitro* diagnostic medical devices (i.e. all *IVDs* other than those covered by Annex II to the *IVDD* and *IVDs* for self-testing), the conformity assessment is performed through a self-assessment of the manufacturer without the intervention of a notified body which is an independent organization designated by the competent authorities of an EU member state to assess the conformity of devices before being placed on the market. The manufacturer must prepare an EC Declaration of Conformity confirming conformity of its products with the essential requirements laid down in the *IVDD* before placing the product on the EU market.

By contrast, the conformity assessment of *in vitro* diagnostic medical devices for self-testing or that are listed in Annex II (i.e. essentially moderate and high risk reagents and reagent products) to the IVDD requires the intervention of a notified body. Following successful completion of a conformity assessment procedure the notified body will issue a CE Certificate of Conformity. The device manufacturer may, after having completed remaining related procedures and obligations, affix the CE mark to its medical device after having prepared and signed a related EC Declaration of Conformity.

The regulation of companion diagnostics will be subject to further requirements once the *in vitro* diagnostic medical devices Regulation (No 2017/746), (“*IVDR*”), becomes applicable on May 26, 2022. The IVDR introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. If the medicinal product has, or is in the process of, been authorized through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorization through any other route provided in EU legislation, the notified body must seek the opinion of the national competent authority of an EU Member State.

Other Healthcare Laws

Pharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the U.S. federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, lease, furnishing, prescribing or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the “*ACA*”), among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation;
- federal civil and criminal false claims laws, including the federal False Claims Act which can be enforced by private individuals on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws prohibit individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (“*HIPAA*”), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“*HITECH*”), and their respective implementing regulations, which impose obligations on certain

healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, known as business associates, as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals and ownership and investment interests held by some of these healthcare professionals and their immediate family members;
- analogous foreign laws and regulations; and
- similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation ((EU) 2016/679), ("*GDPR*"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for controllers and processors of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for high-risk processing, limitations on retention of personal data and mandatory data breach notification and privacy by design requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data out of the EEA to countries that

do not ensure the same level of protection, such as the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA countries may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim compensation for damages resulting from infringement of the GDPR.

Following the United Kingdom's (the "UK") withdrawal from the EU and the expiration of the transition period, from January 31, 2020, companies doing business in the EU and the UK will be obliged to comply with both the GDPR and the U.K. GDPR. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the European Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term.

Brexit and the Regulatory Framework in the United Kingdom

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency (MHRA) is now the UK's standalone regulator.

On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement. The EU-U.K. Trade and Cooperation Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the EU-U.K. Trade and Cooperation Agreement.

Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules.

As part of the EU-U.K. Trade and Cooperation Agreement, the EU and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The EU-U.K. Trade and Cooperation Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release.

The UK has unilaterally agreed to accept EU batch testing and batch release for a period of at least two years until January 1, 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). It is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation on January 31, 2022.

Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain a marketing authorization to market products in the UK. For an initial two year period from January 1, 2021, MHRA is able to rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EEA countries to be granted in Great Britain. This two year period was recently extended to December 31, 2023. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; and updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations

in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

Orphan designation in Great Britain following Brexit is, unlike in the EU, not available pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a marketing authorization. The criteria to be granted an orphan drug designation or essentially identical to those in the European Union but based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the transition period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the European Union will be designated as such in Great Britain.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; it required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; it implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; it expanded the eligibility criteria for Medicaid programs; it created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical

effectiveness research, along with funding for such research; and it established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (“IRA”), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the “donut hole” under the Medicare Part D program beginning in 2025, by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges or additional health reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2031 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services (“HHS”), released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things: (i) allows HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action may be taken in response to the COVID-19 pandemic. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference to pricing systems and publication of discounts and list prices.

The Health Technology Assessment (“HTA”) process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. A new regulation adopted in December 2021 the HTA Regulation, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and to provide the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will apply from 2025 followed by a phased roll-out ending in 2028.

Employees and Human Capital Resources

As of December 31, 2022, we had 28 employees. Our headcount for R&D was 15, and our headcount for G&A was 13. Our employees include 11 executive leadership, administrative, and development personnel based in Switzerland; 8 executive leadership, administrative, and research personnel based in Iceland; 5 executives and administrators based in the United States; 4 management, research and administrative personnel based in France and China. Pursuant to local laws, our employees in Iceland and France are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

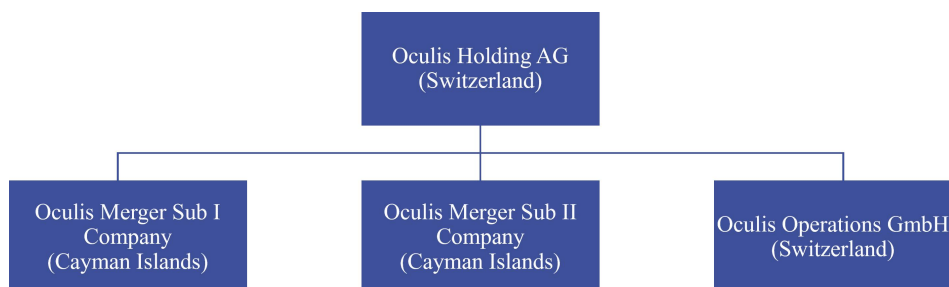
We currently lease approximately 7,200 square feet of laboratory and office space in Iceland, Switzerland and the United States. We believe these facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed. We believe that these facilities are adequate to meet our current needs, but we are constantly evaluating our needs for expanding and or adding to our existing facilities.

Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

C. Organizational Structure

Upon consummation of the Business Combination on March 2, 2023, Merger Sub 1 merged with and into EBAC, with EBAC as the surviving company of the First Merger, and EBAC merged with and into Merger Sub 2, with Merger Sub 2 as the surviving company of the Second Merger and wholly owned subsidiary of the Company. During the first half of 2023, Legacy Oculis will merge with and into Merger Sub 3, with Merger Sub 3 (Oculis Operations GmbH) as the currently planned surviving company and wholly owned subsidiary of Oculis Holding AG of the Third Merger. The following diagram illustrates our corporate structure as of January 15, 2023.



D. Property, Plants and Equipment

We currently lease approximately 7,200 square feet of laboratory and office space in Iceland, Switzerland and the United States. We believe these facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed. We believe that these facilities are adequate to meet our current needs, but we are constantly evaluating our needs for expanding and or adding to our existing facilities.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

You should read the following discussion and analysis of our audited financial condition and results of operations together with our consolidated financial statements appearing elsewhere in this Annual Report on Form 20-F. This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expect,” “anticipate,” “intend,” “believe,” or similar language. All forward-looking statements included in this Annual Report on Form 20-F are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under “Item 3.D. Risk Factors.” Actual results could differ materially from those projected in the forward-looking statements. The terms “Company,” “Oculis,” “we,” “our” or “us” as used herein refer to Oculis and its consolidated subsidiaries unless otherwise stated or indicated by context.

All amounts discussed are in Swiss francs, unless otherwise indicated.

Company Overview

We are a clinical-stage biopharmaceutical company, based in Switzerland, with substantial expertise in therapeutics used to treat ocular diseases, engaged in the development of innovative drug candidates which embrace the potential to address many eye-related conditions. Our focus is on advancing therapeutic candidates intended to treat significant and growing ophthalmic diseases which result in vision loss, blindness or reduced quality of life, for which there are currently limited or no treatment options. Our clinical portfolio currently consists of OCS-01, our lead development candidate which is currently in two ongoing Phase 3 clinical trials, one involving its use as a treatment for diabetic macular edema (“DME”), and the other assessing its utility to treat inflammation and pain following cataract surgery. Our second clinical initiative involves OCS-02, which we anticipate entering two Phase 2b clinical trials in the first half of 2023, the first for use as a potential treatment for keratoconjunctivitis sicca, or dry eye disease (“DED”), and the second trial designed to evaluate its potential as a therapy for the treatment of non-infectious anterior uveitis. Our third clinical candidate is OCS-05, which is a novel neuroprotective agent with potential application in multiple indications, including glaucoma, dry age-related macular degeneration (“AMD”) and diabetic retinopathy (“DR”). We are initially evaluating OCS-05 as a potential treatment for acute optic neuropathy, or AON, for which there is no currently approved therapeutic treatment.

Numerous diseases and disorders, many of which represent significant medical needs, are associated with the human eye. The National Eye Institute, a part of the U.S. National Institutes of Health, estimates that in the United States,

blindness or significant visual impairment impacts more than four million people, including those with vision loss resulting from retinal diseases such as DME, macular degeneration, DR, and retinal vein occlusion (“RVO”); disorders caused by swelling and inflammation such as DED, corneal keratitis and uveitis; and glaucoma, among other disease states. The global market for therapeutics used to treat eye disease is estimated to have exceeded \$22 billion in 2020, according to industry sources.

To date, we have primarily financed our operations through the proceeds from share issuances and grants. We have no products approved for commercialization and have never generated any revenues from product sales. Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. It may be several years, if ever, before we have a product candidate approved for commercialization, and we begin to generate revenue and royalties from product sales. We have also incurred significant operating losses. We incurred net losses of CHF 38.7 million and accumulated losses balance of CHF 111.0 million for the fiscal year ended December 31, 2022.

Factors Affecting Our Performance

Business Environment

The biopharmaceutical industry is extremely competitive. We are subject to risks and uncertainties common to any early-stage biopharmaceutical company. These risks include, but are not limited to, the introduction of new products, therapies, standards of care or technological innovations, our ability to obtain, maintain, protect and enforce our licensed technology, data and other intellectual property and proprietary rights and compliance with extensive government regulation and oversight. Please see the section entitled “*Risk Factors*” for more information. We are also dependent upon the services of key personnel, including our Chief Executive Officer, executive team and other highly skilled employees. Demand for experienced personnel in the pharmaceutical and biotechnology industries is high and competition for talent is intense.

We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions. Many of our competitors are working to develop or have commercialized products similar to those we are developing and have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. Our competitors may also have significantly greater financial resources, established presence in the markets in which we hope to compete, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and registering patients for clinical trials, entering into agreements with CMOs for the manufacture of our product candidates, as well as in acquiring technologies complementary to, or necessary for, our programs.

The Business Combination, PIPE Financing and the CLA

On March 2, 2023, we consummated the Business Combination with Legacy Oculis and EBAC pursuant to the Business Combination Agreement dated October 17, 2022 (the “BCA”). The Business Combination was accounted for as a capital reorganization.

Concurrently with the execution of the BCA, EBAC and Oculis entered into Subscription Agreements with certain investors (the “PIPE Financing”). On March 2, 2023, immediately prior to the closing of the Business Combination, the PIPE Financing was closed, pursuant to the Subscription Agreements, in which subscribers collectively subscribed for 7,118,891 ordinary shares at approximately CHF 9.40 (\$10.00) per share for an aggregate subscription price equal to approximately CHF 66.9 million (or approximately \$71.2 million).

Concurrently with the execution of the BCA, Legacy Oculis and the Lenders party thereto entered into convertible loan agreements pursuant to which the Lenders granted Legacy Oculis a right to receive a convertible loan with certain conversion rights in an aggregate amount of approximately CHF 18.5 million (or approximately \$19.7 million). Following the Second Merger Effective Time on March 2, 2023, Oculis assumed the Convertible Loan Agreements, and immediately after such assumption but before the Oculis Share Contribution, the Lenders exercised their

conversion rights in exchange for Ordinary Shares at CHF 9.40 (\$10.00) per share, on substantially the same terms as the PIPE Investors.

The closing of the Business Combination, the PIPE Financing and the conversion of the CLA provided the Group with gross proceeds of approximately CHF 97.4 million (or approximately \$103.7 million) that was used to finance the continuing development of our clinical stage portfolio. The Company also incurred an estimated CHF 16.7 million (or approximately \$17.5 million) of transaction costs, which represent legal, financial advisory, and other professional fees in connection with the Business Combination and PIPE Financing.

Licensing agreement with Accure Therapeutics

Since our inception, we have entered into strategic collaboration agreements with a range of partners covering a number of our product candidates in our strategy to diversify our product portfolio and become a global ophthalmology company.

On January 29, 2022, Legacy Oculis entered into a License Agreement with Accure Therapeutics for the exclusive global licensing of its OCS-05 technology. Under this agreement, Oculis licensed a small molecule in development as a potential disease modifying neuroprotective agent designed to address neurological damage to the optic nerve.

As of December 31, 2022, Legacy Oculis has paid the full contractual non-refundable up-front fee and reimbursed costs of CHF 3.5 million increasing our licenses intangible asset up to CHF 12.2 million as of December 31, 2022. Legacy Oculis has not reached any milestones or royalties thresholds according to the agreement. If all predefined milestones will be reached, Oculis will be obligated to pay additional CHF 103.6 million. In case of a commercialization, sublicense revenues will be subject to further royalty payments.

Impact of COVID-19, the Russia and Ukraine Conflict, and Global Economic Conditions

As a result of the spread of the COVID-19 pandemic, economic uncertainties have arisen which may negatively affect our financial position, results of operations and cash flows. We have assessed that the COVID-19 pandemic has not so far had a material or direct impact on our operations or financial position. Nevertheless, in light of the ongoing COVID-19 pandemic, we have implemented measures to protect employees and take social responsibilities while at the same time attempting to limit any negative effects on our business.

The duration of uncertainties and the ultimate financial effects resulting from the ongoing COVID-19 pandemic cannot be reasonably estimated at this time. We will continue to monitor these situations closely and implement further measures if we believe they are required.

The conflict between Russia and Ukraine has caused major macroeconomic disruptions that have impacted the global trade and economies. As such increasing inflation around the globe has forced national banks to increase their interest rates, consequently impacting interest yields around the globe. We have assessed the impact of these measures and concluded that these impacted primarily the estimates in relation to the pension plan obligations, as noted below under Item 4.C “*Pension Benefits*” of the consolidated financial statements. As of today, no further material impact has been identified on our business or our ability to continue as a going concern.

Components of Results of Operations

Revenue

We have not generated any revenue from the sale of products since our inception and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or if we enter into collaboration or licensing agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or licensing agreements. However, there can be no assurance as to when we will generate such revenue, if at all.

Grant Income

Grant income reflects reimbursement of research and development expenses and income from certain research projects managed by Icelandic governmental institutions. We maintain a subsidiary in Iceland that provides research and development for our product candidates. Certain expenses qualify for incentives from the Icelandic government in the form of tax credits or cash reimbursements. We do not anticipate generating significant grant income in the future.

Operating Expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates and programs. We expense research and development costs and the cost of acquired intangible assets used in research and development activities as incurred. Research and development expenditures are capitalized only if they meet the recognition criteria of IAS 38 (*“Intangible Assets”*) and are recognized over the useful economic life on a straight-line basis. These expenses include:

- employee-related expenses, including salaries, related benefits and equity-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates and programs, including under agreements with Clinical Research Organizations (*“CROs”*);
- costs related to Contract Manufacturing Organizations (*“CMOs”*) that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the costs of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements;
- research and development-related payments made under third-party licensing agreements; and
- costs related to formulation research, IP expenses, facilities, overhead, depreciation and amortization of laboratory equipment and other expenses.

We historically did not track our research and development costs by project category, primarily because we use our employee and infrastructure resources across multiple research and development programs that we are advancing in parallel, and therefore do not allocate salaries, stock-based compensation, employee benefit expenses or other indirect costs related to our research and development to specific product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any current or future product candidates.

We historically did not track our research and development costs by project category, primarily because our clinical development costs may vary significantly based on factors such as:

- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;

- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- per patient trial costs;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up periods;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- production shortages or other supply interruptions in clinical trial materials;
- the efficacy and safety profile of our product candidates; and
- the number of product candidates we are developing.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- our ability to raise necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in the production of our product candidates;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect and enforce our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if approved;

- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates or programs.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive management, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax, and administrative consulting services; insurance costs; marketing and communications expenses; and other operating costs.

Beginning in 2022, we incurred increased accounting, audit, legal and other professional services costs associated with the Business Combination and preparing to become a public company. We anticipate that our general and administrative expenses will increase in the future in relation with costs associated with being a public company such as increased costs for fees to members of the board of directors, increased employee-related expenses, increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Exchange Act and Nasdaq rules.

Finance expense

Finance expense consists primarily of accrued interest costs associated with the preferred dividend payment of 6.00% to the holders of preferred Series B and C shares. The preferred Series B and C shares are classified as liabilities under IAS 32 and the associated accrued dividend is recognized as interest expense.

Exchange rate differences

Exchange differences consists of currency exchange gains and losses that arise from transaction denominated in currencies other than Swiss Francs.

Taxation

The Company is subject to corporate Swiss federal, cantonal and communal taxation, respectively, in Switzerland, Canton of Vaud, Commune of Ecublens, near Lausanne. We are also subject to taxation in other jurisdictions in which we operate, in particular, the United States, France, China and Iceland where our wholly-owned subsidiaries are incorporated.

We are entitled under Swiss laws to carry forward any losses incurred for a period of 7 years and can offset our losses carried forward against future taxes. As of December 31, 2022, we had tax loss carry-forwards totaling CHF 88.9 million). There is no certainty that we will make sufficient profits to be able to utilize these tax loss carry-forwards in full and no deferred tax assets have been recognized in the financial statements.

A. Operating Results

The financial information below is presented in thousands of CHF. The totals are calculated with the original unit amounts, which could lead to rounding differences. These differences in thousands of units are not changed in order to keep the accuracy of the original data.

The following table summarizes our results of operations for the periods presented:

In CHF thousands	For the Year Ended December 31,				For the Year Ended December 31,			
	2022	2021	Change	% Change	2021	2020	Change	% Change
Grant income	912	960	(48)	(5 %)	960	993	(33)	(3 %)
Operating income	912	960	(48)	(5 %)	960	993	(33)	(3 %)
Research and development expenses	(22,224)	(9,568)	(12,656)	132 %	(9,568)	(9,337)	(231)	2 %
General and administrative expenses	(11,064)	(4,624)	(6,440)	139 %	(4,624)	(3,992)	(632)	16 %
Operating expenses	(33,288)	(14,192)	(19,096)	135 %	(14,192)	(13,329)	(863)	6 %
Operating loss	(32,376)	(13,232)	(19,144)	145 %	(13,232)	(12,336)	(896)	7 %
Finance income	126	21	105	500 %	21	10	11	110 %
Finance expenses	(6,442)	(5,120)	(1,322)	26 %	(5,120)	(2,628)	(2,492)	95 %
Exchange differences	49	(193)	242	(125 %)	(193)	163	(356)	(218 %)
Finance result, net	(6,267)	(5,292)	(975)	18 %	(5,292)	(2,455)	(2,837)	116 %
Loss before tax for the period	(38,643)	(18,524)	(20,119)	109 %	(18,524)	(14,790)	(3,734)	25 %
Income tax expense	(55)	(27)	(28)	104 %	(27)	(83)	56	(67 %)
Loss for the period	(38,698)	(18,552)	(20,146)	109 %	(18,552)	(14,873)	(3,679)	25 %

Comparison of Year Ended December 31, 2022 and 2021

Grant Income

Grant income for the year ended December 31, 2022 and 2021 was CHF 0.9 million and CHF 1.0 million, respectively. The grant income is dependent upon the Icelandic government making such reimbursement available for research and development activities. While certain of our research and development expenses have historically qualified for reimbursement and we anticipate incurring a similar level of costs in the future, there is no assurance that the Icelandic government will continue with the tax reimbursement program.

Research and Development Expenses

In CHF thousands	For the Year Ended December 31,			
	2022	2021	Change	% Change
Personnel expenses	(4,608)	(4,407)	(201)	5 %
Payroll	(4,313)	(4,189)	(124)	3 %
Share-based compensation	(295)	(218)	(77)	35 %
Operating expenses	(17,616)	(5,161)	(12,455)	241 %
External service providers	(17,205)	(4,786)	(12,419)	259 %
Other operating expenses	(184)	(189)	5	(3 %)
Depreciation of PPE	(111)	(78)	(33)	42 %
Depreciation of right-of-use assets	(116)	(108)	(8)	7 %
Total research and development expense	(22,224)	(9,568)	(12,656)	132 %

Research and development expenses were CHF 22.2 million for the year ended December 31, 2022 compared to CHF 9.6 million for the year ended December 31, 2021. The net increase of CHF 12.7 million, or 132%, was primarily due to increased development expenses related to two ongoing Phase 3 clinical trials for OCS-01 and other research and development activities for our active product candidates, as well as the Proof-of-Concept study related to OCS-05. The two ongoing OCS-01 Phase 3 clinical trials are for DME and Post Ocular Surgery indications. We utilize external CROs to conduct these clinical trials. Personnel costs increased by CHF 0.2 million, which was primarily due to additional headcount for internal research and development employees.

General and Administrative Expenses

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2022	2021		
Personnel expenses	(4,449)	(2,416)	(2,033)	84%
Payroll	(3,939)	(2,306)	(1,633)	71%
Share-based compensation	(510)	(110)	(400)	364%
Operating expenses	(6,615)	(2,208)	(4,407)	200%
External service providers	(2,294)	(1,681)	(613)	36%
Other operating expenses	(4,249)	(478)	(3,771)	789%
Depreciation of PPE	(20)	(10)	(10)	100%
Depreciation of right-of-use assets	(52)	(39)	(13)	33%
Total	(11,064)	(4,624)	(6,440)	139%

General and administrative expenses were CHF 11.1 million for the year ended December 31, 2022 compared to CHF 4.6 million for the year ended December 31, 2021. The increase of CHF 6.4 million, or 139%, was primarily due to a CHF 3.8 million increase in other operating expenses mainly associated with the planning and preparation of the Business Combination and Nasdaq listing-related activities. Personnel costs increased by CHF 2.0 million, which was primarily due to additional headcount in general management and finance for public company readiness.

Finance Expenses

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2022	2021		
Interest expense accrued on Series B and C shares	(6,343)	(4,996)	(1,347)	27%
Interest on lease liabilities	(45)	(49)	4	(8%)
Interest expense	(54)	(75)	21	(28%)
Total finance expense	(6,442)	(5,120)	(1,322)	26%

Finance expenses were CHF 6.4 million for the year ended December 31, 2022 and CHF 5.1 million for the year ended December 31, 2021. The increase of CHF 1.3 million, or 26%, was due to a full year of accrued interest expense associated with preferred shares dividends while only 8 months were accrued in 2021. The main preferred Series C round in 2021 for an amount of CHF 52.5 million was raised in April 2021.

Exchange Differences

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2022	2021		
Exchange difference	49	(193)	242	(125%)

Exchange differences were a gain of CHF 49 thousand for the year ended December 31, 2022, compared to a loss of CHF 0.2 million for the year ended December 31, 2021. For the year ended December 31, 2022, favorable currency exchange was mainly due to revaluation of U.S. dollar impacting both the Series C long-term liability, bank cash balances and realized gains, whereas the U.S. dollar trend was less favorable for the year ended December 21, 2021.

Comparison of Years Ended December 31, 2021 and 2020

Grant Income

Grant income for both the years ended December 31, 2021 and 2020 was CHF 1.0 million. The grant income is dependent upon the Icelandic government making such reimbursement available for research and development activities. While certain of our research and development expenses have historically qualified for reimbursement and

we anticipate incurring a similar level of costs in the future, there is no assurance that the Icelandic government will continue with the tax reimbursement program.

Research and Development Expenses

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2021	2020		
Personnel expenses	(4,407)	(3,826)	(581)	15 %
Payroll	(4,189)	(3,612)	(577)	16 %
Share-based compensation	(218)	(214)	(4)	2 %
Operating expenses	(5,161)	(5,510)	349	(6 %)
External service providers	(4,786)	(5,154)	368	(7 %)
Other operating expenses	(189)	(167)	(22)	13 %
Depreciation of PPE	(78)	(89)	11	(12 %)
Depreciation of right-of-use assets	(108)	(99)	(9)	9 %
Total research and development expense	(9,568)	(9,337)	(231)	2 %

Research and development expenses were CHF 9.6 million for the year ended December 31, 2021 compared to CHF 9.3 million for the year ended December 31, 2020. The net increase of CHF 0.2 million, or 2%, was primarily due to the increase in personnel costs by CHF 0.6 million year over year, as additional personnel was hired for internal research and development. The increase was partially offset by a decrease of CHF 0.4 million related to fewer external services providers and consultants.

General and Administrative Expenses

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2021	2020		
Personnel expenses	(2,416)	(1,771)	(645)	36 %
Payroll	(2,306)	(1,657)	(649)	39 %
Share-based compensation	(110)	(114)	4	(4 %)
Operating expenses	(2,208)	(2,221)	13	(1 %)
External service providers	(1,681)	(1,744)	63	(4 %)
Other operating expenses	(478)	(438)	(40)	9 %
Depreciation of PPE	(10)	(15)	5	(33 %)
Depreciation of right-of-use assets	(39)	(24)	(15)	63 %
Total	(4,624)	(3,992)	(632)	16 %

General and administrative expenses were CHF 4.6 million for the year ended December 31, 2021 compared to CHF 4.0 million for the year ended December 31, 2020. The increase of CHF 0.6 million, or 16%, was primarily due to a CHF 0.6 million increase in personnel costs associated with additional headcount for expansion of our operations in connection with the Business Combination and preparing to become a public company.

Finance Expenses

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2021	2020		
Interest expense accrued on Series B and C shares	(4,996)	(2,560)	(2,436)	95 %
Interest on lease liabilities	(49)	(50)	1	(2 %)
Interest expense	(75)	(18)	(57)	317 %
Total finance expense	(5,120)	(2,628)	(2,492)	95 %

Finance expenses were CHF 5.1 million for the year ended December 31, 2021 and CHF 2.6 million for the year ended December 31, 2020. The increase of CHF 2.5 million, or 95%, was due to the additional accrued interest costs associated with preferred dividends as a result of the preferred Series C round which was completed in April 2021.

Exchange Differences

<i>In CHF thousands</i>	For the Year Ended December 31,		Change	% Change
	2021	2020		
Exchange difference	(193)	163	(356)	(218%)

Foreign exchange differences were a loss of CHF 0.2 million for the year ended December 31, 2021, compared to a gain of CHF 0.2 million for the year ended December 31, 2020. For the year ended December 31, 2021, the gain from revaluation of the Series C long-term liability was CHF 0.7 million, while for the 2020 period there was no exchange difference. This main driver of the unfavorable currency exchange in 2021 was mainly due to negative revaluation of CHF 0.8 million of cash balances resulting of the Series C preferred shares issued in April 2021.

B. Liquidity and Capital Resources

Overview

Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. As of December 31, 2022, we have funded our operations primarily with CHF 103.4 million of proceeds from the sale of our preferred stock. On March 2, 2023, we consummated the business combination with EBAC pursuant to the business combination agreement dated October 17, 2022. The closing of the Business Combination, the PIPE Financing and conversion of the CLA provided the Group with gross proceeds of approximately CHF 97.4 million. As of December 31, 2022, we had cash and cash equivalents of CHF 19.8 million and CHF 46.3 million as of December 31, 2021. We had accumulated losses of CHF 111.0 million and CHF 72.3 million as of December 31, 2022, and 2021, respectively.

We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to expand our organization through in-licensing, strategic collaboration, acquisition, and invest in the development of our product candidates through additional research and development activities and clinical trials. See “*Risk Factors—Risks related to development and regulatory approval of our investigational therapies.*” The closing of the Business Combination has and will continue to cause us to incur additional costs associated with operating as a public company, including expenses related to legal, accounting, financial reporting and regulatory matters, maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations.

Based on our current operating plan, we believe that our existing cash and cash equivalents after the closing of the BCA will be sufficient to fund our operations and capital expenses through at least the next twelve months from the date of this Annual Report. In addition, we believe that our cash resources will be sufficient to allow us to fund current planned operations beyond the next twelve months from the date of this Annual Report without additional capital. We have based our estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. We may require additional capital resources due to underestimation of the nature, timing and costs of the efforts that will be necessary to complete the development of our product candidates. We may also need to raise additional funds more quickly if we choose to expand our development activities, our portfolio or if we consider acquisitions or other strategic transactions, including licensing transactions. For more information regarding these risk and factors that could influence our future capital requirements and the timing thereof, please see the section entitled “*Risk Factors.*”

Future Funding Requirements

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. We will not generate revenue from product sales unless and until we successfully complete clinical development and are able to obtain regulatory approval for and successfully commercialize the product candidates we are currently developing or that we may develop. We currently do not have any product candidates approved for commercial sale.

Our product candidates, currently under development or that we may develop, will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting capabilities. There can be no assurance that our research and development activities will be successfully completed, that adequate protection for our licensed or developed technology will be obtained and maintained, that products developed will obtain necessary regulatory approval or that any approved products will be commercially viable.

If we obtain regulatory approval for one or more of our product candidates, we expect to incur significant expenses related to developing our commercialization capabilities to support product sales, marketing and distribution activities, either alone or in collaboration with others. Further, as discussed further below, we expect to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

Until such time, if ever, we can generate substantial product revenue, we may finance our operations through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, marketing, distribution or licensing arrangements or through other sources of financing. Adequate capital may not be available to us when needed or on acceptable terms. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of Ordinary Shares. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures.

Debt financing would also result in fixed payment obligations. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangement with collaborators on terms unfavorable to us or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our shareholders. Please see the section entitled *“Risk Factors—Risks related to our business, financial condition, capital requirements, or financial operations”* for additional risks associated with our substantial capital requirements.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical development of our product candidates. In addition, we have incurred additional costs associated with the Business Combination and will continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur or incremental to operating a private company. Our expenses will also increase as we:

- advance our clinical-stage product candidates, including as we progress our Phase 3 clinical trials for our most advanced programs, OCS-01 for DME and ocular surgery;
- advance our OCS-02 Phase 2b and related manufacturing development activities;
- advance our preclinical stage product candidates into clinical development;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- expand our operational, financial and management systems and increase personnel to support our operations;

- meet the requirements and demands of being a public company;
- maintain, expand, protect and enforce our intellectual property portfolio;
- make milestone, royalty or other payments due under the Novartis Agreement, the Accure Agreement, and any future in-license or collaboration agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- pursue in-licenses or acquisitions of other programs to further expand our pipeline; and
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties.

See the section of this Annual Report titled “*Risk Factors*” for additional risks associated with our substantial capital requirements.

Material Cash Requirements for Known Contractual Obligations and Commitments

We have certain payment obligations under various license and collaboration agreements. Under these agreements, we are required to pay non-refundable, upfront license fees, predefined development and commercial milestone payments and royalties on net sales of licensed products.

License Agreement with Novartis for OCS-02

Pursuant to a license agreement, dated as of December 19, 2018, as amended, by and between us and Novartis (the “*Novartis Agreement*”), we obtained an exclusive, royalty-bearing, sublicensable (subject to certain conditions), assignable (subject to certain conditions), worldwide license under certain patents, know-how and manufacturing platform technology to develop, manufacture and commercialize pharmaceutical, therapeutic or diagnostic products containing a specified single chain antibody fragment formulation as an active ingredient in the licensed field as defined in the Novartis Agreement. The license granted to us by Novartis includes sublicenses of rights granted to Novartis by certain third parties, and our license to such rights is expressly subject to the applicable terms and conditions of the agreements between Novartis and such third parties.

We originally entered into the Novartis Agreement with Alcon Research, Ltd. (“*Alcon*”), which subsequently assigned its rights and obligations under the Novartis Agreement to Novartis in connection with its spin-off from Novartis.

We are deemed the owner of any inventions that are (a) created solely by or on behalf of us pursuant to the Novartis Agreement and (b) severable from the licensed products, and grant Novartis a first right to negotiate a worldwide, royalty-bearing license under any patents directed at such inventions for purposes outside of the licensed field. We also grant Novartis a worldwide, non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up license back under any patents owned by us that (i) cover inventions arising from the Novartis Agreement, the practice of which would infringe the patents licensed to us by Novartis, or (ii) otherwise incorporate Novartis’ proprietary information, in each case, for certain uses outside of the licensed field.

We paid in full the contractual non-refundable up-front fee to Alcon of CHF 4.7 million (\$4.7 million at the exchange rate at the time of payment) in cash. As of December 31, 2022, we were obligated to pay Novartis additional up to CHF 89.7 million (\$97.0 million) in the aggregate upon the achievement of certain development, regulatory, sales and other milestones and tiered royalties ranging from a mid-single digit to a low mid-teen percentage on net sales. In consideration for the exclusive sublicense from Novartis under certain third-party intellectual property rights, we are obligated to pay a low-single digit royalty on our net sales of the licensed product, however, such payments will be deducted from royalties payable to Novartis. Our royalty payment obligations are subject to certain reductions and expire with respect to any licensed product on a country-by-country basis upon the later of (a) the expiration of the last to expire valid claim of any licensed patent covering any such licensed product in such country; (b) the expiration of the period of data exclusivity in any country worldwide; or (c) twelve (12) years after first commercial sale of such licensed product in such country (“*Royalty Term*”).

Under the Novartis Agreement, we are obligated to use diligent efforts to develop, manufacture or have manufactured, and commercialize the licensed products in the licensed field worldwide. The Novartis Agreement will expire upon the last-to-expire Royalty Term. We may terminate the Novartis Agreement without cause at any time upon advance written notice to Novartis. Upon written notice to Novartis, we may terminate the Novartis Agreement for cause due to the following events: (a) an insolvency event occurs; (b) Novartis materially breaches its obligations under the Novartis Agreement and fails to cure such breach within a specified period of time; or (c) upon advance written notice for material scientific, technical or medical reasons or in case of a material adverse change that renders further continuation of the Novartis Agreement by us commercially unreasonable or otherwise not viable. Upon written notice to us, Novartis may terminate the Novartis Agreement for cause due to the following events: (i) we fail to pay any undisputed amount due under the Novartis Agreement and we fail to remedy such failure within a specified period of time; (ii) an insolvency event occurs; or (iii) we materially breach our obligations under the Novartis Agreement and fail to cure such breach within a specified period of time; or (iv) following negative clinical trial results, we terminate development of the licensed product and do not pursue any further indications in the licensed field.

License Agreement with Accure for OCS-05

Pursuant to a license agreement, dated as of January 29, 2022, by and between us and Accure (the “*Accure Agreement*”), we obtained an exclusive, worldwide, sublicensable (subject to certain conditions) and transferable (subject to certain conditions) license under certain patents, know-how and inventory of Accure for any and all uses and purposes, including to perform research, development, manufacturing and commercialization activities in any manner and for any purpose. The licensed patents are co-owned by Accure with third parties who have reserved the right to use the licensed patents for education and research purposes pursuant to an inter-institutional agreement.

As of December 31, 2022, Legacy Oculis has paid the full contractual non-refundable up-front fee of CHF 3.0 million and reimbursed costs in the amount of approximately CHF 0.5 million. As of December 31, 2022, we were obligated to pay Accure (a) up to CHF 103.6 million (\$112.1 million at the December 31, 2022 exchange rate) in the aggregate upon the achievement of certain development, regulatory and sales milestones; (b) tiered royalties ranging from a mid-single digit to a low mid-teen percentage on net sales of licensed products; and (c) high teens on sublicensing revenues received any time after 36 months from the agreement effective date, and a higher percentage on sublicensing revenues received prior to such date, in all cases subject to reduction for any amount that were previously paid or are concurrently or later paid by Oculis to Accure pursuant to Oculis’s milestone payment obligations and such amounts received from a sublicensee will be deducted from amounts owned to Accure. Our royalty payment obligations are subject to certain reductions and expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of any licensed patent covering such licensed product in such country; (ii) the expiration of such licensed product’s Orphan Drug status, if any, in such country; or (iii) ten (10) years following the date of first commercial sale of such licensed product in such country (the “*Payment Period*”).

Under the Accure Agreement, we are obligated to use commercially reasonable efforts to develop and seek regulatory approval for a licensed product in major countries of the territory as defined in the Accure Agreement.

The Accure Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable Payment Period with respect to such licensed product in such country. We may terminate the Accure Agreement in whole or in part at any time upon advance written notice (a) for documented reasonable scientific, regulatory, commercial reasons related to the licensed product without incurring any penalty or liability to Accure and (b) for no reason. Each party may terminate the Accure Agreement with immediate effect upon written notice to the other party (i) in the event such other party commits a material breach of its obligations under the Accure Agreement and fails to cure that breach within a specified period of time or (ii) with certain exceptions, upon such other party’s bankruptcy. Accure may terminate the Accure Agreement with immediate effect upon written notice to us if we file any action to invalidate any of the licensed patents or fail to maintain the licensed patents in major countries of the territory as defined in the Accure Agreement, or, subject to certain exceptions, if we fail to meet certain development obligations and are unable to agree upon modifications to the development plan with Accure.

Other Commitments

Per the Series C Shareholders’ Agreement, a redemption option exists in April 2025 for a pre-specified qualified condition related to an initial public offering, with amounts equivalent to the sum of investors’ Series A, B and C investment, accrued dividends and applicable compounded interests at 0.00%, 6.00% and 8.00% for Series A, B and

C shares, respectively, which could lead to a potential cash-outflow. As of December 31, 2022, the sum of amounts due related to the aforementioned redemption option was approximately CHF 135 million, reflecting investment amounts, cumulative accrued dividend and compounded interest for Series A, B and C preferred shares.

The recent Business Combination with EBAC on March 2, 2023 and Nasdaq listing the following day, meets the pre-specified qualified condition, hence the risk of redemption no longer applies. The preferred shares will be transferred to equity including the accrued dividend.

The majority of our near term cash needs relates to our clinical and CMC projects. We have conducted research and development programs through collaborative programs that include, among others, arrangements with universities, CROs and clinical research sites. As of December 31, 2022, commitments for external research projects totaled CHF 13.1 million, with CHF 12.1 million due within one year and CHF 1.0 million due between one and five years.

In addition, we enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies, manufacturing services, and other services and products for operating purposes, which are generally cancelable upon written notice.

We have entered into two real estate lease agreements for lab and office facilities. At December 31, 2022, these lease agreement have aggregate lease liabilities of CHF 0.1 million due within one year and CHF 0.5 million due in more than one year.

Refer to Note 18 to our audited consolidated financial statements as of December 31, 2022 and 2021 and for the years ended December 31, 2022, 2021 and 2020 included elsewhere in this Annual Report for further details on our obligations and timing of expected future payments.

Cash Flows

The following table summarizes our sources and uses of cash and cash equivalents for each of the periods presented:

In CHF thousands	For the Year Ended December 31,				For the Year Ended December 31,			
	2022	2021	Change	% Change	2021	2020	Change	% Change
Net cash used in operating activities	(25,074)	(13,825)	(11,249)	81 %	(13,825)	(12,029)	(1,796)	15 %
Net cash used in investing activities	(3,548)	(28)	(3,520)	12571 %	(28)	(19)	(9)	47 %
Net cash provided by financing activities	1,714	55,194	(53,480)	(97 %)	55,194	4,859	50,335	1036 %
Net (decrease) increase in cash and cash equivalents	(26,909)	41,341	(68,250)	(165 %)	41,341	(7,189)	48,530	(675 %)

Operating Activities

For the year ended December 31, 2022, operating activities used CHF 25.1 million of cash, primarily consisting of a net loss of CHF 38.6 million partially offset by a decrease in net working capital of CHF 6.0 million and non-cash adjustments of CHF 7.6 million. Changes in net working capital were driven by a CHF 7.9 million increase in accrued expenses and other payables partly offset by CHF 1.8 million increase in other current assets. Our non-cash charges primarily consisted of CHF 6.3 million from interest expense accrued on preferred Series B and C shares, CHF 0.8 million from recognized expense for stock-options and CHF 0.6 million from non-realized foreign exchange differences.

For the year ended December 31, 2021, operating activities used CHF 13.8 million of cash, primarily consisting of our net loss of CHF 18.5 million and increased from changes in net working capital of CHF 0.8 million, partially offset by non-cash adjustments of CHF 5.6 million, which were primarily consisted of CHF 5.0 million from interest expense on preferred Series B and C shares and CHF 0.9 million from compensation expense related to restricted stock awards.

For the year ended December 31, 2020, operating activities used CHF 12.0 million of cash, primarily consisting of our net loss of CHF 14.8 million and decreased from changes in net working capital of CHF 0.5 million, partially offset by non-cash adjustments of CHF 3.3 million, which were primarily consisted of CHF 2.6 million from interest expense on preferred Series B and C shares and CHF 0.3 million from compensation expense related to stock option plans.

Investing Activities

For the years ended December 31, 2022, 2021 and 2020, investing activities used CHF 65 thousand, CHF 28 thousand and CHF 19 thousand, respectively, of cash for the purchases of property, plant, and equipment. For the year ended December 31, 2022, CHF 3.5 million were related to the license agreement with Accure Therapeutics for the exclusive global licensing of OCS-05 technology that was capitalized as intangible assets.

Financing Activities

For the year ended December 31, 2022, net cash provided by financing activities was CHF 1.7 million, which primarily consisted of proceeds from issuance of preferred Series C shares (Series C extension financing), classified as liabilities of CHF 2.0 million net of CHF 0.1 million of transaction costs.

For the year ended December 31, 2021, net cash provided by financing activities was CHF 55.2 million, which primarily consisted of proceeds from issuance of preferred Series C shares of CHF 56.1 million, net of CHF 0.8 million of transaction costs.

For the year ended December 31, 2020, net cash provided by financing activities was CHF 4.9 million, which primarily consisted of proceeds from issuance of preferred Series B shares of CHF 5.0 million, net of CHF 0.1 million of transaction costs.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in the “Item 4.B. Information on the Company—Business Overview” and “Item 5 Operating and Financial Review and Prospects” sections of this Annual Report.

D. Trend Information

Other than as described elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

E. Critical Accounting Estimates

We prepared our consolidated financial statements in accordance with IFRS as issued by the IASB. Refer to Note 3 and 4 to our audited consolidated financial statements included elsewhere in this Annual Report for further details on the most significant accounting policies applied in the preparation of our consolidated financial statements and our critical accounting estimates and judgments.

Item 6. Directors, Senior Management and Employees

A. Directors and senior management.

The following table sets forth the current executive officers and directors of Oculis as of the filing date. Unless otherwise noted, the business address of each of the directors and executive officers of Oculis is Bahnhofstrasse 7, 6300 Zug, Switzerland. It is expected that Oculis' principal executive office will move within two months after the Acquisition Closing to Oculis Holding AG, EPFL Innovation Park, Bat D 3e Route J-D. Colladon, CH-1015 Lausanne, Switzerland.

Name	Age	Title
<i>Executive Officers (Senior Management)</i>		
Riad Sherif, M.D.	55	Chief Executive Officer and Director
Sylvia Cheung	48	Chief Financial Officer
Páll Ragnar Jóhannesson	42	Chief Strategy Officer
<i>Senior Management</i>		
Joanne Chang, M.D., Ph. D.	62	Head of Medical Affairs
Bastian Dehmel, M.D.	52	Head of Development
<i>Non-Employee Directors</i>		
Anthony Rosenberg	70	Chairman of the Board of Directors
Christina Ackermann	58	Director
Lionel Carnot	55	Director
Pravin Dugel, M.D.	59	Director
Martijn Kleijwegt	68	Director
Geraldine O'Keeffe	57	Director

Executive Officers

Riad Sherif, M.D., 55, has served as the Chief Executive Officer and Director of Oculis since December 2017. Previously, from June 2016 to September 2017, Dr. Sherif served as Entrepreneur in Residence at the Novartis Venture Fund. Before that, Dr. Sherif served as the President of Europe, Middle East and Africa of Alcon, Inc. from March 2014 to May 2016. Prior to that, from January 2002 to April 2014, Dr. Sherif held roles of increasing responsibility at Novartis AG, including as the Global Sales Head in the Transplant and Infectious Disease unit, as the Head for Latin America in transplant and infectious disease, as the President of the Novartis Vaccines and Diagnostics Division for Latin America and where he co-founded Synergium a leading biotech company, and most recently as the President of Novartis Pharmaceuticals, Canada. Prior to Novartis, Dr. Sherif worked for several pharmaceutical companies, holding positions of increasing seniority, mainly in marketing and general management with international scope. Dr. Sherif currently serves as a member of the board of directors of Revenio Group corporation. Dr. Sherif previously served as the Vice Chairman for the Innovative Medicine Canada Association, as the Chairman of In-Vivo Montreal, and as the Chairman of the Board Ophthalmic Surgery and Vision Care of Eucomed. Dr. Sherif is a Medical Doctor by training, and holds an MBA from IMD Business School and a Specialized Master's Degree in Medical Management from ESCP.

Sylvia Cheung, 48, has served as the Chief Financial Officer of Oculis since September 2020. Prior to that, from October 2005 to August 2020, Ms. Cheung held executive positions at Anika Therapeutics, Inc., a publicly-traded joint preservation company. Most recently, from April 2013 to August 2020, Ms. Cheung served as the Chief Financial Officer of Anika Therapeutics, Inc. Previously, from 2000 to 2005, Ms. Cheung held a series of financial management positions of increasing responsibility at Transkaryotic Therapies, Inc., which was acquired by Shire Pharmaceuticals in 2005. Before that, from 1995 to 2000, Ms. Cheung served as a Senior Associate at PricewaterhouseCoopers. Ms. Cheung holds a Bachelor of Business Administration degree in Accounting from the University of Massachusetts in Amherst, an MBA from Boston University, and was certified as Certified Public Accountant in Massachusetts.

Páll Ragnar Jóhannesson, 42, has served as the Chief Strategy Officer of Oculis since September 2020. Previously, from January 2018 to September 2020, Mr. Jóhannesson served as the Chief Financial Officer of Oculis. Additionally,

Mr. Jóhannesson has served as the Managing Director of Oculis Iceland ehf. since May 2015. Prior to that, from February 2012 to April 2015, Mr. Jóhannesson held a series of corporate finance positions of increasing responsibility at Straumur Investment Bank, and most recently, from September 2013 to April 2015, Mr. Jóhannesson served as the Managing Director, Corporate Finance. Before that, from January 2009 to November 2011, Mr. Jóhannesson served as a Director, Corporate Finance at Íslandsbanki and its predecessor Glitnir Bank. Mr. Jóhannesson holds a B.Sc. in Industrial Engineering from the University of Iceland, an M.Phil in Management Science from the University of Cambridge, and was certified as securities broker in Iceland.

Senior Management

Joanne Chang, M.D., Ph.D., 62, has served as the Head of Medical Affairs of Oculis since September 2021. Previously, from September 2017 to August 2021, Dr. Chang served as the Worldwide Medical Affairs Head Ophthalmology of Novartis. Prior to that, from January 2014 to August 2017, Dr. Chang served as the Head, Clinical Development & Medical Affairs for the U.S. and Canada of Alcon. Before that, from April 2010 to December 2013, Dr. Chang served as the Vice President, Chief Medical Officer of Novartis Pharma China. Prior to that, from August 2008 to March 2010, Dr. Chang served as Vice President, Evidence Based Medicine of Novartis, United States. Before that, from July 2000 to July 2004, Dr. Chang served as Executive Director, US Health Economics, Outcomes and Reimbursement of Bayer Pharmaceuticals. Prior to that, from June 2000 to June 2004, Dr. Chang served as Director, HEOR, Global Strategic Marketing & Medical Affairs of Sanofi. Before that, from July 1999 to May 2000, Dr. Chang served as Director, Global Health Economics of Johnson & Johnson. Prior to that, from August 1995 to June 1999, Dr. Chang served as Associate Medical Director and Medical Director, Clinical Development of Abbott Laboratories. Dr. Chang holds an M.D. from Wuhan University School of Medicine, a Ph.D. from the University of Maryland Baltimore, and was a post-doctoral fellow at Johns Hopkins University School of Medicine.

Bastian Dehmel, M.D., 52, has served as the Head of Development of Oculis since January 2022. Previously, from October 2017 to December 2021, Dr. Dehmel served as the Chief Medical Officer of OxThera AB. Before that, from 2006 to July 2017, Dr. Dehmel held roles of increasing responsibility at Amgen, including as Senior Medical Manager, as International Medical Director, as Clinical Research Medical Director, and most recently, from December 2013 to July 2017, Dr. Dehmel served as Global Development Executive Medical Director of Amgen. Prior to that, from 2005 to 2006, Dr. Dehmel served as International Medical Advisor of NovoNordisk. Before that, from 2003 to 2005, Dr. Dehmel served as Medical Advisor Diabetes of GlaxoSmithKline Germany. Dr. Dehmel holds a Doctor of Medicine (M.D.) from Free University Berlin Medical School and received his clinical training in Internal Medicine at Charité University in Berlin, Germany.

Non-Employee Directors

Anthony Rosenberg, 70, has served as Chairman of the board of directors of Oculis since April 2018. Since April 2015, Mr. Rosenberg has served as the Chief Executive Officer of TR Advisory Services GmbH. Additionally, from April 2015 to April 2020, Mr. Rosenberg served as a Managing Director of MPM Capital.

Prior to that, from 2005 to 2012, Mr. Rosenberg held a series of business development and licensing positions of increasing seniority at Novartis, and most recently, from 2012 to 2015, Mr. Rosenberg served as the Corporate Head of M&A and Licensing at Novartis International AG. Mr. Rosenberg currently serves on the boards of directors of Argenx BV and Cullinan Oncology. Mr. Rosenberg previously served on the boards of directors of TriNetX and Radius Health, Inc. Mr. Rosenberg holds a B.Sc. (Hons) from the University of Leicester and a M.Sc. in Physiology from the University of London.

Christina Ackermann, 58, has served as Executive Vice President, General Counsel & President of Ophthalmic Pharmaceuticals at Bausch + Lomb since January 2022. Ms. Ackermann joined Bausch Health as Executive Vice President, General Counsel, in August 2016. Prior to Bausch Health, Ms. Ackermann was part of the Novartis group of companies for 14 years, most recently serving as Senior Vice President, General Counsel for Alcon, where she was responsible for the legal, intellectual property and compliance functions, in addition to Trade Compliance Function, Enterprise Risk Management and Diversity & Inclusion. Previously, she served as Global Head, Legal and General Counsel at Sandoz, the generics division of Novartis, from 2007 to 2012. She joined Novartis Pharma in 2002 as Head, Legal Technical Operations and Ophthalmics, and assumed the role of Head Legal General Medicine in July 2005. Before Novartis, Ms. Ackermann served in Associate General Counsel roles with Bristol Myers Squibb and DuPont Pharmaceuticals, as well as in private practice, where she focused on securities, and mergers & acquisitions. Since

August 2021, Ms. Ackermann has served on the board of directors of Graybug Vision, where she is Chair of the Nominating and Corporate Governance Committee and a member of the Compensation Committee. Ms. Ackermann holds a LL.B in law from Queen's University in Ontario, Canada and a post graduate degree in EU competition law from King's College in London, England. We believe that Ms. Ackermann's experience in business, legal affairs, compliance, global security and enterprise risk management makes her well qualified to serve as a director.

Lionel Carnot, 55, has served as a member of the board of directors of Oculis since December 2017. Since March 2012, Mr. Carnot has served as the Partner of Earlybird Venture Capital. Additionally, since 2005, Mr. Carnot has served as the Managing Director of Bay City Capital LLC. Prior to that, from 2000 to 2005, Mr. Carnot served as an Associate of The Pritzker Organization, LLC. Before that, from 1999 to 2000, Mr. Carnot served as a Principal of Oracle Partners. Prior to that, from 1997 to 1998, Mr. Carnot served as a Senior Associate of Booz Allen and Hamilton. Before that, from 1995 to 1997, Mr. Carnot served as a Product Manager of Eli Lilly & Co. Prior to that, from 1991 to 1994, Mr. Carnot served as a Senior Consultant of Accenture. Before that, from 1989 to 1991, Mr. Carnot served as a sales and marketing professional at Rhone-Poulenc. Mr. Carnot currently serves on the board of directors of iSTAR Medical, iQone Healthcare Group, and Priothera. Mr. Carnot previously served on the board of directors of Atlantic Therapeutics, Merus, Interleukin Genetics, Madrigal Pharmaceuticals Inc., Nabsys, Bioseek, Pathway Diagnostics, and Reliant Pharmaceuticals. Mr. Carnot holds an MBA with Distinction from INSEAD and a M.Sc. in Molecular Biology from the University of Geneva.

Pravin Dugel, M.D., 59, is currently the President of Iveric Bio. He joined as Executive Vice President in April 2020 and was promoted to President of the Company in May 2021. Dr. Dugel was previously Managing Partner, Retinal Consultants of Arizona and the Retinal Research Institute; Clinical Professor, USC Eye Institute, Keck School of Medicine, University of Southern California; and Founding Member, Spectra Eye Institute in Sun City, Arizona. Dr. Dugel has authored more than 200 papers, 35 book chapters and has been invited to lecture at several marquis medical meetings and to serve as a visiting professor at universities worldwide, including in Japan, India, China, Malaysia, Egypt, the United Kingdom, France, Germany, Austria, Italy, Poland, Denmark, Norway, Czechoslovakia, Canada and Australia. Dr. Dugel is internationally recognized as a major clinical researcher and has been a principal investigator in over 100 multicenter clinical trials. His research and educational contributions earned him the prestigious Senior Honor Award from the American Academy of Ophthalmology (AAO). He has been elected and previously served as the Retina Subspecialty Day Board.

Chairman for the American Academy of Ophthalmology Annual Meeting, as a member of the Board of Directors of the largest retina society in the United States, the American Society of Retina Specialists (ASRS), and the largest retina society in Europe, EURETINA. Dr. Dugel graduated from Columbia University in New York City. He then attended UCLA School of Medicine where he obtained his M.D. He completed his residency in ophthalmology at the USC Eye Institute, Keck School of Medicine and completed his medical retina fellowship at the Bascom Palmer Eye Institute and his surgical retina fellowship at the USC Eye Institute, where he was elected to serve on the faculty as the Resident Director.

Martijn Kleijwegt, 68, has served as a member of our Board since the Acquisition Closing. Previously, he served as a member and the Chairman of the EBAC Board from EBAC's inception in January 2021 to March 2023. Mr. Kleijwegt founded LSP in 1998 and is currently a partner at EQT Life Sciences (f/k/a Life Science Partners). Mr. Kleijwegt brings over 30 years of hands-on finance and investment experience to EBAC. Mr. Kleijwegt currently serves on the boards of Vico Therapeutics, A-M Pharma and Oxthera. Mr. Kleijwegt has a master's degree in Economics from Amsterdam University.

Geraldine O'Keeffe, 57, joined LSP in 2008. She became a Partner of the firm in 2010. Ms. O'Keeffe's prime focus and responsibility within LSP is to invest in listed securities. Prior to joining LSP, she held the position of Senior Healthcare Analyst at Fortis Investment Banking. In that position, she researched a wide range of innovative life sciences companies, both in Europe and the US. Ms. O'Keeffe brings strong analytical and investment skills to the LSP team. Before joining the financial community, she worked within the life sciences industry for a number of years, gaining first-hand product development experience in a commercial setting. Prior to working in the industry, she lectured in Biomedical Sciences for several years at the Dublin Institute of Technology. Ms. O'Keeffe has a Bachelor's degree in Biochemistry and Microbiology from University College Cork and a Master's degree in Biotechnology from University College Galway. She also conducted post-graduate research, inter alia at the prestigious Max Planck Institute for Biophysical Chemistry in Göttingen, Germany. In addition, Ms. O'Keeffe is also a graduate of The Dublin School of Business.

Diversity of the Board of Directors

The table below provides certain information regarding the diversity of our board of directors as of the filing date of this Annual Report.

Board Diversity Matrix				
Country of Principal Executive Offices	Switzerland			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	7			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	2	5	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			0	
LGBTQ+			0	
Did Not Disclose Demographic Background			0	

Family Relationships

There are no family relationships among any of our executive officers or directors.

Corporate Governance

We structured our corporate governance in a manner we believe closely aligns our interests with those of our shareholders. Notable features of this corporate governance include:

- We have six independent directors and our audit, remuneration, and nomination and governance committees are composed entirely of independent directors. Our independent directors will meet regularly without the presence of our corporate officers or non-independent directors;
- at least one of our independent directors qualifies as an “audit committee financial expert” as defined by the SEC; and
- We implemented a range of other corporate governance practices, including a robust director education program.

Non-Classified Board of Directors

In accordance with our articles of association, our board of directors is not divided into classes of directors. The directors were appointed until the end of the general meeting of shareholders called to approve our annual accounts for the 2024 financial year.

B. Compensation

Compensation of Executive Officers

Historically, our executive compensation program has reflected our innovative growth and development-oriented corporate culture. To date, the compensation of our Chief Executive Officer and our other executive officers has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of restricted common stock awards and/or stock options. Our executive officers who are full-time employees, like all other full-time employees, are participants in applicable retirement plans in the jurisdiction in which they reside. As we transition from a private company to a publicly traded company, we will evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances merit. At a minimum, we expect to review executive

compensation periodically with input from a third-party compensation consultant. As part of this review process, we expect the board of directors and the remuneration committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive with our peers. In connection with our executive compensation program, we will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to align salaries with market levels after taking into account individual responsibilities, performance and experience. In addition, our executives are entitled to annual cash bonuses for their performance over the fiscal year, based on goals established by our board of directors. Furthermore, we have a formal process with respect to the grant of equity incentive awards to our employees, including our executive officers. We believe that equity incentive awards provide our employees with a strong link to our long-term performance, create an ownership culture and help to align the interests of our employees, including our executive officers, and our stockholders. In addition, we believe that equity incentive awards with time-based vesting features promote employee retention because this feature incentivizes our employees, including our executive officers, to remain in our employment during the vesting period.

Compensation of Directors

Our board of directors adopted a board of directors' compensation policy that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. As of the filing date, we pay each eligible director who is not an employee of the Company annual cash retainers, as set forth below.

	Annual Cash Retainer
Board of Directors	\$ 45,200
Board of Directors Chair	\$ 84,750
Audit Committee Chair	\$ 22,600
Audit Committee Member	\$ 11,300
Remuneration Committee Chair	\$ 13,560
Remuneration Committee Member	\$ 6,780
Nomination and Governance Committee Chair	\$ 10,170
Nomination and Governance Committee Member	\$ 5,085

In addition, each eligible director elected or appointed to our board of directors is eligible to participate in the Stock Option and Incentive Plan Regulation 2023 of the Company (the "2023 Plan"), subject to its terms and conditions as approved and amended by our board of directors from time to time. Upon joining the Company, the Company issues to eligible directors a one-time equity incentive award in the form of stock option or similar awards under the 2023 Plan or other equity incentive plans then in effect, at an estimated equity value of \$240,000. The exact number of options to be granted and the vesting schedule shall be determined by the Company in the grant notice in its free discretion and only such grant notice shall have legal effect. The Company will also issue to eligible directors an annual equity incentive award in the form of stock option or similar awards under the 2023 Plan or other equity incentive plans then in effect, at an estimated equity value of \$120,000.

The eligible directors are not eligible to any benefits other than those set out in the directors compensation policy, unless our board of directors decides otherwise. The Company reimburses all reasonable expenses in accordance with the terms and conditions of the Company's travel and expense policy then in effect.

Compensation of Directors and Executive Officers

For the year ended December 31, 2022, the aggregate compensation paid and accrued to the members of our board of directors and our executive officers for services in all capacities was CHF 2.1 million.

For the year ended December 31, 2022, fees, salaries and other short-term employee benefits paid and accrued to the members of our board of directors and our executive officers was CHF 1.8 million.

The amount contributed by us to provide post-employment benefits to executive officers amounted to a total of CHF 0.2 million for the year ended December 31, 2022.

During the year ended December 31, 2022, 110,468 options to purchase registered ordinary shares were granted to members of our board of directors and our executive officers for a total fair value of CHF 210 thousand.

For the year ended December 31, 2022, share-based compensation expense incurred for the members of our board of directors and our executive officers accounted for CHF 144 thousand. See Note 12 to our audited consolidated financial statements included elsewhere in this Annual Report for further details regarding the share options and restricted stock, including the exercise price and the expiration date.

Risk Oversight

The board of directors is responsible for overseeing our risk management process. The board of directors focuses on our general risk management strategy, the most significant risks, and oversees the implementation of risk mitigation strategies by management. The audit committee is also responsible for discussing our policies with respect to risk assessment and risk management. The board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

Code of Business Conduct and Ethics

Our board of directors adopted a Code of Business Conduct and Ethics applicable to the directors, executive officers and employees that complies with the rules and regulations of Nasdaq and the SEC. The Code of Business Conduct and Ethics is available on our website. In addition, we posted on the Corporate Governance section of our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics. The reference to our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

Stock Option and Incentive Plan Regulation 2023

The Stock Option and Incentive Plan Regulation 2023 (the "2023 Plan") was approved by our board of directors on the Acquisition Closing Date and provides for the grant of options, restricted stock awards or units or stock appreciation rights to acquire the Ordinary Shares.

The purpose of the 2023 Plan is to attract and retain highly qualified personnel and to provide key employees with additional incentive to increase their efforts on behalf and in the best interest of us and our subsidiaries by giving them the opportunity to acquire a proprietary interest in us as an incentive for them to remain in the service of us. The terms of the 2023 Plan are described in more detail below.

The 2023 Plan shall be administered by a plan administrator (one or several persons) elected by our board of directors from time to time. The plan administrator acts within the guidelines set and approved by our board of directors or a committee thereof and is authorized to, among others, determine (i) which eligible persons are to receive awards under the 2023 Plan, (ii) the time or times when such options or rights grants are to be made, (iii) the nature of the shares and the number of awards covered by each such grant, (iv) the time or times at which each option or stock appreciation rights is to become exercisable, (v) the vesting conditions applicable to the options or rights, (vi) the maximum term

for which the options or rights are to remain outstanding, and (vii) any terms and conditions of any restricted stock award, in each case, subject to the guidelines set and approved by our board of directors or a committee thereof. Persons eligible to participate in our 2023 Plan are employees, members of the board of directors and consultants of Oculis or a subsidiary. The plan administrator determines within the guidelines set and approved by our board of directors or a committee which eligible persons are to receive rights to acquire options under the 2023 Plan.

The Plan provides for up to 7,835,544 registered shares corresponding to 16% of the Ordinary Shares on a fully diluted basis at the Acquisition Closing Date. In the event registered shares that otherwise would have been issuable under the 2023 Plan are withheld by us in payment of the exercise price or withholding obligations, such shares shall remain available for issuance under the 2023 Plan. In the event an outstanding award for any reason expires or is cancelled, forfeited or terminated, the shares allocable to the unexercised or unsettled portion shall remain available for issuance under the 2023 Plan.

A participant may only exercise an option or stock appreciation right to the extent that the option or stock appreciation right has vested and has not lapsed under the 2023 Plan. Unless otherwise determined by our board of directors at the grant date or set forth in the grant notice, an option or an award in the form of a restricted stock unit or stock appreciation right granted under the 2023 Plan typically vests as to 25% of the award at the end of the first year following the vesting start date, with the remaining 75% of the award vesting monthly over the 3 years after the first year following the vesting start date. Any restricted stock may not be transferred or pledged. Such restriction expires with the expiration of any repurchase right for the restricted stock. The 2023 Plan provides provisions that govern the exercise of any awards held by the participant at the time the legal relationship forming the basis of the service is coming to an end. Generally, any award not vested shall immediately lapse at the time a notice of termination has been received (regardless of which party gives notice) or at the end of the term in case of a board member. If indicated in the grant notice or otherwise resolved by the board of directors, upon the occurrence of a “Corporate Transaction” (as defined in the 2023 Plan), all options and awards in the form of a restricted stock unit or stock appreciation rights (i) shall fully vest and (ii) in the case of options and stock appreciation rights must be immediately exercised, except if such options or awards in the form of a restricted stock unit or stock appreciation rights are repurchased by Oculis or a third party designated by Oculis for a cash consideration equivalent to the economic value applicable to such option or stock appreciation right under the 2023 Plan.

Our board of directors has complete and exclusive power and authority to amend or modify the 2023 Plan in any or all respects. Such amendment or modification shall be communicated in appropriate form as an amendment of the 2023 Plan. Unless such change is required to comply with applicable law, listing requirements, accounting rules or tax requirements, no such amendment or modification shall, without the consent of the concerned participant, adversely affect materially his/her rights and obligations under the 2023 Plan.

C. Board Practices

Composition of Our Board of Directors

Our board of directors is currently composed of seven members. In accordance with our articles of association, the board of directors is not divided into classes of directors. Each director was appointed at the closing of the Business Combination on March 2, 2023, to serve as director until the end of the general meeting of shareholders called to approve our annual accounts for the 2024 financial year.

Six of seven directors are independent as defined in Nasdaq listing standards and applicable SEC rules and our board of directors has an independent audit committee, a nomination and governance committee, and a remuneration committee.

Committees of our Board of Directors

Our board of directors has three standing committees: an audit committee, a remuneration committee, and a nominating and nomination and governance committee. The board has adopted written charters that are available to shareholders on our website at <https://investors.oculis.com/corporate-governance>. The reference to our website address in this Annual Report on Form 20-F does not include or incorporate by reference the information on our website into this Annual Report on Form 20-F.

Audit Committee

The audit committee consists of Lionel Carnot, Geraldine O’Keeffe and Christina Ackermann. The audit committee assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Mr. Carnot serves as chairperson of the audit committee. In addition, the audit committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our board of directors has determined that Mr. Carnot, Ms. O’Keeffe and Ms. Ackermann satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act and Mr. Carnot qualifies as an “audit committee financial expert,” as such term is defined in the rules of the SEC.

Each of the members of our audit committee will qualify as independent directors according to the rules and regulations of the SEC and Nasdaq with respect to audit committee membership. In addition, all of the audit committee members meet the requirements for financial literacy under applicable SEC and Nasdaq rules and at least one of the audit committee members qualifies as an “audit committee financial expert,” as such term is defined in Item 407(d) of Regulation S-K. The audit committee is governed by a charter that complies with applicable Nasdaq rules, which charter was posted on our website prior to the listing of our common shares on Nasdaq. We have adopted an audit committee charter, which details the principal functions of the audit committee, including:

- review and discuss with management the annual and quarterly financial statements and reports, including earnings press releases and financial information and earnings guidance given to analysts and rating agencies;
- propose to the board to approve the quarterly and annual reports;
- inform the board on its assessment of the financial statements and decide whether to recommend the statutory and consolidated financial statements to the board for approval and presentation to the meeting of shareholders;
- review in cooperation with the auditor and the management whether the accounting principles applied by the company and any of its subsidiaries are appropriate;
- review and assess the qualifications, independence, performance, and effectiveness of the auditor and recommend to the board the nomination of the auditor;
- review the scope of the prospective audit by the auditor, the estimated fees and any other matters pertaining to such audit as the committee may deem appropriate;
- approve any proposal of audit and non-audit services to be provided by the auditor to the company to ensure auditor independence;
- review and assess the auditor’s report, management letters and take notice of all comments of the auditor on accounting procedures and systems of control;
- review with the auditors and management the auditor’s reports to the committee/board on critical accounting policies and practices used (and any changes thereto), on alternative treatments of financial information discussed with management and on other material written communication between the auditor and management;
- review with the auditor any audit problems or difficulties and management’s response, including any restrictions on the scope of the auditor’s activities or on access to requested information, and any significant disagreements with management;
- at least annually monitor, review and discuss with the auditor and with management the adequacy and effectiveness of the company’s policies and procedures regarding internal controls over financial reporting and risk assessment and the company’s compliance therewith;

- monitor compliance with respect to our Code of Business Conduct and Ethics, as may be amended from time to time;
- periodically review the company's policies and procedures for risk management and assess the effectiveness thereof;
- periodically review the company's policies and procedures designed to ensure compliance with laws, regulations and internal rules and policies;
- establishing procedures for the receipt, retention and treatment of complaints received by the company regarding accounting, internal accounting controls or auditing matters, as well as the confidential, anonymous submission by officers, employees or directors of the company of concerns regarding questionable accounting or auditing matters;
- monitor compliance with respect to our Related Person Transactions Policy, as may be amended from time to time, and review, approve and/or ratify proposed transactions that have been identified as related person transactions thereunder; and
- discuss with management and, if appropriate, the company's external advisors any legal matters (including the status of pending or threatened litigation) that may have a material impact on the company's financial statements and any material reports or inquiries from regulatory or governmental agencies which could materially impact the company's contingent liabilities and risks.

Remuneration Committee

The remuneration committee consists of Christina Ackermann, Pravin Dugel, and Lionel Carnot. The remuneration committee assists the board of directors in determining compensation for our executive officers and our directors. Ms. Ackermann serves as chairperson of the remuneration committee.

As of the first day of trading, we were subject to the Swiss provisions regarding compensations for listed companies under the Swiss Code of Obligations, which require Swiss corporations listed on a stock exchange to establish a remuneration committee. In accordance with the Swiss Code of Obligations, the members of our remuneration committee must be elected by our general meeting of shareholders and the aggregate amount of compensation of each of our directors and our executive committee must also be approved by our general meeting of shareholders, in each case commencing with our first annual general meeting of shareholders as a public company. On March 2, 2023 the general meeting of shareholders approved the compensation packages for the Board and the executive committee until the general meeting of shareholders to be held in 2024. Our board of directors has appointed Ms. Ackermann as the chair of the remuneration committee and will fill any vacancies on the remuneration committee until completion of the next annual general meeting of shareholders.

Each of the members of our remuneration committee qualifies as independent directors according to the rules and regulations of the SEC and Nasdaq with respect to remuneration committee membership, including the heightened independence standards for members of a remuneration committee. The remuneration committee is governed by a charter that was posted on our website prior to the listing of our common shares on Nasdaq. We have adopted a remuneration committee charter, which details the principal functions of the remuneration committee, including:

- prepare and recommend to the board for approval (i) a compensation policy for the board and (ii), if so requested by the board, a compensation policy for the executive committee; and thereafter, annually review such policy or policies and recommend changes, if any, for approval by the board;
- may periodically review the company's compensation policies for its employees who are not members of the executive committee;
- review and recommend to the board for approval any compensation and other payments to present and former non-employee directors of the company to the extent not already provided for in the compensation policy for the board;

- propose to the board the resolution to be submitted to the general meeting for the maximum total compensation of the board and executive committee;
- evaluate annually the performance the CEO (as defined in the organizational rules) and submit such evaluation for review and discussion by the board, in each case in executive session without the presence of the CEO;
- review and recommend for approval by the board the annual base salary, incentive compensation and equity compensation of the CEO and, in consultation with the CEO, of the other members of the executive committee, and the overall compensation of the CEO and executive committee;
- review and approve any employment contracts, severance contracts, or other agreements that the company proposes to enter into with any present, future or former members of the executive committee;
- establish an incentive compensation plan providing for variable compensation of the members of the executive committee based on the achievement of the company's corporate goals and the individuals' performance, and approve any changes to such plan as may be proposed by the CEO from time to time;
- approve any incentive compensation plans providing for variable compensation of employees of the company (excluding any member of the executive committee) and any changes thereto, as may be proposed by the CEO from time to time;
- develop and periodically review equity compensation plans, and submit such plans and any changes to such plans to the board for approval;
- review and approve any perquisite benefits plans proposed by the CEO for the members of the executive committee;
- review the annual corporate goals proposed by the CEO, and recommend such goals as approved by the committee for approval by the board;
- determine the level of achievement of the corporate goals as approved by the board upon completion of each calendar year, and apply such achievement level to the determination of the variable compensation of the members of the executive committee in accordance with the applicable incentive compensation plan;
- evaluate its own performance on a periodic basis as part of the board performance assessment process;
- supervise the preparation of the annual compensation report and submit it to the board for approval; and
- review the remuneration committee charter annually and submit any recommended changes to the board for approval.

Nomination and Governance Committee

The nomination and governance committee consists of Dr. Pravin Dugel, Geraldine O'Keeffe, and Martijn Kleijwegt. The nomination and governance committee assists our board of directors in identifying individuals qualified to become our directors consistent with criteria established by us and in developing our code of business conduct and ethics. Dr. Dugel serves as chairperson of the nomination and governance committee. The nomination and governance committee is governed by a charter that was posted on our website prior to the listing of our common shares on Nasdaq. We have adopted a nomination and governance committee charter, which details the principal functions of the nomination and governance committee, including:

- establish and periodically review the qualification criteria for board candidates;

- conduct the search for board candidates based on the qualification criteria established by the committee and any other criteria that the committee may consider appropriate, and recommend suitable candidates to the board to be nominated for election by the shareholders;
- periodically review the policies and principles for corporate governance of the company, including the organizational rules, and recommend changes, if any, to the board for approval;
- make recommendations to the board on board and committee compositions, including the board and committee chairperson and the size of the board and the committees, taking into account the independence standards established by applicable laws, the company's articles of association, the organizational rules, the committee policies and corporate governance principles;
- conducting the search for candidates for the position of CEO of the company, and shall recommend suitable candidates for evaluation and appointment by the board;
- identify candidates for the election to the board on its own as well as by considering recommendations from shareholders, other members of the board, officers and employees of the company, and other sources that the committee deems appropriate;
- establish a process for and conduct an annual review of the performance of the board, its committees, and individual board members in their role as members of the board or a committee of the board; and consider the results of the annual performance review when determining whether or not to recommend the nomination of a director for an additional term on the board or a committee, and for developing proposals for improving corporate governance policies and effectiveness of the board and its committees;
- prepare and review, at least annually, a succession plan for the directors of the board, the CEO, and the members of the executive committee; and
- review the corporate governance report of the company for inclusion in the annual report for the approval of the board and approve any other written public disclosures on corporate governance matters including, but not limited to, environmental, social and governance-related matters.

D. Employees

As of December 31, 2022, we had 28 employees. Our headcount for R&D was 15, and our headcount for G&A was 13. Our employees include 11 executive leadership, administrative, and development personnel based in Switzerland; 8 executive leadership, administrative, and research personnel based in Iceland; 5 executives and administrators based in the United States; 4 management, research and administrative personnel based in France and China. Pursuant to local laws, our employees in Iceland and France are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “*Item 7.A Major Shareholders*” and “*Item 6.B Compensation*” for a discussion of the 2022 Plan.

F. Disclosure of a registrant's action to recover erroneously awarded compensation.

Not applicable.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information regarding the beneficial ownership of Ordinary Shares as of March 2, 2023:

- each person known by us to be the beneficial owner of more than 5% of the Ordinary Shares;
- each of our directors and members of Executive Management; and
- all our directors and members of Executive Management as a group.

Except as otherwise noted herein, the number and percentage of Ordinary Shares beneficially owned is determined in accordance with Rule 13d-3 of the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any Ordinary Shares as to which the holder has sole or shared voting power or investment power and also any Ordinary Shares which the holder has the right to acquire within 60 days of the Closing Date through the exercise of any option, warrant or any other right.

We have based percentage ownership on 32,733,373 Ordinary Shares outstanding as of the Closing Date, March 2, 2023. The table below does not include earn-out shares which are issued and contingently forfeitable and are not deemed to be outstanding.

Name and Address of Beneficial Owners	Number of Shares	%
Directors and Executive Officers ⁽¹⁾		
Riad Sherif ⁽²⁾	878,486	2.68 %
Sylvia Cheung ⁽³⁾	166,313	*
Páll Ragnar Jóhannesson ⁽⁴⁾	514,124	1.57 %
Christina Ackermann	—	*
Lionel Carnot	—	*
Pravin Dugel, M.D.	—	*
Martijn Kleijwegt ⁽⁵⁾	1,997,302	6.10 %
Geraldine O’Keeffe	—	*
Anthony Rosenberg ⁽⁶⁾	96,670	*
All officers and directors as a group (9 individuals)	3,652,895	11.16 %
Five Percent Holders of the Company		
LSP 7 Coöperatief U.A. ⁽⁷⁾	4,023,015	12.29 %
Certain funds managed by Pivotal Partners ⁽⁸⁾	3,032,296	9.26 %
Brunnur vaxtarsjóður slhf. ⁽⁹⁾	2,335,841	7.14 %
BVCF Management (BEYEOTECH) ⁽¹⁰⁾	2,070,020	6.32 %
Novartis Bioventures Ltd. ⁽¹¹⁾	2,177,902	6.65 %

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

- (1) Unless otherwise noted, the business address of each of the directors and executive officers of Oculis is EPFL Innovation Park, Bat D 3e Route J-D, Colladon, CH-1015 Lausanne, Switzerland.
- (2) Consists of 878,447 Ordinary Shares issued in exchange for 768,424 ordinary shares of Oculis held prior to the Acquisition Closing Date.
- (3) Consists of (i) 66,808 Ordinary Shares issued in exchange for 58,438 ordinary shares of Oculis held prior to the Acquisition Closing Date and (ii) 99,505 Ordinary Shares issuable upon conversion of options to be granted to replace 87,039 Oculis share options, vested and fully exercisable within 60 days of March 2, 2023.
- (4) Consists of (i) 249,224 Ordinary Shares issued to replace 218,000 ordinary shares of Oculis beneficially owned through Sjónarhóll fjárfestingar ehf., over which Mr. Jóhannesson has sole voting and dispositive power, prior

to the Acquisition Closing Date and (ii) 264,900 Ordinary Shares issuable upon conversion of options to be granted to replace 231,712 Oculis share options, vested and fully exercisable within 60 days of March 2, 2023.

- (5) The shares reported above are held in the name of LSP Sponsor EBAC B.V. (“LSP Sponsor”). The shares reported above are net of the shares forfeited as a result of the level of EBAC redemptions and net of the shares transferred to EBAC’s public shareholders who did not redeem their shares. MRMJ Holding B.V., a Dutch limited liability company, is the majority owner of LSP Sponsor and as such, MRMJ Holding B.V. has voting and investment discretion with respect to the shares held of record by LSP Sponsor and may be deemed to have shared beneficial ownership of the shares held by LSP Sponsor. René Kuijten, Joachim Rothe, Martijn Kleijwegt and Mark Wegter who are directors of MRMJ Holding B.V. have voting and investment discretion with respect to the shares owned by MRMJ Holding B.V. and may be deemed to have indirect shared beneficial ownership of the shares held by LSP Sponsor. Mr. Kuijten, Mr. Rothe, Mr. Kleijwegt and Mr. Wegter each disclaim beneficial ownership over the founder shares except to the extent of their pecuniary interest therein.
- (6) Consists of 96,670 Ordinary Shares issued in exchange for 84,559 ordinary shares of Oculis held prior to the Acquisition Closing Date.
- (7) Consists of (i) 3,789,600 PIPE Shares and (ii) 233,415 Ordinary Shares issued in exchange for 197,745 preferred shares of Oculis held prior to the Acquisition Closing Date. LSP 7 Management B.V. is the sole director of LSP 7 Coöperatief UA. The managing directors of LSP 7 Management B.V. are Martijn Kleijwegt, Rene Kuijten and Joachim Rothe. As such, LSP 7 Management B.V., Martijn Kleijwegt, Rene Kuijten and Joachim Rothe may be deemed to be individuals identified in this footnote is Johannes Vermeerplein 9 1071 DV Amsterdam, Netherlands.
- (8) Consists of (i) 209,781 Ordinary Shares issued upon conversion of the Convertible Loan Agreement held by Pivotal bioVenture partners Fund I, L.P. (“Pivotal”), (ii) 2,171,415 Ordinary Shares issued in exchange for 1,576,657 preferred shares of Oculis held by Pivotal prior to the Acquisition Closing Date, (iii) 57,219 Ordinary Shares issued upon conversion of the Convertible Loan Agreement held by NFLS Beta Limited (“NFLS Beta”) and (iv) 593,881 Ordinary Shares issued in exchange for 435,505 preferred shares of Oculis held by NFLS Beta prior to the Acquisition Closing Date. The general partner of Pivotal is Pivotal bioVenture Partners Fund I G.P., L.P. (“Pivotal GP”). The general partner of Pivotal GP is Pivotal bioVenture Partners Fund I U.G.P., Ltd (the “Ultimate General Partner”). Richard Coles, Peter Bisgaard and Vincent Sai Sing Cheung are directors of the Ultimate General Partner, and may, along with the Ultimate General Partner be deemed to have shared voting and investment control and power over the shares owned by Pivotal. Such persons disclaim beneficial ownership of such securities except to the extent of any pecuniary interest therein. The Ultimate General Partner is wholly owned by Pivotal Partners Ltd (“Pivotal Partners”). Pivotal Partners is wholly owned by Pivotal Life Sciences Holdings Limited (“Pivotal Life Sciences”). Pivotal Life Sciences is wholly owned by Nan Fung Life Sciences Holdings Limited (“Nan Fung Life Sciences”), and Nan Fung Life Sciences is wholly owned by NF Investment Holdings Limited (“NFIHL”). NFLS Beta is wholly owned by NFLS Platform Holdings Limited, which is wholly owned by Nan Fung Life Sciences. Nan Fung Life Sciences is wholly owned by Nan Fung Group Holdings Limited (“NFGHL” and together with Pivotal, Pivotal GP, Ultimate General Partner, Pivotal Partners, Pivotal Life Sciences, Nan Fung Life Sciences and NFIHL, the “Pivotal Parties”). The members of the Executive Committee of NFGHL make voting and investment decisions with respect to shares of our common stock held by NFLS Beta. Kam Chung Leung, Frank Kai Shui Seto, Vincent Sai Sing Cheung, Pui Kuen Cheung, Vanessa Tih Lin Cheung, Meng Gao and Chun Wai Nelson Tang are the members of the Executive Committee of NFGHL. Such persons disclaim beneficial ownership of such securities except to the extent of any pecuniary interest therein. The Pivotal Parties share voting and dispositive power over the shares held by Pivotal. The business address of Pivotal, Pivotal GP, Ultimate General Partner, Pivotal Partners and Pivotal Life Sciences is 501 Second Street, Suite 200, San Francisco, CA 94107. The address of NFGHL is 23rd Floor, Nan Fung Tower, 88 Connaught Road Central and 173 Des Voeux Road Central, Central, Hong Kong. The address of NFIHL is Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands.
- (9) Consists of 2,335,841 Ordinary Shares issued in exchange for 1,931,692 preferred shares of Oculis held prior to the Acquisition Closing Date. Voting and dispositive decisions require a majority vote of the directors of Brunnur vaxtarsjóður slhf., composed of three individuals, Guðbjörg Edda Eggertsdóttir, Hjörleifur Pálsson and Guðrún Tinna Ólafsdóttir, and, as such, each disclaim any beneficial ownership of any such shares, except to

the extent of his or her pecuniary interest therein. The business address of Brunnur vaxtarsjóður slhf. is Borgartún 33, 105, 105 Reykjavík, Iceland.

- (10) Consists of 2,070,020 Ordinary Shares issued in exchange for 1,635,339 preferred shares of Oculis held prior to the Acquisition Closing Date. Voting and dispositive decisions require a majority vote of the investment committee composed of six individuals, Zhi Yang, Robert Li, Vanessa Huang, Huacheng Wei, Maggie Chen, and Rachel Zhao, and, as such, each disclaim any beneficial ownership of any such shares, except to the extent of his or her pecuniary interest therein. The business address of BEYEOTECH is 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands.
- (11) Consists of (i) 255,000 PIPE Shares owned by Novartis Bioventures Ltd., (ii) 1,521,182 Ordinary Shares issued in exchange for 1,102,245 preferred shares of Oculis held by Novartis Bioventures Ltd. prior to the Acquisition Closing Date and (iii) 401,720 Ordinary Shares issued in exchange for 351,390 ordinary shares of Oculis held by Novartis Pharma AG prior to the Acquisition Closing Date. The foregoing shares are directly owned by Novartis Bioventures Ltd. and Novartis Pharma AG, respectively. Novartis Bioventures Ltd. and Novartis Pharma AG are each wholly-owned indirect subsidiaries of Novartis AG, which is an indirect beneficial owner of the reported securities. As the indirect parent of Novartis Bioventures, Ltd. and Novartis Pharma AG, Novartis AG shares voting and dispositive power over, and may be deemed to beneficially own, the reported securities. The business address of Novartis Bioventures Ltd., Novartis Pharma AG and Novartis AG is Lichtstrasse 35, 4056 Basel, Switzerland.

Significant Changes in Percentage Ownership

In March 2023, we experienced significant changes in the percentage ownership held by major shareholders as a result of the Business Combination.

Voting Rights

The voting rights of the principal shareholders do not differ from the voting rights of other shareholders.

Shareholders in the United States

As of February 15, 2023, to the best of our knowledge 56,821,856 of our outstanding ordinary shares were held by 14 shareholders of record in the United States. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy that sets forth certain policies and procedures for the review and approval or ratification of transactions involving us in which a related person has or will have a direct or indirect material interest, as determined by the audit and risk committee of the Board. A “related person” for purposes of the policy means: (i) enterprises that directly or indirectly through one or more intermediaries, control or are controlled by, or are under common control with, us; (ii) associates (defined as, unconsolidated enterprises in which we have a Significant Influence or which has Significant Influence over us); (iii) individuals owning, directly or indirectly, an interest in the voting power of us that gives them Significant Influence over us, and close members of any such individual’s family; (iv) key management personnel (i.e., having authority and responsibility for planning, directing and controlling our activities), including directors and close members of such individuals’ families; and (v) enterprises in which a substantial interest in the voting power is owned, directly or indirectly, by any person described in (iii) or (iv) above or over which such a person is able to exercise Significant Influence, including enterprises owned by our directors or major shareholders and enterprises that have a member of key management in common with us. “Significant Influence” for purposes of the policy means the power to participate in the financial and operating policy decisions of an enterprise but is less than control over those policies, provided that shareholders beneficially owning a 10% or more interest in the voting power of the enterprise concerned are presumed to have a significant influence on such enterprise.

Pursuant to the policy, each executive director, nominee for the position of executive director, and executive officer shall promptly notify the designated contact of any transaction involving us and a related person. The designated contact will present any new related person transactions, and proposed transactions involving related persons, to the audit committee of the board of directors at its next occurring regular meeting. If the audit committee determines that the related person involved has a direct or indirect material interest in the transaction, and therefore that the transaction is a related party transaction, the Audit and Risk Committee shall consider all relevant facts and circumstances, including the commercial reasonableness of the terms, the benefit and perceived benefit, or lack thereof, to Oculis, opportunity costs of alternate transactions, the materiality and character of the Related Person's direct or indirect interest, and the actual or apparent conflict of interest of the Related Person. The audit committee will not approve or ratify a Related Person transaction unless it shall have determined that, upon consideration of all relevant information, the transaction is in, or not inconsistent with, our best interests. On an annual basis, the audit committee shall review previously approved related person transactions, under the standard described above, to determine whether such transactions should continue. If after the review described above, the Audit and Risk Committee determines not to approve or ratify a related person transaction (whether such transaction is being reviewed for the first time or has previously been approved and is being reviewed), the transaction will not be entered into or continued.

Agreements with our Executive Officers and Directors

Aside from standard employment agreements, there are no transactions between our directors and executive officers on the one hand and us on the other. The remuneration of the directors and executive officers (excluding non-executive directors), who are the key management personnel, is described in the section entitled "*Compensation.*"

Indemnification Agreements

The Articles of Association provide that we will indemnify our directors and officers to the fullest extent permitted by Swiss law, subject to certain exceptions contained in our proposed constitution.

In connection with the Business Combination, we also entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements provide the indemnitees with contractual rights to indemnification, and expense advancement and reimbursement, to the fullest extent permitted under Swiss law, subject to certain exceptions contained in those agreements.

C. *Interests of Experts and Counsel*

Not applicable.

Item 8. Financial Information.

A. *Consolidated Statements and Other Financial Information*

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1.

Legal Proceedings

As of the date of this report, we are not party to any material legal proceedings. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on its financial position, results of operations or cash flows.

B. *Significant Changes*

Please see Note 22. Subsequent Events, included in the audited consolidated financial statements starting at page F-1 included elsewhere in this Form 20-F. Other than the events included in this note, no significant changes have occurred.

Item 9. The Offer and Listing.

A. Offer and Listing Details

Ordinary Shares and Warrants are listed on The Nasdaq Stock Market LLC under the symbols OCS and OCSAW, respectively. Prior to March 6, 2023, there was no public trading market for our Ordinary Shares or Warrants. Holders of Ordinary Shares and Warrants should obtain current market quotations for their securities.

B. Plan of Distribution

Not applicable.

C. Markets

Ordinary Shares and Warrants are listed on The Nasdaq Stock Market LLC under the symbol “OCS” and “OCSAW”, respectively, since March 6, 2023. Prior to March 6, 2023, there was no public trading market for our Ordinary Shares or Warrants.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

A copy of our Amended and Restated Articles of Association have been previously filed as Exhibit 1.1 to our report on Form 20-F filed with the SEC on March 8, 2023, and is incorporated by reference into this annual report. The information called for by this Item 10B: Additional Information - Memorandum and Articles of Association has been reported previously in our Registration Statement on Form F-4, filed with the SEC on February 2, 2023 (the “Registration Statement”), under the headings “Description of New Parent Securities and Proposed Articles of Association” and “Comparison of Shareholder Rights,” and is incorporated by reference into this Annual Report. There are no limitations on the rights to own securities, including the rights of non-resident or foreign shareholders to hold or exercise voting rights on the securities imposed by the laws of Switzerland or by our Articles.

C. Material Contracts

In addition to the contracts described elsewhere in this Annual Report, the following are summaries of each material contract to which we are a party for the two years preceding the date of this Annual Report. For additional information on our material contracts, please see “*Item 4. Information on the Company*,” “*Item 6. Directors, Senior Management and Employees*,” and “*Item 7.B Related Party Transactions*” of this Annual Report.

Material Contracts Relating to the Business Combination

Business Combination Agreement

On October 17, 2022, we entered into a business combination agreement (the “Business Combination Agreement”) with EBAC and Legacy Oculis. The Business Combination Agreement provided for, among other things, the following transactions on the closing date: (i) the PIPE Investors transferred \$71,188,910 to EBAC in exchange for 7,118,891 PIPE Shares; (ii) EBAC underwent the First Merger; and as part of the First Merger, (1) each share of EBAC Common Stock (including those held by the PIPE Investors) was automatically converted into the Surviving EBAC Shares (2) each EBAC Warrant outstanding immediately prior to the First Merger Effective time was automatically converted into Surviving EBAC Warrants and (3) EBAC deposited, or cause to be deposited, with the Exchange Agent (held solely on behalf of the holders of EBAC Common Stock and EBAC Warrants) the Surviving EBAC Shares and Surviving EBAC Warrants on the terms and subject to the conditions set forth in the Business Combination Agreement and in the Ancillary Agreements; (iii) on the day before the Acquisition Closing Date and following the First Merger Effective Time but prior to the Second Merger Effective Time, the Exchange Agent, solely on behalf of the holders of Surviving EBAC Shares and Surviving EBAC Warrants, undertook the Exchange Agent Contribution Actions in exchange for receipt of the New Parent Interests Consideration; (iv) in connection with the Exchange Agent Contribution, on the day before the Acquisition Closing Date and prior to the Second Merger Effective Time, the Exchange Agent distributed (1) the Ordinary Shares as part of the New Parent Interests Consideration to the holders of Surviving EBAC Shares and (2) the Warrants as part of the New Parent Interests Consideration to the holders of Surviving EBAC Warrants; (v) on the day before the Acquisition Closing Date and following the completion of the Exchange Agent Contribution Actions, at the Second Merger Effective Time, EBAC underwent the Second Merger, pursuant to which, among other things, the separate corporate existence of EBAC ceased, and following the Acquisition Closing, Merger Sub 2 was liquidated and its assets distributed to Oculis; (vi) after the Second Merger Effective Time but before the Oculis Share Contribution, it was the intention of the parties to the Convertible Loan Agreements that Oculis assumed the Convertible Loan Agreements, pursuant to which the Lenders granted Oculis a right to receive a convertible loan with certain conversion rights in an aggregate amount of \$19,670,000, and that immediately after such assumption but before the Oculis Share Contribution, the Lenders exercised their conversion rights in exchange for Ordinary Shares at \$10.00 per share, on the same terms as the PIPE Investors; (vii) at approximately 10:00 a.m. Eastern Time on the Acquisition Closing Date, those Oculis Shareholders executing the Oculis Shareholders Support Agreements and the exchange notice contemplated by the Business Combination Agreement effected the contribution to Oculis of all Company Share Capital held by such Oculis Shareholders free and clear of all liens (other than general restrictions on transfer under applicable securities laws or the articles of association of Oculis) in exchange for Ordinary Shares on the terms and subject to the conditions set forth in the Business Combination Agreement and Oculis Shareholders Support Agreement; and (viii) during the first half of 2023, we will undergo the Third Merger.

We consummated transactions i-vii contemplated by the Business Combination Agreement on March 2, 2023 and will consummate transaction viii in the first half of 2023.

Subscription Agreements related to the PIPE Financing

In connection with the foregoing and concurrently with the execution of the Business Combination Agreement, EBAC entered into Initial Subscription Agreements with the Initial PIPE Investors pursuant to which the Initial PIPE Investors agreed to purchase from EBAC, severally and not jointly, and EBAC agreed to issue from treasury and sell to the Initial PIPE Investors, a number of EBAC Class A Common Stock equal to (i) the total subscription amount from the Initial PIPE Investors (\$63,303,910) divided by (ii) \$10.00. Subsequent to the Initial PIPE Financing, in January 2023, EBAC entered into the Subsequent Subscription Agreements with the Subsequent PIPE Investors, pursuant to which the Subsequent PIPE Investors agreed to subscribe for, and EBAC agreed to issue to the Subsequent PIPE Investors, a number of EBAC Class A Common Stock equal to (i) the total subscription amount from the Subsequent PIPE Investors (\$7,885,000) divided by (ii) \$10.00. The aggregate amount of EBAC Class A Common Stock issued pursuant to the PIPE Financing was 7,118,891 for aggregate gross proceeds of \$71,188,910. The shares of EBAC Class A Common Stock issued from treasury to the PIPE Investors pursuant to the Subscription Agreements was not registered under the Securities Act, in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act (as defined below). In connection with the Acquisition Closing, we granted the PIPE Investors certain customary registration rights in connection with the PIPE Financing, including demand and piggyback rights as set forth in the Registration Rights and Lock-Up Agreement. The PIPE Financing was contingent upon, among other things, the Acquisition Closing.

The PIPE Financing closed on March 2, 2023.

The Convertible Loan Agreements

Also concurrently with the execution of the Business Combination Agreement, Legacy Oculis and the Lenders party thereto entered into convertible loan agreements pursuant to which the Lenders granted Legacy Oculis a right to receive a convertible loan with certain conversion rights in an aggregate amount of \$12,670,000. Subsequent to the execution of the Business Combination Agreement, on January 20, 2023 and as amended and restated on February 22, 2023, Legacy Oculis and an additional Lender entered into a convertible loan agreement in substantially the same form as the initial convertible loan agreement, pursuant to which, among other things, the Lender party thereto granted us a right to receive a convertible loan with certain conversion rights in an aggregate amount of \$7,000,000. The aggregate amount raised under the Convertible Loan Agreements was \$19,670,000. Following the Second Merger Effective Time on March 2, 2023, we assumed the Convertible Loan Agreements, and immediately after such assumption but before the Oculis Share Contribution, the Lenders exercised their conversion rights in exchange for Ordinary Shares at \$10.00 per share, on substantially the same terms as the PIPE Investors. In accordance with the Convertible Loan Agreements, upon conversion, the Lenders were granted certain customary registration rights, substantially on the same terms as those offered pursuant to the Subscription Agreements.

D. Exchange Controls

There are no foreign exchange controls or foreign exchange regulations under the currently applicable laws of Switzerland.

E. Taxation

Material Swiss Tax Considerations

In the opinion of Vischer Ltd., the following are the material Swiss tax consequences of receiving, owning and disposing of Ordinary Shares and Warrants.

This summary is based upon Swiss tax laws, and the practices of the Swiss tax authorities, in effect on the date of this annual report. Such laws and administrative practice are subject to change at any time, possibly with retroactive effect. The summary does not constitute legal or tax advice and is intended only as a general guide. It is not exhaustive and shareholders should consult their own tax advisors about the Swiss tax consequences (and tax consequences under the laws of other relevant jurisdictions) of the acquisition, ownership and disposal of Ordinary Shares and Warrants and as to their tax position.

Please be aware that the residence concept used under the respective headings applies for Swiss tax assessment purposes only. Any reference in this section to a tax, duty, levy impost or other charge or withholding of a similar nature refers to Swiss tax law and/or concepts only.

Holding Ordinary Shares

Swiss Withholding Tax

Under present Swiss tax law, dividends and similar cash or in-kind distributions made by the Oculis to a holder of Ordinary Shares (including liquidation proceeds and bonus shares) are subject to Swiss federal withholding tax (the “*Withholding Tax*”), currently at a rate of 35% (applicable to the gross amount of taxable distribution), unless these payments are repayments of the par value of Ordinary Shares or, within the limitations accepted by the legislation in force and the respective administrative practice of the reserve from capital contribution (*Reserve aus Kapitaleinlage*). Oculis is obliged to deduct the Withholding Tax from the gross amount of any taxable distribution and to pay the tax to the Swiss Federal Tax Administration within 30 days of the due date of such distribution, unless a notification procedure applies (the notification procedure does not apply to portfolio holdings).

Swiss resident individuals who hold their Ordinary Shares as private assets (“*Resident Private Shareholders*”) are in principle eligible for a full refund or credit against income tax of the Withholding Tax if they duly report the underlying income in their income tax return. In addition Domestic Commercial Shareholders who, among other things, are also the beneficial owners of the Ordinary Shares and the dividends or the other distributions made or paid by Oculis on

the Ordinary Shares are in principle eligible for a full refund or credit against income tax of the Withholding Tax if they, inter alia, duly report the underlying income in their income statements or income tax return, as the case may be.

Shareholders who are not resident in Switzerland for tax purposes, and who, during the respective taxation year, have not engaged in a trade or business carried on through a permanent establishment with fixed place of business situated in Switzerland for tax purposes, and who are not subject to corporate or individual income taxation in Switzerland for any other reason (collectively, “*Non-Resident Shareholders*”) may be entitled to a total or partial refund of the Withholding Tax if the country in which such recipient resides for tax purposes maintains a bilateral treaty for the avoidance of double taxation with Switzerland and further conditions of such treaty are met. Non-Resident Shareholders should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund) may differ from country to country. Non-Resident Shareholders should consult their own legal, financial or tax advisors regarding receipt, ownership, purchases, sale or other dispositions of Ordinary Shares and the procedures for claiming a refund of the Withholding Tax.

Swiss Federal Stamp Taxes

To the extent Oculis issues new shares, Oculis will bear the Swiss federal issue stamp tax (*Emissionsabgabe*) on the issuance of such Ordinary Shares of 1% of the offering price, net of certain deductions. The delivery of newly issued shares against payment of the offering price is generally not subject to Swiss federal securities turnover tax (*Umsatzabgabe*).

To the extent Oculis offers existing shares currently held by Oculis or certain existing shareholders of Oculis, the sale and delivery of any such existing shares will, subject to statutory exemptions, be subject to Swiss federal securities turnover tax (*Umsatzabgabe*) at an aggregate tax rate of up to 0.15% of the consideration paid on such sale and will be borne (or compensated) by the current holders of such existing Ordinary Shares.

Any subsequent transactions in Ordinary Shares in the secondary markets are subject to Swiss securities turnover tax at an aggregate rate of 0.15% of the consideration paid for such Ordinary Shares, however, only if a bank or other securities dealer in Switzerland or Liechtenstein, as defined in the Swiss Federal Stamp Tax Act (*Stempelabgabengesetz*), is a party or an intermediary to the transaction and no exemption applies.

Swiss Federal, Cantonal and Communal Individual Income Tax and Corporate Income Tax

a. Non-Resident Shareholders

Non-Resident Shareholders are not subject to any Swiss federal, cantonal or communal income tax on dividend payments and similar distributions because of the mere holding of Ordinary Shares. The same generally applies for capital gains on the sale of Ordinary Shares. For Withholding Tax consequences, please see the section entitled “—*Material Swiss Tax Considerations—Swiss Withholding Tax.*”

b. Resident Private Shareholders and Domestic Commercial Shareholders

Resident Private Shareholders who receive dividends and similar cash or in-kind distributions (including liquidation proceeds as well as bonus shares or taxable repurchases of Ordinary Shares as described above), which are not repayments of the par value of Ordinary Shares or, within the limitations accepted by the legislation in force and the respective administrative practice, reserve from capital contribution (*Kapitaleinlagereserven*), are required to report such distributions in their individual income tax returns. A gain or a loss by Resident Private Shareholders realized upon the sale or other disposition of ordinary shares to a third party will generally be a tax-free private capital gain or a not tax-deductible capital loss, as the case may be. Furthermore, the Swiss federal income tax on dividends is currently reduced to 70% of regular taxation (*Teilbesteuerung*), if the investment amounts to at least 10% of the total share capital of the issuer. On cantonal and communal level, the same provisions regarding partial taxation apply, with income reduced to between 50% and 80% depending on the canton of residency.

Domestic Commercial Shareholders who receive dividends and similar cash or in-kind distributions (including liquidation proceeds as well as bonus shares) are required to recognize such payments in their income statements for the relevant tax period and are subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be, on any net taxable earnings accumulated (including the dividends) for such period.

Commercial Shareholders who are corporate taxpayers may qualify for participation relief on dividend distributions (*Beteiligungsabzug*), if, inter alia, Ordinary Shares held have a market value of at least CHF 1 million. For cantonal and communal income tax purposes, the regulations on participation relief are broadly similar, depending on the canton of residency. For Domestic Commercial Shareholders who are individual taxpayers, the Swiss federal individual income tax on Dividends is reduced to 70% of regular taxation (*Teilbesteuerung*), if the investment is held in connection with the conduct of a trade or business or qualifies as an opted business asset (*gewillkürtes Geschäftsvermögen*) according to Swiss tax law and amounts to at least 10% of the total share capital of the Company. On cantonal and communal level the same provisions regarding partial taxation apply, with income reduced to between 50% and 80% depending on the canton of residency

Domestic Commercial Shareholders are required to recognize a gain or loss realized upon the disposal of ordinary shares in their income statement for the respective taxation period and are subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be, on any net taxable earnings (including the gain or loss realized on the sale or other disposition of ordinary shares) for such taxation period.

Swiss Wealth Tax and Capital Tax

a. Non-Resident Shareholders

Non-Resident Shareholders holding Ordinary Shares are not subject to cantonal and communal wealth or annual capital tax because of the mere holding of Ordinary Shares.

b. Resident Private Shareholders

Resident Private Shareholders are required to report the market value of their Ordinary Shares at the end of each tax period as part of their private wealth, which is subject to cantonal and communal wealth tax.

c. Domestic Commercial Shareholders

Domestic Commercial Shareholders are required to report their Ordinary Shares as part of their business wealth or taxable capital, as defined in the applicable cantonal and communal tax laws, which is subject to cantonal and communal wealth or annual capital tax.

Gift and Inheritance Taxes

The transfer of Ordinary Shares may be subject to cantonal and/or communal gift, estate or inheritance taxes if the donor is, or the deceased was, resident for tax purposes in a Swiss canton levying such taxes.

Automatic Exchange of Information in Tax Matters

On November 19, 2014, Switzerland signed the Multilateral Competent Authority Agreement. The Multilateral Competent Authority Agreement is intended to ensure the uniform implementation of Automatic Exchange of Information (the “*AEOI*”). The Swiss Federal Act on the International Automatic Exchange of Information in Tax Matters (the “*AEOI Act*”) entered into force on January 1, 2017. The AEOI Act is the legal basis for the implementation of the AEOI standard in Switzerland.

The AEOI is being introduced in Switzerland through bilateral agreements or multilateral agreements. The agreements have been, and will be, concluded on the basis of guaranteed reciprocity, compliance with the principle of specialty (i.e., the information exchanged may only be used to assess and levy taxes (and for criminal tax proceedings)) and adequate data protection.

Based on such multilateral and bilateral agreements and the implementing laws of Switzerland, Switzerland collects data in respect of financial assets, which may include Ordinary Shares, held in, and income derived thereon and credited to, accounts or deposits with a paying agent in Switzerland for the benefit of individuals resident in an EU member state or in a treaty state since 2017, and exchanges it since 2018. Switzerland has signed and is expected to sign AEOI agreements with other countries. A list of such agreements of Switzerland in effect or signed and becoming effective can be found on the website of the State Secretariat for International Finance.

Swiss Facilitation of the Implementation of the U.S. Foreign Account Tax Compliance Act

Switzerland has concluded an intergovernmental agreement with the United States to facilitate the implementation of U.S. Foreign Account Tax Compliance Act. The agreement ensures that the accounts held by U.S. persons with Swiss financial institutions are disclosed to the U.S. tax authorities either with the consent of the account holder or by means of group requests within the scope of administrative assistance. Information will not be transferred automatically in the absence of consent, but instead will be exchanged only within the scope of administrative assistance on the basis of the double taxation agreement between the United States and Switzerland. On September 20, 2019, the protocol of amendment to the double taxation treaty between Switzerland and the U.S. entered into force allowing the U.S. competent authority in accordance with the information reported in aggregated form to request all the information on U.S. accounts without a declaration of consent and on non-consenting non-participating financial institutions.

On October 8, 2014, the Swiss Federal Council approved a mandate for negotiations with the United States on changing the current direct-notification-based regime to a regime where the relevant information is sent to the Swiss Federal Tax Administration, which in turn provides the information to the U.S. tax authorities.

THE MATERIAL SWISS TAX DISCUSSION SET FORTH ABOVE IS INCLUDED FOR GENERAL INFORMATION ONLY AND MAY NOT BE APPLICABLE DEPENDING UPON A SWISS HOLDER'S PARTICULAR SITUATION. SWISS HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS WITH RESPECT TO, THE OWNERSHIP AND DISPOSITION OF ORDINARY SHARES AND WARRANTS, INCLUDING THE TAX CONSEQUENCES UNDER NON-SWISS, AND OTHER TAX LAWS AND TAX TREATIES AND THE POSSIBLE EFFECTS OF CHANGES IN SWISS OR OTHER TAX LAWS.

Dutch Withholding Tax

Oculus does not intend to withhold Dutch dividend withholding tax on the payment of the EBAC Share Redemption Amount. It can, however, not be excluded that the Dutch tax authorities may seek to impose Dutch dividend withholding tax in respect of any distributions made by or on behalf of EBAC, including the payment of the EBAC Share Redemption Amount to the extent that it exceeds the aggregate recognized paid-in capital per redeemed share (please see *“Risk Factors — Risks Related to government regulation — Tax authorities may challenge EBAC’s tax residency, which could adversely affect its tax burden and financial position.”*).

We urge you to consult with your tax advisors with respect to the potential tax consequences of an exercise of redemption rights to you.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a discussion of certain material U.S. federal income tax considerations generally applicable to the acquisition, ownership, and disposition of Ordinary Shares by a “U.S. Holder.” This discussion applies only to Ordinary Shares that are held by a U.S. Holder as “capital assets” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not describe all U.S. federal income tax considerations that may be relevant to a U.S. Holder in light of such U.S. Holder’s particular circumstances, nor does it address any state, local, or non-U.S. tax considerations, any non-income tax (such as gift or estate tax) considerations, the alternative minimum tax, the special tax accounting rules under Section 451(b) of the Code, the Medicare contribution tax on net investment income, or any tax consequences that may be relevant to U.S. Holders that are subject to special tax rules, including, without limitation:

- banks or other financial institutions;
- insurance companies;
- mutual funds;
- pension or retirement plans;
- S corporations;
- broker or dealers in securities or currencies;

- traders in securities that elect mark-to-market treatment;
- regulated investment companies;
- real estate investment trusts;
- trusts or estates;
- tax-exempt organizations (including private foundations);
- persons that hold Ordinary Shares as part of a “straddle,” “hedge,” “conversion,” “synthetic security,” “constructive sale,” or other integrated transaction for U.S. federal income tax purposes;
- persons that have a functional currency other than the U.S. dollar;
- certain U.S. expatriates or former long-term residents of the United States;
- persons owning (directly, indirectly, or constructively) 5% (by vote or value) or more of our stock;
- persons that acquired Ordinary Shares pursuant to an exercise of employee stock options or otherwise as compensation;
- partnerships or other entities or arrangements treated as pass-through entities for U.S. federal income tax purposes and investors in such entities;
- “controlled foreign corporations” within the meaning of Section 957(a) of the Code;
- “passive foreign investment companies” within the meaning of Section 1297(a) of the Code; and
- corporations that accumulate earnings to avoid U.S. federal income tax.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds Ordinary Shares, the tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership and the partner. Partnerships holding Ordinary Shares should consult their tax advisors regarding the tax consequences in their particular circumstances.

This discussion is based on the Code, the U.S. Treasury regulations promulgated thereunder, administrative rulings, and judicial decisions, all as currently in effect and all of which are subject to change or differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences described herein. Furthermore, there can be no assurance that the Internal Revenue Service (the “IRS”) will not challenge the tax considerations described herein and that a court will not sustain such challenge.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of Ordinary Shares, that is, for U.S. federal income tax purposes:

- an individual who is a U.S. citizen or resident of the United States;
- a corporation (including an entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more “United States persons” within the meaning of Section 7701(a)(30) of the Code have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable U.S. Treasury regulations to be treated as a United States person.

THIS DISCUSSION IS FOR GENERAL INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF ORDINARY SHARES IN THEIR PARTICULAR CIRCUMSTANCES.

Distributions on Ordinary Shares

Subject to the PFIC rules discussed below under “—*Passive Foreign Investment Company Rules*,” distributions on Ordinary Shares generally will be taxable as a dividend for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Such distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the applicable U.S. Holder’s adjusted tax basis in its Ordinary Shares. Any remaining excess will be treated as gain realized on the sale or other taxable disposition of Ordinary Shares and will be treated as described below under “—*Sale or Other Taxable Disposition of Ordinary Shares*.” The amount of any such distributions will include any amounts required to be withheld by us (or another applicable withholding agent) in respect of any non-U.S. taxes. Any such amount treated as a dividend will be treated as foreign-source dividend income. Any such dividends received by a corporate U.S. Holder generally will not qualify for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. With respect to non-corporate U.S. Holders, any such dividends generally will be taxed at currently preferential long-term capital gains rates only if (i) Ordinary Shares are readily tradable on an established securities market in the United States or we are eligible for benefits under an applicable tax treaty with the United States, (ii) we are not treated as a PFIC with respect to the applicable U.S. Holder at the time the dividend was paid or in the preceding year, and (iii) certain holding period and other requirements are met. Any such dividends paid in a currency other than the U.S. dollar generally will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of actual or constructive receipt.

As noted above and subject to applicable limitations, taxing jurisdictions other than the United States may withhold taxes from distributions on Ordinary Shares, and a U.S. Holder may be eligible for a reduced rate of withholding to the extent there is an applicable tax treaty between the applicable taxing jurisdiction and the United States and/or may be eligible for a foreign tax credit against the U.S. Holder’s U.S. federal income tax liability. Recently issued U.S. Treasury regulations, which apply to foreign taxes paid or accrued in taxable years beginning on or after December 28, 2021, may in some circumstances prohibit a U.S. Holder from claiming a foreign tax credit with respect to certain foreign taxes that are not creditable under applicable tax treaties. In lieu of claiming a foreign tax credit, a U.S. Holder may, at such U.S. Holder’s election, deduct foreign taxes in computing such U.S. Holder’s taxable income, subject to generally applicable limitations under U.S. tax law. An election to deduct foreign taxes in lieu of claiming a foreign tax credit applies to all foreign taxes paid or accrued in the taxable year in which such election is made. The foreign tax credit rules are complex and U.S. Holders should consult their tax advisers regarding the application of such rules, including the creditability of foreign taxes, in their particular circumstances.

Sale or Other Taxable Disposition of Ordinary Shares

Subject to the PFIC rules discussed below under “—*Passive Foreign Investment Company Rules*,” upon any sale or other taxable disposition of Ordinary Shares, a U.S. Holder generally will recognize gain or loss in an amount equal to the difference, if any, between (i) the sum of (A) the amount of cash and (B) the fair market value of any other property received in such sale or disposition and (ii) the U.S. Holder’s adjusted tax basis in the Ordinary Shares. Any such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder’s holding period for such Ordinary Shares exceeds one year. Long-term capital gain recognized by non-corporate U.S. Holders generally will be taxed at currently preferential long-term capital gains rates. The deductibility of capital losses is subject to limitations. For foreign tax credit purposes, any such gain or loss generally will be treated as U.S. source gain or loss.

If the consideration received by a U.S. Holder upon a sale or other taxable disposition of Ordinary Shares is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of such payment calculated by reference to the exchange rate in effect on the date of such sale or disposition. A U.S. Holder may have foreign currency gain or loss to the extent of the difference, if any, between (i) the U.S. dollar value of such payment on the date of such sale or

disposition and (ii) the U.S. dollar value of such payment calculated by reference to the exchange rate in effect on the date of settlement.

U.S. Holders should consult their tax advisors regarding the tax consequences of a sale or other taxable disposition of Ordinary Shares, including the creditability of foreign taxes imposed on such sale or disposition by a taxing jurisdiction other than the United States, in their particular circumstances.

Passive Foreign Investment Company Rules

The U.S. federal income tax treatment of U.S. Holders could be materially different from that described above if we are treated as a PFIC for U.S. federal income tax purposes. A non-U.S. corporation generally will be treated as a PFIC for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (ii) at least 50% of its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business), and gains from the disposition of passive assets.

Assuming that the First Merger and the Second Merger, taken together, qualified as an F-reorganization for U.S. federal income tax purposes, we will be treated as the successor to EBAC for U.S. federal income tax purposes, including for purposes of the PFIC rules. Since EBAC was a blank-check company with no current active business, based upon the composition of EBAC's income and assets, we believe that EBAC was a PFIC for the taxable year ended December 31, 2022. However, the determination of whether a non-U.S. corporation is a PFIC is a must be made on an annual basis. As a result, our actual PFIC status for any taxable year will not be determinable until after the end of such year. The determination of whether or not we are a PFIC is a fact-intensive determination and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of Ordinary Shares from time to time, which may fluctuate considerably. As a result, there can be no assurance with respect to our status as a PFIC for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for any taxable year.

Although PFIC status is generally determined annually, if we are determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder in its Ordinary Shares and the U.S. Holder did not make either a mark-to-market election or a qualifying electing fund ("QEF") election or, which are referred to collectively as the "PFIC Elections" for purposes of this discussion, for the first taxable year in which we are treated as a PFIC, and in which the U.S. Holder held (or was deemed to hold) Ordinary Shares, or the U.S.

Holder does not otherwise make a purging election, as described below, the U.S. Holder generally will be subject to special and adverse rules with respect to (i) any gain recognized by the U.S. Holder on the sale or other taxable disposition of its Ordinary Shares and (ii) any "excess distribution" made to the U.S. Holder (generally, any distributions to the U.S. Holder during a taxable year of the U.S. Holder that are greater than 125% of the average annual distributions received by the U.S. Holder in respect of its Ordinary Shares during the three preceding taxable years of the U.S. Holder or, if shorter, the U.S. Holder's holding period in its Ordinary Shares).

Under these rules:

- the U.S. Holder's gain or excess distribution will be allocated ratably over the U.S. Holder's holding period in its Ordinary Shares;
- the amount allocated to the U.S. Holder's taxable year in which the U.S. Holder recognized the gain or received the excess distribution, and to any period in the U.S. Holder's holding period before the first day of the first taxable year in which we are treated as a PFIC, will be taxed as ordinary income;

- the amount allocated to other taxable years (or portions thereof) of the U.S. Holder and included in the U.S. Holder's holding period will be taxed at the highest tax rate in effect for that year and applicable to the U.S. Holder; and
- an additional tax equal to the interest charge generally applicable to underpayments of tax will be imposed on the U.S. Holder with respect to the tax attributable to each such other taxable year of the U.S. Holder.

PFIC Elections

If we are treated as a PFIC and Ordinary Shares constitute "marketable stock," a U.S. Holder may avoid the adverse PFIC tax consequences discussed above if such U.S. Holder makes a mark-to-market election with respect to its Ordinary Shares for the first taxable year in which the U.S. Holder holds (or is deemed to hold) Ordinary Shares and each subsequent taxable year. Such U.S. Holder generally will include for each of its taxable years as ordinary income the excess, if any, of the fair market value of its Ordinary Shares at the end of such year over its adjusted tax basis in its Ordinary Shares. The U.S. Holder also will recognize an ordinary loss in respect of the excess, if any, of its adjusted tax basis in its Ordinary Shares over the fair market value of its Ordinary Shares at the end of its taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). The U.S. Holder's adjusted tax basis in its Ordinary Shares will be adjusted to reflect any such income or loss amounts, and any further gain recognized on a sale or other taxable disposition of its Ordinary Shares will be treated as ordinary income.

The mark-to-market election is available only for "marketable stock," generally, stock that is regularly traded on a national securities exchange that is registered with the Securities and Exchange Commission, including the Nasdaq (on which Ordinary Shares are currently listed), or on a foreign exchange or market that the IRS determines has rules sufficient to ensure that the market price represents a legitimate and sound fair market value. As such, such election generally will not apply to any of our non-U.S. subsidiaries, unless the shares in such subsidiaries are themselves "marketable stock." As such, U.S. Holders may continue to be subject to the adverse PFIC tax consequences discussed above with respect to any lower-tier PFICs, as discussed below, notwithstanding their mark-to-market election with respect to Ordinary Shares.

If made, a mark-to-market election would be effective for the taxable year for which the election was made and for all subsequent taxable years unless Ordinary Shares cease to qualify as "marketable stock" for purposes of the PFIC rules or the IRS consents to the revocation of the election. U.S. Holders should consult their tax advisors regarding the availability and tax consequences of a mark-to-market election with respect to Ordinary Shares in their particular circumstances.

The tax consequences that would apply if we were a PFIC and a U.S. Holder made a valid "qualified electing fund" election under Section 1295 of the Code (a "QEF Election") for the first year such U.S. Holder owns our Ordinary Shares would also be different from the adverse PFIC tax consequences described above. A U.S. Holder that makes a QEF Election will include in income its pro rata share of our net capital gains (as long-term capital gain) and other earnings and profits (as ordinary income), on a current basis, in each case whether or not distributed, in the taxable year of the U.S. Holder in which or with which our taxable year ends if we is treated as a PFIC for that taxable year. A U.S. Holder generally can make a separate election to defer the payment of taxes on undistributed income inclusions under the QEF Election rules, but if deferred, any such taxes will be subject to an interest charge.

If a U.S. Holder has made a QEF Election with respect to our Ordinary Shares, and the special tax and interest charge rules do not apply to such shares (because the QEF Election was made in the U.S. Holder's first year holding stock of a PFIC or a purging election was made, as described below), any gain recognized on the sale of our Ordinary Shares will generally be taxable as capital gain and no interest charge will be imposed under the PFIC rules. U.S. Holders that make a QEF Election with respect to a PFIC are currently taxed on their pro rata shares of such PFIC's earnings and profits, whether or not distributed. In such case, a subsequent distribution of such earnings and profits that were previously included in income should generally not be taxable as a dividend to such U.S. Holders. The tax basis of a U.S. Holder's shares in a PFIC with respect to which a QEF Election has been made will be increased by amounts that are included in taxable income, and decreased by amounts distributed but not taxed as dividends, under the above rules. Similar basis adjustments apply to property if by reason of holding such property the U.S. Holder is treated under the applicable attribution rules as owning shares in a PFIC with respect to which a QEF Election has been made.

In order to comply with the requirements of a QEF Election, a U.S. Holder generally must receive a PFIC Annual Information Statement (as defined in Section 1.1295-1(g) of the Treasury Regulations) from us. If we are determined to be a PFIC for any taxable year, we will endeavor to make available to U.S. Holders a PFIC Annual Information Statement with respect to such taxable year. However, there is no assurance that New Parent will have timely knowledge of its status as a PFIC in the future or that it will make available a PFIC Annual Information Statement. U.S. Holders are urged to consult their tax advisors with respect to any QEF Election previously made with respect to EBAC Common Stock.

If we are treated as a PFIC and a U.S. Holder failed or was unable to timely make a PFIC Election for prior periods, the U.S. Holder might seek to make a purging election to rid its Ordinary Shares of the PFIC taint. Under the purging election, the U.S. Holder will be deemed to have sold its Ordinary Shares at their fair market value and any gain recognized on such deemed sale will be treated as an excess distribution, as described above. As a result of the purging election, the U.S. Holder will have a new adjusted tax basis and holding period in Ordinary Shares solely for purposes of the PFIC rules.

Related PFIC Rules

If we are treated as a PFIC and, at any time, has a non-U.S. subsidiary that is treated as a PFIC, a U.S. Holder generally would be deemed to own a proportionate amount of the shares of such lower-tier PFIC, and generally could incur liability for the deferred tax and interest charge described above if we receive a distribution from, or sell or otherwise dispose of all or part of our interest in, such lower-tier PFIC, or the U.S. Holder otherwise was deemed to have sold or otherwise disposed of an interest in such lower-tier PFIC. U.S. Holders should consult their tax advisors regarding the application of the lower-tier PFIC rules in their particular circumstances.

A U.S. Holder that owns (or is deemed to own) shares in a PFIC during any taxable year, may have to file an IRS Form 8621 (whether or not a QEF election or a mark-to-market election is made) and to provide such other information as may be required by the U.S. Treasury Department. Failure to do so, if required, will extend the statute of limitations applicable to such U.S. Holder until such required information is furnished to the IRS and could result in penalties

THE PFIC RULES ARE VERY COMPLEX AND U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF SUCH RULES IN THEIR PARTICULAR CIRCUMSTANCES.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

U.S. Holders should consult their tax advisors regarding the information reporting requirements and the application of the backup withholding rules in their particular circumstances.

THIS DISCUSSION IS FOR GENERAL INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, AND LOCAL AND NON-U.S. INCOME AND NON-INCOME TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF ORDINARY SHARES, INCLUDING THE IMPACT OF ANY POTENTIAL CHANGE IN LAW, IN THEIR PARTICULAR CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.oculis.com. We intend to post our Annual Report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of our company, such references are not necessarily complete, and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders

We intend to submit any annual report provided to security holders in electronic format as an exhibit to a current report on Form 6-K.Item

Item 11. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks that may result in changes of foreign currency exchange rates and interest rates, as well as the overall change in economic conditions in the countries where we conduct business.

The company takes a conservative approach to manage currency exchange risk by prioritizing long term stability and natural hedging of currencies with the underlying currency flow of operations. Other conservative measures include diversification of banks utilized by the Company and cash preservation in low risk short term investments.

For more information about financial risks we are exposed to, refer to note 20 of our audited consolidated financial statements, included elsewhere in this Annual Report.

Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Use of Proceeds.

Not applicable.

Item 15. Controls and Procedures.

Disclosure Controls and Procedures

Our management evaluated, with the participation of the Chief Executive Officer and Chief Financial Officer, the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, as a result of the material weakness described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were not effective to accomplish their objectives at the reasonable assurance level. In light of this fact, our management has performed additional procedures and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the consolidated financial statements for the periods covered by and included in this Annual Report on Form 20-F fairly state, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with IFRS. The identified material weakness did not result in a material misstatement to our financial statements in current and prior years.

Previously-Identified Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2021, two material weaknesses were identified in our internal control over financial reporting. The material weaknesses identified were related to (i) a lack of sufficient internal accounting personnel to support an efficient and structured financial statement close process and allow for the appropriate monitoring of financial reporting matters; and (ii) the maintenance of effective controls over information technology general controls for IT accounting and financial reporting systems.

Remediation Activities and Plans

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2022, management concluded that the previously-identified material weakness related to the maintenance of effective

controls over information technology general controls for IT accounting and financial reporting systems had been remediated. The remediation was accomplished through the implementation and controls testing of a new ERP system, as well as implementation of ERP system controls and manual controls. We have concluded that the material weakness has been remediated since each component for which management had identified a material weakness has been operating effectively for a sufficient period of time.

In relation to the previously-identified material weakness related to the lack of sufficient internal accounting personnel to support an efficient and structured financial statement close process, the Company has undertaken efforts to strengthen the organization, systems and processes of our accounting and finance department in 2022, including additions of internal accounting personnel and strengthening of external resources to support the Company's financial statement preparation reporting and reporting processes. The Company plans to continue to remediate the outstanding material weakness in 2023 by adding of accounting personnel to allow for the appropriate monitoring of financial reporting matters, enhancing of financial statements review procedures, and utilization of ERP system controls where applicable.

The identified control deficiencies related to this material weakness did not result in a material misstatement to our financial statements in current and prior years.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of the Company's registered public accounting firm on management's assessment of the Company's internal control over financial reporting since we are an emerging growth company.

Changes in Internal Control Over Financial Reporting

Other than those changes disclosed above under "Remediation Activities and Plans," there were no other changes in internal control over financial reporting that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Board has determined that Mr. Carnot (Chair) qualifies as an "audit committee financial expert" as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Mr. Carnot (Chair), Ms. Ackermann and Ms. O'Keeffe are independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.¹

¹ NTD: To confirm based on D&O questionnaires.

Item 16B. Code of Ethics

Our board of directors adopted a Code of Business Conduct applicable to the directors, executive officers and other team members, that complies with the rules and regulations of Nasdaq and the SEC. The Code of Ethics is available on our website. In addition, we posted on the Corporate Governance section of our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the

Code of Ethics. The reference to our website address in this Annual Report on Form 20-F does not include or incorporate by reference the information on our website into this Annual Report on Form 20-F.

Item 16C. Principal Accountant Fees and Services

For the year ended December 31, 2022 and 2021, PricewaterhouseCoopers SA was our independent registered public accounting firm.

The following table shows the aggregate fees for services rendered by PwC to us and our subsidiaries, in the fiscal year ended December 31, 2022 and 2021.

(in CHF thousands)	Year Ended December 31,	
	2022	2021
Audit Fees	1,285	310
Audit-Related Fees	5	5
Tax Fees	289	20
Total	1,579	335

Auditor Name	Auditor Location
PricewaterhouseCoopers SA	Pully, Switzerland

Audit fees include fees billed for professional services rendered for audits of our annual consolidated financial statements, reviews of consolidated quarterly information, statutory audit of the Company and our subsidiaries and review of our securities offering documents. The increase of CHF 1.0 million was primarily due to the audit services for assurance in connection with the BCA and associated SEC regulatory filings required to become a public company.

Audit-related fees include fees billed for assurance and related services in connection with capital increases and services that generally only the independent accountant can reasonably provide.

Tax Fees include fees billed for professional services for tax compliance, tax advice and tax planning. The increase of CHF 0.25 million was primarily due to tax services in connection with the BCA and associated SEC filings required to become a public company.

Audit and Risk Committee Pre-Approval Policies and Procedures

Our audit and risk committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors. All of the services related to us provided by PricewaterhouseCoopers SA during the last fiscal year have been pre-approved by the audit and risk committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant.

Not applicable.

Item 16G. Corporate Governance.

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq rules, we will comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- Exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- Exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- Exemption from quorum requirements for shareholder meetings. Swiss practice with respect to quorum requirements for shareholder meetings in lieu of the requirement under Nasdaq Listing Rules that the quorum be not less than 33 1/3% of the outstanding voting shares;
- Exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers;
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- Exemption from the requirement that our audit committee have review and oversight responsibilities over all “related party transactions,” as defined in Item 7.B of Form 20-F;
- Exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibilities. We currently have three directors who serve on the compensation committee who meets the heightened independence standards for members of a compensation committee; and
- Exemption from the requirements that director nominees are selected, or recommended for selection by our board, either by (1) independent directors constituting a majority of our board’s independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq’s Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to Swiss requirements in lieu of many of the Nasdaq corporate governance rules, we intend to comply with the Nasdaq corporate governance rules applicable to foreign private issuers.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer. See the exhibit titled “*Description of Securities*” for additional information.

Item 16H. Mine Safety Disclosure.

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 17. Financial Statements.

See pages F-1 through F-171 of this Annual Report.

Item 18. Financial Statements.

Not applicable.

Item 19. Exhibits

EXHIBIT INDEX

Exhibit	Description	Incorporation By Reference			
		Schedule/ Form	File Number	Exhibit	File Date
1.1**	Articles of Association of the Company.	20-F	001-41636	1.1	03.08.2023
2.1**	Specimen Unit Certificate	S-1	333-253220	4.1	03.04.2021
2.2**	Specimen Class A Ordinary Share Certificate	S-1	333-253220	4.2	08.04.2020
2.3**	Specimen Warrant Certificate	S-1	333-253220	4.3	03.04.2021
2.4**	Warrant Agreement, dated March 15, 2021, between EBAC and Continental Stock Transfer & Trust Company, as warrant agent	8-K	001-40211	4.1	03.18.2021
2.5*	Description of Securities				
4.1**†+	Business Combination Agreement, dated as of October 17, 2022, by and among EBAC and Oculis	8-K	001-40211	2.1	10.17.2022
4.2**††	License Agreement by and among Alcon Research, LTD., and Oculis, dated December 19, 2018	F-4	333-268201	10.8	12.12.2022
4.3**††	Amendment to License Agreement by and among Alcon Research, LTD. and Oculis, dated September 11, 2020	F-4	333-268201	10.9	12.12.2022
4.4**††	Letter Agreement by and among Novartis Technology LLC and Oculis, dated October 12, 2021	F-4	333-268201	10.11	12.12.2022
4.5**††	License Agreement by and among Accure Therapeutics SL and Oculis, dated January 29, 2022	F-4	333-268201	10.12	12.12.2022
4.6**	Oculis Shareholder Support Agreement, dated as of October 17, 2022, by and among Oculis, EBAC the other parties thereto	8-K	001-40211	10.4	10.17.2022

4.7**	Sponsor Support Agreement, dated as of October 17, 2022, by and among the Sponsor, EBAC and Oculus	8-K	001-40211	10.5	10.17.2022
4.8**	Form of PIPE Subscription Agreement by and among EBAC and certain investors party thereto	8-K	001-40211	10.1	10.17.2022
4.9**	Form of Convertible Loan Agreement by and among Oculus SA and certain shareholders party thereto	8-K	001-40211	10.2	10.17.2022
4.10**	Form of Shareholder Non-Redemption Agreement, by and among Sponsor and certain investors party thereto	8-K	001-40211	10.3	10.17.2022
4.11**	Amended and Restated Registration Rights and Lock-Up Agreement, dated as of March 2, 2023, by and among the Company and the other signatories to be a party thereto	20-F	001-41636	4.11	03.07.2023
4.12**#	Stock Option and Incentive Plan Regulation 2023 of Oculus Holding AG	F-4	333-268201	10.13	01.06.2023
4.13**#	Form of Indemnification Agreement with the officers and directors	F-4	333-268201	10.10	01.06.2023
4.14**	Administrative Services Agreement, dated March 15, 2021, between EBAC and the Sponsor	8-K	001-40211	10.4	03.18.2021
8.1**	List of Subsidiaries of the Company	20-F	001-41636	8.1	03.07.2023
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer and the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				

101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

† Certain schedules and exhibits to this Exhibit have been omitted pursuant to Company S-K Item 601(b)(2). The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

†† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

+ Certain schedules and exhibits to this Exhibit have been omitted pursuant to Regulation S-K Item 601(a)(5). The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

Indicates a management contract or any compensatory plan, contract or arrangement

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this report on its behalf.

March 28, 2023

OCULIS HOLDING AG

By: /s/ Riad Sherif

Name: Riad Sherif

Title: Chief Executive Officer

Oculis SA
Consolidated Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm (PCAOB ID 1358)	F-1
Consolidated Statements of Loss for the years ended December 31, 2022, 2021 and 2020	F-2
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022, 2021 and 2020	F-3
Consolidated Statements of Financial Position as of December 31, 2022 and 2021	F-4
Consolidated Statements of Changes in Equity for the years ended December 31, 2022, 2021 and 2020	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020	F-6
Notes to the Consolidated Statements	F-7

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Oculis Holding AG

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Oculis SA and its subsidiaries (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of loss, comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with the International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers SA
Lausanne, Switzerland
March 28, 2023

We have served as the Company's auditor since 2019.

Consolidated Statements of Loss
(in CHF thousands, except per share data)

	Note	For the Years Ended December 31,		
		2022	2021	2020
Grant income	6. (A) / 10	912	960	993
Operating income		912	960	993
Research and development expenses	6. (B)	(22,224)	(9,568)	(9,337)
General and administrative expenses	6. (B)	(11,064)	(4,624)	(3,992)
Operating expenses		(33,288)	(14,192)	(13,329)
Operating loss		(32,376)	(13,232)	(12,336)
Finance income	6. (C)	126	21	10
Finance expense	6. (C)	(6,442)	(5,120)	(2,628)
Exchange differences	6. (D)	49	(193)	163
Finance result, net		(6,267)	(5,292)	(2,455)
Loss before tax for the period		(38,643)	(18,524)	(14,790)
Income tax expense	6. (E)	(55)	(27)	(83)
Loss for the period		(38,698)	(18,552)	(14,873)
Loss per share:				
Basic and diluted, loss for the period attributable to equity holders	21	(12.94)	(6.68)	(5.77)

The accompanying notes form an integral part of the consolidated financial statements.

Consolidated Statements of Comprehensive Loss
(in CHF thousands)

	Note	For the Years Ended December 31,		
		2022	2021	2020
Loss for the period		(38,698)	(18,552)	(14,873)
Other comprehensive loss				
<u>Items that will not be reclassified to profit or loss</u>				
Actuarial gains/(losses) of defined benefit plans	4. (C) / 11	744	88	(115)
<u>Items that may be reclassified subsequently to profit or loss</u>				
Currency translation differences	2. (D)	3	(28)	28
Other comprehensive profit/(loss) for the period		747	60	(87)
Total comprehensive loss for the period		(37,951)	(18,492)	(14,960)

The accompanying notes form an integral part of the consolidated financial statements.

Consolidated Statements of Financial Position
(in CHF thousands)

	Note	As of December 31,	
		2022	2021
ASSETS			
Non-current assets			
Property, plant & equipment	7	365	431
Intangible assets	8	12,206	8,724
Right-of-use assets	9	758	855
Financial assets	13	50	52
Deferred income tax assets	6. (E)	24	-
Total non-current assets		13,403	10,062
Current assets			
Other current assets	10	2,959	944
Accrued income	10	912	760
Cash and cash equivalents	13	19,786	46,277
Total current assets		23,657	47,981
TOTAL ASSETS		37,060	58,043
EQUITY AND LIABILITIES			
Equity attributable to equity holders of the parent			
Share capital	15. (A)	340	335
Share premium	15. (A)	10,540	10,434
Reserve for share-based payment	12	2,771	1,967
Actuarial loss on post employment benefit obligations	4. (C) / 11	(264)	(1,008)
Treasury shares	15. (C)	(100)	(100)
Cumulative translation adjustments		(300)	(303)
Accumulated losses		(110,978)	(72,280)
Total Equity		(97,991)	(60,955)
Non-current liabilities			
Long-term lease liabilities	9	491	577
Long-term financial debt	14	122,449	113,502
Defined benefit pension liabilities	4. (C) / 11	91	845
Deferred income tax liabilities	6. (E)	-	11
Total non-current liabilities		123,031	114,936
Current liabilities			
Trade payables	16	3,867	824
Accrued expenses and other payables	17	8,011	3,045
Short-term lease liabilities	9	142	193
Total current liabilities		12,020	4,062
Total Liabilities		135,051	118,998
TOTAL EQUITY AND LIABILITIES		37,060	58,043

The accompanying notes form an integral part of the consolidated financial statements.

Consolidated Statements of Changes in Equity
(in CHF thousands)

	Note	Attributable to equity holders of the parent							Total
		Share capital	Share premium	Reserve for share-based payment	Treasury shares	Cumulative translation adjustments	Actuarial gain / (loss) on post-employment benefit obligations	Accumulated losses	
Balance as of January 1, 2020		289	9,476	1,312	(100)	(303)	(981)	(38,855)	(29,163)
Loss for the period		-	-	-	-	-	-	(14,873)	(14,873)
Other comprehensive loss:									
Actuarial loss on post-employment benefit obligations	4. (C) / 11	-	-	-	-	-	(115)	-	(115)
Currency translation differences	2. (D)	-	-	-	-	28	-	-	28
Sub-total other comprehensive loss for the period		-	-	-	-	28	(115)	-	(87)
Total comprehensive loss for the period		-	-	-	-	28	(115)	(14,873)	(14,960)
Share based payment	12	-	-	328	-	-	-	-	328
Restricted shares awards	12	8	149	-	-	-	-	-	157
Transaction costs	15	-	(15)	-	-	-	-	-	(15)
Balance as of December 31, 2020		297	9,609	1,640	(100)	(275)	(1,096)	(53,728)	(43,654)
Balance as of January 1, 2021		297	9,609	1,640	(100)	(275)	(1,096)	(53,728)	(43,654)
Loss for the period		-	-	-	-	-	-	(18,552)	(18,552)
Other comprehensive profit:									
Actuarial gain on post-employment benefit obligations	4. (C) / 11	-	-	-	-	-	88	-	88
Currency translation differences	2. (D)	-	-	-	-	(28)	-	-	(28)
Sub-total other comprehensive profit for the period		-	-	-	-	(28)	88	-	60
Total comprehensive loss for the period		-	-	-	-	(28)	88	(18,552)	(18,492)
Share based payment	12	-	-	328	-	-	-	-	328
Restricted shares awards	12	39	837	-	-	-	-	-	876
Transaction costs	15	-	(12)	-	-	-	-	-	(12)
Balance as of December 31, 2021		335	10,434	1,967	(100)	(303)	(1,008)	(72,280)	(60,955)
Balance as of January 1, 2022		335	10,434	1,967	(100)	(303)	(1,008)	(72,280)	(60,955)
Loss for the period		-	-	-	-	-	-	(38,698)	(38,698)
Other comprehensive profit:									
Actuarial gain on post-employment benefit obligations	4. (C) / 11	-	-	-	-	-	744	-	744
Currency translation differences	2. (D)	-	-	-	-	3	-	-	3
Sub-total other comprehensive profit for the period		-	-	-	-	3	744	-	747
Total comprehensive loss for the period		-	-	-	-	3	744	(38,698)	(37,951)
Share based payment	12	-	-	804	-	-	-	-	804
Transaction costs	15	-	(9)	-	-	-	-	-	(9)
Stock options exercised	12	5	115	-	-	-	-	-	120
Balance as of December 31, 2022		340	10,540	2,771	(100)	(300)	(264)	(110,978)	(97,991)

The accompanying notes form an integral part of the consolidated financial statements.

Consolidated Statements of Cash Flows
(in CHF thousands)

	Note	For the Years Ended December 31,		
		2022	2021	2020
Operating activities				
Loss before tax		(38,643)	(18,524)	(14,790)
Non cash adjustments:				
- Net financial result		(500)	53	(155)
- Depreciation of property, plant and equipment	7	132	88	104
- Depreciation of right-of-use assets	9	167	147	124
- Recognized expense for stock option plan	12	804	328	328
- Payroll expenses related to restricted stock	12 / 15	-	876	157
- Interest expense on Series B & C preferred shares	14	6,343	4,996	2,560
- Interests on lease liabilities	9	45	49	50
- Post-employment benefits	11	(9)	(139)	77
- Non-realized foreign exchange differences	6. (D) / 14	583	(792)	28
Working capital adjustments:				
- De/(Increase) in other current assets	10	(1,796)	(731)	169
- De/(Increase) in accrued income	10	(152)	233	230
- Changes in receivables/payables from/to related parties		-	29	10
- (De)/Increase in trade payables	16	3,043	30	(649)
- (De)/Increase in accrued expenses and other payables	17	4,903	(352)	(211)
Interest received		126	-	-
Interest paid		(100)	(116)	(58)
Taxes paid		(20)	-	-
Net cash flows used in operating activities		(25,074)	(13,825)	(12,029)
Investing activities				
Payment for purchase of property, plant and equipment	7	(65)	(28)	(19)
Payment for purchase of intangible assets	8	(3,483)	-	-
Net cash used in investing activities		(3,548)	(28)	(19)
Financing activities				
Transaction costs for issuance of preferred shares/capital increase	14 / 15	(63)	(804)	(67)
Transactions costs related to the BCA	2. (E)	(214)	-	-
Proceeds from capital increase	15. (A)	120	-	-
Proceeds from issuance of preferred shares, classified as liabilities	14	2,030	56,096	5,025
Principal payment of lease obligation	9	(159)	(98)	(98)
Net cash from financing activities		1,714	55,194	4,859
(De)/Increase in cash and cash equivalents		(26,909)	41,341	(7,189)
Cash and cash equivalents, beginning of period		46,277	4,952	12,152
Exchange difference	13	418	(15)	(12)
Cash and cash equivalents, end of period	13	19,786	46,277	4,952
Net cash and cash equivalents variation		(26,909)	41,341	(7,189)
Supplemental Non-Cash Financing Information				
Transaction costs related to the BCA recorded in accrued expenses and other payables/trade payables		356	-	-

The accompanying notes form an integral part of the consolidated financial statements.

1. CORPORATE INFORMATION

Oculus SA (“Oculus”, the “Group”, or the “Company”) is a limited company (société anonyme) with registered office at EPFL Innovation Park, c/o Bâtiment D, 1015 Lausanne, Ecublens, Switzerland and its shares are not publicly traded. It was established on December 11, 2017.

The Company controls four wholly owned subsidiaries: Oculus ehf (“Oculus Iceland”), which was incorporated in Reykjavik, Iceland on October 28, 2003, Oculus France SARL (“Oculus France”) which was incorporated in Paris, France on March 27, 2020, Oculus US Inc. (“Oculus US”) which was incorporated in Delaware, USA, on May 26, 2020, and Oculus HK, Limited (“Oculus HK”) which was incorporated in Hong Kong, China on June 1, 2021. The Company and its subsidiaries form the Oculus Group (the “Group”).

The purpose of the Company is the research, study, development, manufacture, promotion, sale and marketing of pharmaceutical products and substances as well as the purchase, sale and exploitation of intellectual property rights, such as patents and licenses, in this field. More precisely, Oculus is a global biopharmaceutical company developing treatments to save sight and improve eye care with breakthrough innovations. The Company’s differentiated pipeline includes candidates for topical retinal treatments, topical biologics and disease modifying treatments.

The consolidated financial statements of Oculus as of and for the year ended December 31, 2022, were approved and authorized for issue by the Company's Board of Directors on March 28, 2023.

2. BASIS OF PREPARATION AND CHANGES TO THE GROUP'S ACCOUNTING POLICIES

(A) Going concern

The Group's accounts are prepared on a going concern basis. To date, the Group has financed its cash requirements primarily from share issuances, as well as government research and development grants. The recent business combination with European Biotech Acquisition Corp. (“EBAC”) and the listing in NASDAQ early in March 2023 raised additional funding to secure business continuity as explained under note 2. (E). The Board of Directors believes that the Group has the ability to meet its financial obligations for at least the next 12 months.

The Company is a clinical stage company and is exposed to all the risks inherent to establishing a business. Inherent to the Company’s business are various risks and uncertainties, including the substantial uncertainty as to whether current projects will succeed. The Company’s success may depend in part upon its ability to (i) establish and maintain a strong patent position and protection, (ii) enter into collaborations with partners in the biotech and pharmaceutical industry, (iii) successfully move its product candidates through clinical development, and (iv) attract and retain key personnel. The Company’s success is subject to its ability to be able to raise capital to support its operations. To date, the Company has financed its cash requirements primarily through share issuances and grant income. Shareholders should note that the long-term viability of the Company is dependent on its ability to raise additional capital to finance its future operations. The Company will continue to evaluate additional funding through public or private financings, debt financing or collaboration agreements. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to (i) significantly delay, scale back or discontinue the development of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to product candidates that the Company would otherwise seek to develop itself, on unfavorable terms.

The conflict between Russia and Ukraine has caused major macroeconomic disruptions that have impacted the global trade and economies. As such increasing inflation around the globe has forced national banks to increase their interest rates, consequently impacting interest yields around the globe. The Group has assessed the impact of these measures and concluded that this impacted primarily the estimates in relation to the pension plan obligations, as noted below under 4. (C). As of today, no further material impact has been identified on the Group’s business nor its ability to continue as a going concern.

(B) Statement of compliance

The consolidated financial statements of Oculis SA are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

(C) Basis of measurement

The policies set out below are consistently applied to all the years presented. The consolidated financial statements have been prepared under the historical cost convention.

The totals are calculated with the original unit amounts, which could lead to rounding differences. These differences in thousands of units are not changed in order to keep the accuracy of the original data.

(D) Functional currency

The consolidated financial statements of the Group are expressed in CHF, which is the Company's functional and the Group's presentation currency. The functional currency of the Company and Oculis Iceland is CHF. The functional currency of Oculis France is EUR, of Oculis US is USD and of Oculis Hong Kong is HKD.

Assets and liabilities of foreign operations are translated into CHF at the rate of exchange prevailing at the reporting date and their statements of profit or loss are translated at yearly average exchange rates. The exchange differences arising on translation for consolidation are recognized in other comprehensive income.

(E) Business Combination Agreement

On October 17, 2022, Oculis SA entered into a Business Combination Agreement ("BCA") with European Biotech Acquisition Corp., a NASDAQ listed blank check company incorporated in Cayman Islands as an exempted company ("EBAC"). This merger and subsequent listing in NASDAQ provides the Company with additional funding from EBAC's Trust fund, additional subscription agreements from private investments by third-party investors (the "PIPE") and conversion of Convertible Loan Agreements (the "CLAs").

As of December 31, 2022, the Company has capitalized CHF 0.6 million of transactions costs linked to the BCA transaction within Other current assets that met the following criteria: 1) directly attributable to the issue of equity instruments, 2) incurred after BCA agreement signature, at which date the transaction was considered highly probable and finally, 3) related to newly issued shares (incremental costs). The paid portion of transaction costs for an amount of CHF 0.2 million was also reflected in the financing activities of the Consolidated Statements of Cash flows. For further details about the closing of the BCA transaction, refer to note 22.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies adopted in the preparation of these financial statements are set out below. The policies set out below are consistently applied to all the years presented, unless otherwise stated.

(A) Current vs. non-current classification

The Company presents assets and liabilities in the balance sheet based on current/non-current classification. The Company classifies all amounts to be realized or settled within 12 months after the reporting period to be current and all other amounts to be non-current.

(B) Foreign currency transactions

Foreign currency transactions are translated into the functional currency Swiss Francs (CHF) using prevailing exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into CHF at rates of exchange prevailing at reporting date. Any gains or losses from these translations are included in the statements of loss in the period in which they arise.

(C) Group accounting

Oculis SA has four wholly owned subsidiaries, including Oculis Iceland, Oculis France, Oculis US and Oculis Hong Kong. The Company's consolidated financial statements present the aggregate of the five Group entities, after elimination of intra-group transactions, balances, investments and capital.

(D) Segment reporting

The Company is managed and operated as one business. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business and accordingly, has one reporting segment.

The Company has locations in five countries: Switzerland, Iceland, France, USA and Hong Kong. An analysis of non-current assets by geographic region is presented in Note 5.

(E) Leases

All leases are accounted for by recognizing a right-of-use asset and a lease liability except for leases of low value assets and leases with a duration of 12 months or less.

Lease liabilities are measured at the present value of the expected contractual payments due to the lessor over the lease term, with the discount rate determined by reference to the rate inherent in the lease unless this is not readily determinable, in which case the Group's incremental borrowing rate on commencement date of the lease is used. Variable lease payments are only included in the measurement of the lease liability if they depend on an index or rate and remain unchanged throughout the lease term. Other variable lease payments are expensed.

On initial recognition, the carrying value of the lease liability also includes:

- o amounts expected to be payable under any residual value guarantee; and
- o the exercise price of any purchase option granted in favor of the group if it is reasonably certain to assess that option.

Right-of-use assets are initially measured at the amount of the lease liability, reduced for any lease incentives received, and increased for lease payments made at or before commencement of the lease and initial direct costs incurred.

Subsequent to the initial measurement, lease liabilities increase as a result of interest charged at a constant rate on the balance outstanding and are reduced for lease payments made. Right-of-use assets are depreciated on a straight-line basis over the remaining expected term of the lease or over the remaining economic life of the asset if this is judged to be shorter than the lease term.

When the Group revises its estimate of the term of any lease, it adjusts the carrying amount of the lease liability to reflect the expected payments over the revised term, which are discounted using a revised discount rate. The carrying value of lease liabilities is similarly revised if the variable future lease payments dependent on a rate or index is revised. In both cases, an equivalent adjustment is made to the carrying value of the right-of-use asset, with the revised carrying amount being amortized over the remaining lease term. If the carrying amount of the right-of-use asset is adjusted to zero, any further reduction is recognized in profit or loss.

(F) Grant income recognition

Grant income is recognized where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with, and in the year when the related expenses are incurred.

(G) Taxes

Taxes reported in the consolidated income statements include current and deferred taxes on profit. Taxes on income are accrued in the same periods as the revenues and expenses to which they relate.

Deferred tax is the tax attributable to the temporary differences that appear when taxation authorities recognize and measure assets and liabilities with rules that differ from those of the consolidated accounts. Deferred income tax is calculated using the liability method and determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized, or the deferred income tax liability is settled. Any changes to the tax rates are recognized in the income statement unless related to items directly recognized in equity or other comprehensive loss.

Deferred tax liabilities are recognized on all taxable temporary differences. Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences or the unused tax losses can be utilized. Deferred income tax assets from tax credit carry forwards are recognized to the extent that the national tax authority confirms the eligibility of such a claim and

that the realization of the related tax benefit through future taxable profits is probable. Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income tax assets and liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

(H) Earnings / (loss) per share

The Company presents basic earnings / (loss) per share for each period in the financial statements. The earnings (loss) per share is calculated by dividing the earnings / (loss) of the period by the weighted average number of shares outstanding during the period. Diluted earnings per share, applicable in case of positive result, reflect the potential dilution that could occur if dilutive securities such as preferred shares or share options were vested or exercised into common shares.

(I) Preferred shares

Judgment was required in determining the classification of the preferred shares issued by the Company as either equity or liabilities. The preferred shareholders hold certain preference rights that include preferential distribution of proceeds in the case of liquidity events as defined in the shareholder agreements. Under IAS 32 the Company classifies the Preferred Shares as liabilities. This applies to Series A, B and C shares as per Note 14.

(J) Property, plant and equipment

All property, plant and equipment are shown at cost, less subsequent depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the items. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably.

Depreciation is calculated on a straight-line basis over the useful life, according to the following schedule:

Category	Useful life in years
Laboratory equipment	5 - 7
Laboratory fixtures and fittings	10
Office - IT tools	2 - 3
Office furniture and equipment	5

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date. An asset's carrying amount is impaired immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposal or retirement of tangible fixed assets are determined by comparing the net proceeds received with the carrying amounts and are included in the consolidated income statements.

(K) Intangible assets

(a) Research and development costs

Research expenditure is recognized in expense in the year in which it is incurred. Internal development expenditure is capitalized only if it meets the recognition criteria of IAS 38 "Intangible Assets". Where regulatory and other uncertainties are such that the criteria are not met, which is almost invariably the case prior to approval of the drug by the relevant regulatory authority, the expenditure is recognized in the income statement. Where, however, recognition criteria are met, internal development expenditure is capitalized and amortized on a straight-line basis over its useful economic life. The amortization of the licenses will start when the market approval is obtained.

(b) Licenses

Licenses acquired are capitalized as intangible assets at historical cost and amortized over their useful lives, which are determined on a basis of the expected pattern of consumption of the expected future economic benefits embodied in the licenses and which therefore commence only once the necessary regulatory and marketing approval has been received. These licenses are tested for impairment in the last quarter of each financial period, or when there is any indication for impairment.

Amortization of capitalized licenses is charged to research and development expenses.

(c) Impairment of licenses

Impairment of capitalized licenses is charged to research and development expenses.

(L) Impairment of non-financial assets

Assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less costs of disposal and value-in-use.

For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash flows of other assets ("cash-generating units"). Impairment losses are recognized in the income statement. Prior impairments of non-financial assets are reviewed for possible reversal of the impairment at each reporting date.

(M) Financial instruments

The principal financial instruments used by the Group are as follows:

- o Other current assets
- o Cash and short-term deposits
- o Long-term financial debt
- o Lease liabilities
- o Trade and other payables

These financial instruments are carried at amortized cost.

Due to their short-term nature, the carrying value of cash and cash equivalents, other current assets, and trade and other payables approximates their fair value. For details of the fair value hierarchy, valuation techniques, and significant unobservable inputs related to determining the fair value of long-term financial debt, refer to Note 20.

(a) Other current assets

The carrying amount of other receivables/current assets is reduced through the use of an allowance account, and the amount of the loss is recognized in the income statement. Subsequent recoveries of amounts previously written off are credited to the income statement.

(b) Cash and cash equivalents

Cash and cash equivalents include cash on hand and highly liquid investments with original maturities of three month or less. These investments are readily convertible to known amounts of cash.

(c) Long-term financial debt

Long-term financial debt exclusively results from the issuance of preferred shares that qualify as financial liabilities under IAS 32. Long-term financial debt is carried at amortized cost, plus the accrued interest/preferred dividend payments that are due by the Group under certain conditions. Refer to Note 14 for further information.

(d) Lease liabilities

Lease liabilities are measured at the present value of the expected contractual payments due to the lessor over the lease term, with the discount rate determined by reference to the rate inherent in the lease unless this is not readily determinable, in which case the Group's incremental borrowing rate on commencement date of the lease is used.

(e) Trade and other payables

Trade and other payables are amounts due to third parties in the ordinary course of business.

(N) Employee benefits

(a) Pension obligations

The Group operates a defined benefit pension plan for its Swiss-based employees, which is held in multi-employer fund. The pension plan is funded by payments from employees and from the Company. The Company's contributions to the defined contribution plans are charged to the income statement in the year to which they relate.

The liability / asset recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the balance sheet date less the fair value of plan assets and the possible effect of the asset ceiling, together with adjustments for unrecognized past-service costs. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method.

When the company has a surplus in the defined benefit pension plans, it measures the net defined benefit asset at the lower of:

- o The surplus in the defined benefit pension plans
- o The asset ceiling (being the present value of any economic benefits available in the form of refunds from the plan or reductions in future contributions to the plan), determined using the discount rate.

The company does not expect any refunds or contribution reductions in case of a surplus in the defined benefit pension plan calculated per IAS 19, therefore no assets would be recognized in the Consolidated Statements of Financial Position.

The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension liability.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise.

Past-service costs are recognized immediately in income, unless the changes to the pension plan are conditional on the employees remaining in service for a specified period of time (the vesting period). In this case, the past-service costs are amortized on a straight-line basis over the vesting period.

(b) Employee participation

The Group operates an equity-settled, share-based compensation plan, under which the entity receives services from employees as consideration for equity instruments (e.g. options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognized as an expense.

Non-market vesting conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each reporting period, the entity revises its estimates of the number of options that are expected to vest based on the non-marketing vesting conditions. It recognizes the impact of the revision to original estimates, if any, in the income statement, with a corresponding adjustment to equity.

When the options are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised.

(O) Capitalization of transaction costs

The Company capitalizes transaction costs within Other current assets in the Company's consolidated balance sheet when costs are directly attributable to new equity financing instrument (including business combination related transactions) when it is highly probable that the financing transaction will take place in the future. If and when the Company completes the transaction, capitalized transaction costs will be offset against the proceeds and will be recorded as a reduction of share premium within the Company's consolidated balance sheet. If the Company determines that it is not highly probable that the transaction will be completed, the Company will

write-off capitalized transaction costs incurred during that respective quarter in the consolidated statement of loss.

(P) Standard and Interpretations in issue not yet adopted

There are no IFRS standards, amendments or interpretations not yet effective that would be expected to have a material impact on Oculus.

4. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

The Group's principal accounting policies are set out in Note 3 of the Group's consolidated financial statements and conform to International Financial Reporting Standards (IFRS). Significant judgments and estimates are used in the preparation of the consolidated financial statements which, to the extent that actual outcomes and results may differ from these assumptions and estimates, could affect the accounting in the areas described in this section.

(A) Impairment of licenses

The Group assesses whether there are any indicators of impairment for all licenses at each reporting date, which refers exclusively to the licenses of two specific product candidates: OCS-02 and OCS-05. Given the stage Oculus' development activities and the importance of both products in Oculus' portfolio, the impairment test is performed first on the basis of a fair value model for the entire Company using a market approach, and second on the basis of the continued development feasibility of the relevant product candidate. Refer to Note 8.

(B) Deferred income taxes

Deferred income tax assets are recognized for all unused tax losses only to the extent that it is probable that taxable profits will be available against which the losses can be utilized. Judgment is required from management to determine the amount of tax asset that can be recognized, based on forecasts and tax planning strategies. Given the uncertainty in the realization of future taxable profits, no deferred tax asset on unused tax losses has been recognized as of December 31, 2022, 2021 and 2020. Refer to Note 6. (E).

(C) Pension benefits

The present value of the pension obligations depends on several factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost (income) for pensions include the discount rate. Any changes in these assumptions will impact the carrying amount of pension obligations. The independent actuary of the Group uses statistical based assumptions covering future withdrawals of participants from the plan and estimates on life expectancy. The actuarial assumptions used may differ materially from actual results due to changes in market and economic conditions, higher or lower withdrawal rates or longer or shorter life spans of participants. These differences could have a significant impact on the amount of pension income or expenses recognized in future periods.

The Group determines the appropriate discount rate at the end of each year. This is the interest rate used to determine the present value of estimated future cash outflows expected to be required to settle the pension obligations. In determining the appropriate discount rate, the Group considers the interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating the terms of the related pension liability. Other key assumptions for pension obligations are based in part on current market conditions. Refer to Note 11.

(D) Share-based compensation

The Company operates an equity-settled, share-based compensation plan. The fair value of the employee services received in exchange for the grant of equity-based awards is recognized as an expense. The total amount to be expensed over the vesting period is determined by reference to the fair value of the instruments granted, excluding the impact of any non-market vesting conditions, if applicable. Non-market vesting conditions are included in assumptions about the number of instruments that are expected to become exercisable. At each balance sheet date, the Company revises its estimates of the number of instruments that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity over the remaining vesting period.

Stock options granted are valued using the Black-Scholes option-pricing model (see Note 12). This valuation model as well as parameters used such as expected volatility and expected term of the stock options are partially based on management's estimates. The Company estimates the fair value of non-vested stock awards (restricted shares and restricted share units) using a reasonable estimate of market value of the common stock on the date of the award. The Company classifies its share-based payments as equity-classified awards as they are settled in shares of the common stock. The Company measures equity-classified awards at their grant date fair value and does not subsequently remeasure them. Compensation costs related to equity-classified awards are equal to the fair value of the award at grant-date amortized over the vesting period of the award using the graded method. The Company reclassifies a portion of vested awards to share premium as the awards vest. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised.

5. SEGMENT INFORMATION

Overview of non-current assets, excluding financial and deferred income tax assets, by geographic area:

in CHF thousands

	Switzerland		Iceland		Others		Total	
	2022	2021	2022	2021	2022	2021	2022	2021
Intangible assets	12,206	8,724	-	-	-	-	12,206	8,724
Property, plant & equipment	24	29	338	400	3	2	365	431
Right-of-use assets	-	52	758	803	-	-	758	855
Total	12,230	8,805	1,096	1,203	3	2	13,329	10,010

6. INCOME AND EXPENSES

(A) GRANT INCOME

Grant income reflects research and development expenses reimbursements and certain research projects managed by Icelandic governmental institutions.

Government grants correspond to tax reimbursements on research and development expenses and as subsidies on specific research projects by Icelandic governmental institutions. Icelandic government grant income for the year ended December 31, 2022, is CHF 912 thousand compared to CHF 960 thousand and CHF 993 thousand for the same periods in 2021 and 2020, respectively. Refer to Note 10.

(B) OPERATING EXPENSES

in CHF thousands

	For the Years Ended December 31,								
	Research and Development Expenses			General and Administrative Expenses			Total Operating Expenses		
	2022	2021	2020	2022	2021	2020	2022	2021	2020
Personnel expense	(4,608)	(4,407)	(3,826)	(4,449)	(2,416)	(1,771)	(9,057)	(6,823)	(5,597)
Payroll	(4,313)	(4,189)	(3,612)	(3,939)	(2,306)	(1,657)	(8,252)	(6,495)	(5,269)
Share-based compensation	(295)	(218)	(214)	(510)	(110)	(114)	(804)	(328)	(328)
Operating expenses	(17,616)	(5,161)	(5,510)	(6,615)	(2,208)	(2,221)	(24,231)	(7,369)	(7,732)
External service providers	(17,205)	(4,786)	(5,154)	(2,294)	(1,681)	(1,744)	(19,499)	(6,467)	(6,898)
Other operating expenses	(184)	(189)	(167)	(4,249)	(478)	(438)	(4,433)	(667)	(606)
Depreciation of PPE	(111)	(78)	(89)	(20)	(10)	(15)	(132)	(88)	(104)
Depreciation of right-of-use assets	(116)	(108)	(99)	(52)	(39)	(24)	(167)	(147)	(124)
Total	(22,224)	(9,568)	(9,337)	(11,064)	(4,624)	(3,992)	(33,288)	(14,192)	(13,329)

The increase in Research and Development expenses in 2022 from 2021 was primarily due to the increased clinical and technical development activities for the company's late-stage clinical assets OCS-01 and OCS-02.

In General and Administrative expenses, for the year ended December 31, 2022, CHF 3.4 million were related to the BCA transaction. Please refer to the disclosures on the Business Combination Agreement in Note 2. (E).

(C) FINANCE INCOME AND EXPENSE

Finance income
in CHF thousands

	For the Years Ended December 31,		
	2022	2021	2020
Interest income	126	21	10
Total finance income	126	21	10

Finance expense
in CHF thousands

	For the Years Ended December 31,		
	2022	2021	2020
Interest expense accrued on Series B and C preferred shares	(6,343)	(4,996)	(2,560)
Interests on lease liabilities	(45)	(49)	(50)
Interest expense	(54)	(75)	(18)
Total finance expense	(6,442)	(5,120)	(2,628)

Finance expenses represent mainly interests related to the preferred dividend owed to the preferred Series B and C shares (refer to Note 14). Preferred Series B and C shares qualify as liabilities under IAS 32 and the related accrued dividends as interest expense.

(D) CURRENCY EXCHANGE

For the year ended December 31, 2022, the Company recognized currency exchange gains of CHF 49 thousand, compared to a loss of CHF 193 thousand in 2021 and a gain of CHF 163 thousand in 2020. For the year ended December 31, 2022, the loss from revaluation of the Series C long-term liability (refer to Note 14) was CHF 628 thousand, while for the 2021 period there was a gain of CHF 734 thousand. This main driver of the currency exchange result in the period was partially offset by a net gain from revaluation of USD cash balances of approximately CHF 581 thousand for the year ended December 31, 2022.

(E) INCOME TAX AND DEFERRED TAX

in CHF thousands	For the Years Ended December 31,		
	2022	2021	2020
Current income tax (expense) / benefit	(90)	(22)	(1)
Deferred tax (expense) / income	35	(5)	(82)
Total tax (expense) / income reported in the income statement	(55)	(27)	(83)

The Group's expected tax expense for each year is based on the applicable tax rate in each individual jurisdiction, which ranged between approximately 8.5% and 28% for 2022, 2021 and 2020 in the tax jurisdictions in which the Group operates. The weighted average tax rate applicable to the profits of the consolidated entities was 13.9% for 2022 and 13.6% for both 2021 and 2020. The tax on the Group's profit / (loss) before tax differs from the statutory amount that would arise using the weighted average applicable tax rate as follows:

in CHF thousands	For the Years Ended December 31,		
	2022	2021	2020
Groups average expected tax rate	13.9%	13.6%	13.6%
Accounting loss before income tax	(38,643)	(18,524)	(14,790)
Taxes at weighted average income tax	5,380	2,521	1,997
Effect of unrecorded tax losses	(4,468)	(1,869)	(1,732)
Effect of non deductible expenses	(968)	(679)	(348)
Total tax income / (expense) reported in the income statement	(55)	(27)	(83)

As of December 31, 2022 and 2021, the Group has tax losses which arose mainly in Switzerland that are available for offset against future taxable profits of the company until expiration. Deferred tax assets have not been recognized in respect of these losses in Switzerland as it is not probable that future taxable profit will be available against which the unused tax losses can be utilized. This does not affect the management assumption on the going concern hypothesis of the Group. Below is the maturity of the Group reportable losses:

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
2025	16,733	16,733
2026	13,113	13,113
2027	12,437	12,437
2028	14,865	14,865
2029	31,790	-
Total	88,938	57,148

The Group did not recognize the following temporary differences:

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Pension	91	845
Tax losses in Switzerland	88,938	57,148
Leasing	(125)	(85)
Intangible asset	(4,025)	(4,025)
Total	84,879	53,883

The amount of previously reported tax losses for prior years has been adjusted to the amounts as per filed and approved tax declarations by tax authorities of the Canton Vaud.

The deferred tax assets recorded in 2022 relate to the treatment of FX differences according to the Icelandic tax rule that FX differences for the year must be spread over three tax years. The deferred tax liability recorded in 2021 related to temporary differences on the valuation of property, plant and equipment in Iceland.

The balance sheet contains the following	For the Years Ended December 31,	
	2022	2021
Deferred tax assets	24	-
Deferred tax liabilities	-	(11)

7. PROPERTY, PLANT AND EQUIPMENT

The following tables present the movements in the net book values of property, plant and equipment:

<i>in CHF thousands</i>	Lab - equipment	Lab - fixtures and fittings	Office equipment & hardware	Total
Acquisition cost:				
Balance as of December 31, 2020	540	195	88	823
Acquisitions	15	-	13	28
Balance as of December 31, 2021	555	195	101	851
Acquisitions	45	-	20	65
Balance as of December 31, 2022	600	195	121	916

	Lab - equipment	Lab - fixtures and fittings	Office equipment & hardware	Total
Accumulated depreciation:				
Balance as of December 31, 2020	(246)	(44)	(41)	(332)
Depreciation expense	(59)	(15)	(14)	(88)
Balance as of December 31, 2021	(305)	(59)	(55)	(420)
Depreciation expense	(70)	(28)	(34)	(132)
Balance as of December 31, 2022	(375)	(87)	(89)	(551)
Carrying amount:				
As of December 31, 2021	249	135	46	431
As of December 31, 2022	225	108	32	365

8. INTANGIBLE ASSETS

The following tables summarizes the movement of intangibles assets:

in CHF thousands

	Licenses	Total
Acquisition cost:		
Balance as of December 31, 2020	8,724	8,724
Additions	-	-
Balance as of December 31, 2021	8,724	8,724
Additions	3,482	3,482
Balance as of December 31, 2022	12,206	12,206

	Licenses	Total
Accumulated amortization:		
Balance as of December 31, 2020	-	-
Amortization charge	-	-
Balance as of December 31, 2021	-	-
Amortization charge	-	-
Balance as of December 31, 2022	-	-
Carrying amount:		
As of December 31, 2021	8,724	8,724
As of December 31, 2022	12,206	12,206

The increase in 2022 compared to 2021 in the amount of CHF 3,482 thousand was related to the License Agreement with Accure Therapeutics for the exclusive global licensing of its OCS-05 (formerly ACT-01) technology, entered into on January 29, 2022. This License Agreement contains an upfront payment of CHF 3,000 thousand, a reimbursement of development related cost up to CHF 500 thousand, certain milestone payments for achievements of specified development events, sales-based milestone payments and sales-based royalty payments. The Company intends to advance the development of OCS-05 with the focus on multiple ophthalmology neuroprotective applications. As of December 31, 2022, CHF 3,000 thousand upfront payment and CHF 482 thousand reimbursed costs in relation to the OCS-05 clinical study were capitalized as intangible assets in accordance with IAS 38.

(A) Intangible assets amortization

The products candidates related to the capitalized intangible assets are not yet available for use. The amortization of the licenses will start when the market approval is obtained.

(B) Annual impairment testing

Oculus performs an assessment of its licenses in the context of its annual impairment test. Given the stage of Oculus' development activities and the importance of the relevant product candidates, OCS-02 and OCS-05, in Oculus' portfolio, the impairment test is performed first on the basis of a fair value model for the entire Company using a market approach and second on the basis of the continued development feasibility of both candidates.

Oculus performs its annual impairment tests on its entire portfolio of research and development assets, by deriving the fair value from an observable valuation for the entire Company (enterprise value) based on the latest rounds of external financing. The enterprise value of Oculus, i.e. the Company's total value, is derived from the latest issuance of preferred shares. The fair value of the asset portfolio is derived by deducting the carrying value of tangible assets, which consist primarily of cash and cash equivalents, from the Company valuation. In 2022 and 2021 this resulted in a derived fair value of Oculus' portfolio of research and development assets that was multiple times the carrying value of its intangible assets.

OCS-02 and OCS-05, are additionally tested for impairment by assessing their probability of success. Assessments include reviews of the following indicators, and if the candidate fails any of these indicators the entire balance is written off:

- Importance allocated to the candidate within Oculus' development portfolio, including future contractual commitments and internal budgets approved by the Board of Directors for ongoing and future development;
- Consideration of the progress of technical development and clinical trials, including obtaining technical development reports, efficacy and safety readout data, and discussions with regulatory authorities for new trials; and
- Consideration of market potentials supported where available by external market studies, and assessments of competitor products and product candidates.

In 2022, 2021 and 2020, review of all these indicators for OCS-02 and OCS-05 (in 2022) was positive. No impairment losses were recognized in 2022, 2021 and 2020.

9. RIGHT-OF-USE ASSETS AND LEASE LIABILITIES

The following table presents the right-of-use assets:

in CHF thousands

	Right-of-use assets	
	2022	2021
Balance as of January 1,	855	948
Indexation for the period	70	26
Addition/remeasurement/renewal of lease period Oculus SA office lease	-	28
Depreciation charge for the period	(167)	(147)
Balance as of December 31,	758	855

There are no variable lease payments which are not included in the measurement of lease obligations. Expected extension options have been included in the measurement of lease liabilities.

The following table presents the lease obligations:

in CHF thousands

	Lease liabilities	
	2022	2021
Balance as of January 1,	(770)	(833)
Addition/remeasurement/renewal of lease period Oculus SA office lease	-	(28)
FX revaluation	48	18
Indexation for the period	(70)	(26)
Interest expense for the period	(45)	(49)
Lease payments for the period	204	147
Balance as of December 31,	(633)	(770)

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Current	(142)	(193)
Non-current	(491)	(577)
Total	(633)	(770)

10. OTHER CURRENT ASSETS AND ACCRUED INCOME

Other current assets:

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Prepaid and other CMC, research and clinical expenses	1,586	674
Prepaid expenses	1,207	119
VAT	165	150
Other receivables	1	1
Total	2,959	944

As of December 31, 2022, capitalized transaction costs of CHF 570 thousand regarding the BCA agreement have been recorded under Prepaid expenses as explained under Note 2 (E). The increase in the Prepaid and other technical development (CMC), research and clinical expenses balance relates to our contract with Sandoz. Refer to Note 18.

Accrued income:

<i>in CHF thousands</i>	Accrued income	
	2022	2021
Balance as of January 1,	760	993
Accrued income recognized during the year	912	960
Payments received during the year	(726)	(1,198)
FX revaluation	(34)	4
Balance as of December 31,	912	760

Iceland offers incentives for research and development in the form of tax credits for innovation companies as outlined in Act No 152/2009. The aid is granted as a reimbursement of companies' paid income tax or paid out in cash when the tax credit is higher than the calculated income tax. The tax credit is subject to companies having a research project approved as eligible for tax credit by the Icelandic Centre for Research (Rannís). These grants are claimed together with annual tax filings in ISK and reimbursed in the fourth quarter of the following year, which implies a revaluation based on ISK/CHF closing rate at each reporting date.

On May 11, 2020, the Icelandic Parliament passed a legislation changing certain provisions of Act No 152/2009 on tax credits for innovation companies. The changes involve temporary provisions which may affect Oculis potential grant income for costs incurred in 2020 and 2021. The changes involve (i) the increase of possible tax credit for SMEs from 20% to 35%; (ii) an increase in the overall cap on eligible costs from ISK 900 million to ISK 1,100 million; and (iii) the introduction of a new annual cap on outsourced expenses at ISK 200 million, which was previously only subject to the overall cap on eligible expenses.

11. PENSIONS AND OTHER POST-EMPLOYMENT BENEFIT PLANS

The Company's Swiss pension plan is classified as a defined benefit plan under IFRS. Employees of the Icelandic, French, Hong Kong and American subsidiaries are covered by local post-retirement defined contribution plans.

(A) Iceland pension

Pension costs are charged to the income statement when incurred. CHF 112 thousand, CHF 117 thousand and CHF 127 thousand were recorded related to Iceland pension expenses in 2022, 2021 and 2020, respectively.

(B) French retirement plan

Pension costs are charged to the income statement when incurred. In 2022, pension costs amounted to CHF 42 thousand, CHF 47 thousand in 2021 and CHF 20 thousand in 2020.

(C) U.S. retirement plan

The U.S. entity adopted a 401(k) defined contribution plan effective December 1, 2020. There were no employer contributions made and plan administration cost was immaterial in 2022, 2021 and 2020.

(D) Hong Kong

Pension costs are charged to the income statement when incurred. In 2022, pension costs amounted to CHF 4 thousand. The subsidiary in Hong Kong did not employ any personnel in 2021 and 2020. Consequently, there was no pension expense in 2021 and 2020.

(E) Switzerland pension plan

The Company's Swiss entity is affiliated to a collective foundation administrating the pension plans of various unrelated employers that qualifies as defined benefit plan under IAS 19. For employees in Switzerland, the pension fund provides post-employment, death-in-service and disability benefits in accordance with the Swiss Federal Law on Occupational Retirement, Survivor's and Disability Pension Plans which specifies the minimum benefits that are to be provided.

The pension plan of the Company's Swiss entity is fully segregated from the ones of other participating employers. The collective foundation has reinsured all risks with an insurance company. The most senior governing body of the collective foundation is the Board of Trustees. All governing and administration bodies have an obligation to act in the interests of the plan beneficiaries.

The retirement benefits are based on the accumulated retirement capital, which is made of the yearly contributions towards the old age risk by both employer and employee and the interest thereon until retirement. The employee contributions are determined based on the insured salary, depending on the age, staff level and saving amount of the beneficiary. The interest rate is determined annually by the governing body of the collective plan in accordance with the legal framework, which defines the minimum interest rates.

If an employee leaves the pension plan before reaching retirement age, the law provides for the transfer of the vested benefits to a new pension plan. These vested benefits comprise the employee and the employer contributions plus interest, the money originally brought into the pension plan by the beneficiary and an additional legally stipulated amount. On reaching retirement age, the plan beneficiary may decide whether to withdraw the benefits in the form of an annuity or (entirely or partly) as a lump-sum payment. The annuity is calculated by multiplying the balance of the retirement capital with the applicable conversion rate.

All actuarial risks of the plan, e.g. old age, invalidity and death-in-service or investment, are fully covered by insurance. However, the collective foundation is able to withdraw from the contract with the Company at any time, in which case the Company would be required to join another pension plan. In addition, the risk premiums may be adjusted by the insurance company periodically.

The Company's Swiss pension plan is fully reinsured with Swiss Life ("Swiss Life Business Protect"), therefore the plan assets are 100% covered by an insurance contract. The insurance company bearing the investment risk is also making these investments on behalf of the collective foundation. As a result, the assets of the plan consist of a receivable from the insurance police.

The assets are invested by the pension plan, to which many companies contribute, in a diversified portfolio that respects the requirements of the Swiss Law. The insurance policy has been treated as a qualifying insurance policy and therefore the pension assets are presented as one asset and are not desegregated and presented in classes that distinguish the nature and risks of those assets.

The following tables summarize the components of net benefit expense recognized in the income statement, amounts recognized in the balance sheet and gains/(losses) recognized in other comprehensive loss.

<i>in CHF thousands</i>	For the Years Ended December 31,	
	2022	2021
Actuarial gains / (losses) recognized in other comprehensive loss:		
On plan assets	26	18
On obligation	718	70
Total	744	88

<i>in CHF thousands</i>	For the Years Ended December 31,	
	2022	2021
Net benefit expense (recognized in personnel costs):		
Current service cost	(446)	(296)
Interest cost on benefit obligation	(31)	(8)
Interest income	26	6
Impact of plan changes	37	151
Administration cost	(6)	(3)
Net benefit income / (expense)	(420)	(150)

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Benefit asset / (liability)		
Defined benefit obligation	(6,494)	(5,666)
Fair value of plan assets	6,403	4,821
Net benefit asset / (liability)	(91)	(845)

The impact of plan changes relates mainly to the changes of applicable rates for converting mandatory savings when employees do retire (see also below).

Changes in the present value of the defined benefit obligation are as follows:

<i>in CHF thousands</i>	For the Years Ended December 31,	
	2022	2021
Defined benefit obligation at 1 January	(5,666)	(5,231)
Interest cost	(31)	(8)
Current service cost	(446)	(296)
Administrative expenses	(6)	(3)
Contributions paid by participants	(1,686)	(1,702)
Employees' contributions	(185)	(126)
Benefits deposited	770	1,479
Impact of plan changes	37	151
Actuarial gain on obligation	718	70
Defined benefit obligation at December 31,	(6,494)	(5,666)

Changes in the fair value of plan assets are as follows:

<i>in CHF thousands</i>	For the Years Ended December 31,	
	2022	2021
Fair value of plan assets at 1 January	4,821	4,159
Expected return	26	6
Contributions by employer	429	289
Contributions by employees	185	126
Benefits paid from plan assets	(770)	(1,479)
Contributions paid by participants	1,686	1,702
Actuarial gains / (losses)	26	18
Fair value of plan assets at December 31,	6,403	4,821

The Group expects to contribute CHF 431 thousand to its defined benefit pension plan in 2023. The average duration of the plan was 14.0 years and 16.6 years as of December 31, 2022 and 2021, respectively.

The principal assumptions used in determining pension benefit obligations for the Group's plan are shown below:

	As of December 31,	
	2022	2021
Discount rate	2.30 %	0.35 %
Future salary increases	1.20 %	1.00 %
Future pensions increases	0.00 %	0.00 %
Retirement age	M65/W64	M65/W64
Demographic assumptions	BVG 2020 GT	BVG 2020 GT

In regard to the underlying estimates for the calculation of the defined benefit pension liabilities the Company updated, among other minor updates, the discount rate assumption to 2.30% as of December 31, 2022, 0.35% as of December 31, 2021 and 0.15% as of December 31, 2020. The change of estimate was due to major changes in the Swiss interest environment driven by increasing inflation. All the actuarial assumptions changes resulted in an actuarial gain of defined benefit pension liabilities of CHF 719 thousand. The net result is a reduction of defined benefit pension liabilities of CHF 845 thousand as of December 31, 2021 to CHF 91 thousand as of December 31, 2022. Furthermore, the assumption for future salary increases has been adjusted to 1.20% (1.00% in 2021 and 2020). Other assumptions for defined benefit pension liabilities remain unchanged.

In 2022, the guaranteed interest to be credited to employees' savings was 1.0% (same as in 2021) for mandatory retirement savings, and 0.25% for supplementary retirement savings. Given current Swiss interest environment, the Company updated the estimated interest to be credited to employees' savings up to 2.30%. The applicable rate for converting mandatory savings at age 65 for male and 64 for female employees retiring in 2022 was 6.50% and will be reduced to 6.20% for 2023 and 5.90% for 2024 and subsequent years. The rate for converting supplementary savings to an annuity decreases from 4.71% in 2022, to 4.49% in 2023 and subsequent years for male employees and decreases from 4.76% in 2022 to 4.54% in 2023 and subsequent years for female employees.

Sensitivity analysis

A quantitative sensitivity analysis for significant assumptions as of December 31, 2022 and 2021 is shown below:

<i>in CHF thousands</i>	Discount rate		Future salary increase		Mortality assumptions	
	+0.25%	-0.25%	+0.50%	-0.50%	+1 year	-1 year
Assumptions as of December 31, 2022						
Potential defined benefit obligation	(6,274)	(6,741)	(6,527)	(6,462)	(6,553)	(6,429)
Decrease / (increase) from actual defined benefit obligation	221	(247)	(32)	32	(58)	65
Assumptions as of December 31, 2021						
Potential defined benefit obligation	(5,442)	(5,922)	(5,681)	(5,652)	(5,750)	(5,614)
Decrease / (increase) from actual defined benefit obligation	224	(256)	(15)	14	(84)	52

The sensitivity analysis above is subject to limitations and has been determined based on a method that extrapolates the impact on net defined benefit obligation as a result of reasonable changes in key assumptions occurring at the end of the reporting period.

12. SHARE BASED PAYMENT

On June 19, 2018, the Board of Directors approved a revised stock option and incentive plan (the "Plan"). The Plan allows for the grant of equity incentives, including share-based options and restricted stock.

Share-based option awards

Each share-based option granted under the Plan entitles the grantee to acquire from the Company common shares with payment in cash of the exercise price. For each grant of share-based options, the Company offers options, with the issuance of a grant notice, which details the terms of the option, including exercise price, vesting conditions and expiration date. The terms of each grant are set by the Board of Directors.

The volatility used in the estimation of fair value is calculated utilizing the volatility of the share prices of a set list of publicly traded peer companies based on commensurate expected terms as of the grant date. In the event that a company used in the volatility calculation has not been publicly traded for the requisite amount of time, the entirety of its trading history was used.

Under the Plan, share-based option awards of 550,468 in 2022, 298,972 in 2021 and 406,141 in 2020 shares were granted. All shares granted in 2022, 2021 and 2020 had a four-year vesting schedule.

The total expense recognized in the income statement for share options granted amounts to CHF 804 thousand for 2022 and CHF 328 thousand for 2021 and 2020. The reserve for share option increased from CHF 1,640 thousand as of December 31, 2020 to CHF 1,967 thousand as of December 31, 2021 and to CHF 2,771 thousand as of December 31, 2022. The following table illustrates the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of these awards:

	For the Years Ended 31 December,		
	2022	2021	2020
Exercise price	CHF 3.41	CHF 2.70	CHF 2.11 to 2.47
Share price (option-pricing model)	CHF 3.41	CHF 2.70	CHF 1.92 to 2.47
Risk free interest rate	0.74 %	0.00 %	(0.94%) to 0.00%
Expected term	2.5 years	2.5 years	2.5 to 5.5 years
Expected volatility	96.3 %	82.1 %	90.8-101%
Dividend yield	—	—	—

The number and weighted average exercise prices of share-based options under the Plan are as follows:

	Number of Options	Weighted Average Exercise Price (CHF)	Range of Expiration Dates
Oustanding at January 1, 2020	608,059	2.13	2026-2028
Forfeited during the year	(37,981)	2.18	2027
Granted during the year	406,141	2.39	2027-2029
Oustanding at December 31, 2020	976,220	2.24	2026-2029
Exercisable at December 31, 2020	443,781	2.12	2026-2029
Oustanding at January 1, 2021	976,220	2.24	2026-2029
Forfeited during the year	(147,607)	2.39	2027-2028
Granted during the year	298,972	2.70	2030
Oustanding at December 31, 2021	1,127,585	2.34	2026-2030
Exercisable at December 31, 2021	664,192	2.17	2026-2030
Oustanding at January 1, 2022	1,127,585	2.34	2026-2030
Forfeited during the year	(82,445)	2.69	2023-2030
Granted during the year	550,468	3.41	2031
Exercised during the year	(53,500)	2.11	
Oustanding at December 31, 2022	1,542,108	2.73	2027-2031
Exercisable at December 31, 2022	716,919	2.25	2027-2031

The average fair value at grant date of the awards granted during the year ended December 31, 2022 was CHF 3.41 per award, CHF 2.70 during the year ended December 31, 2021 and CHF 2.40 during the year ended December 31, 2020.

The range of exercise prices of the outstanding awards at December 31, 2022 was CHF 2.11 to CHF 3.41, CHF 2.11 to CHF 2.70 at December 31, 2021 and CHF 2.11 to CHF 2.47 at December 31, 2020.

Restricted Stock Awards

Each restricted stock granted under the Plan is immediately exercised and the expense is recorded at grant in full. The Company is holding a call option to repurchase shares diminishing rateably on a monthly basis over three years from grant. For each grant of restricted stock, the Company issues a grant notice, which details the terms of

the grant, including the number of awards, exercise price and expiration date. The terms of each grant are set by the Board of Directors.

The number and weighted average exercise prices of restricted stock under the Plan are as follows:

	Number of Restricted Stocks	Weighted Average Exercise Price (CHF)
Issued and exercised at January 1, 2020	571,783	1.79
Granted and exercised during the year	80,327	1.95
Issued and exercised at December 31, 2020	652,110	1.81
Not subject to repurchase at December 31, 2020	472,502	1.80
Issued and exercised at January 1, 2021	652,110	1.81
Granted and exercised during the year	386,116	2.27
Issued and exercised at December 31, 2021	1,038,226	1.98
Not subject to repurchase at December 31, 2021	621,343	1.82
Issued and exercised at January 1, 2022	1,038,226	1.98
Issued and exercised at December 31, 2022	1,038,226	1.98
Not subject to repurchase at December 31, 2022	817,022	1.90

Restricted stock is granted and expensed at fair value. The payroll expense related to restricted stock, including the total expense and the part contributable towards restricted stock issuance, is as follows:

<i>in CHF thousands</i>	For the Years Ended 31 December,		
	2022	2021	2020
Total payroll expense related to restricted stock	—	(951)	170
Expense contributable towards restricted stock issuance	—	(828)	148

<i>in CHF thousands</i>	For the Years Ended 31 December,		
	2022	2021	2020
Fair value of restricted stock issued	—	876	157
Expense contributable towards restricted stock issuance	—	828	148
Grantee contributions for restricted stock issuance	—	48	9

13. CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist primarily of cash balances held at banks and in the currencies:

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Cash and cash equivalent	19,786	46,277
Total	19,786	46,277

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
by currency		
Swiss Franc	7,216	23,987
Iceland Krona	383	726
Euro	2,350	4,202
US Dollar	9,741	17,325
Other	96	37
Total	19,786	46,277

14. LONG-TERM FINANCIAL LIABILITIES

As of December 31, 2022, the Company had 12,712,863 preferred shares for an amount of CHF 1,350 thousand. These shares are divided into 1,623,793 registered "A Series" shares of CHF 0.10 each, 5,191,512 registered "B Series" of CHF 0.10 each, 5,699,813 registered "C1a Series" shares (denominated in USD) of CHF 0.10 each and 197,745 registered "C1b Series" shares (denominated in USD) of CHF 0.50 each.

On July 22, 2022, the Company completed the closing of an extension round to the Series C equity financing of approximately CHF 2.0 million (\$2.1 million) with an issuance of 197,745 shares of preferred shares ("Series C1b Shares" at a per share purchase price of CHF 10.27 (\$10.64) and a nominal per share value of CHF 0.50. The Series C1b shareholders have the same rights and preferences as the Series C shareholders. Same as Series A, B and C preferred shares, the Series C1b preferred shares qualify as financial liability instruments under IAS 32 and are presented on the Balance Sheet as long-term financial debt.

All preferred shares have a liquidation preference corresponding to their respective initial purchase price. Furthermore, the "B Series" and "C Series" shares include a preferred dividend payment of 6.00% (as a compounded interest).

The Shareholders' Agreement contains a redemption option upon certain events with amounts equivalent to the sum of investors' Series C investment and applicable interests at 0.00%, 6.00% and 8.00% for Series A, B and C shares, respectively. The Company considered the expected future cash outflows and concluded that the probability of the certain events occurring to be remote. Refer to Note 18 for discussion on the redemption feature.

The B Series and C Series shares include a preferred dividend payment of 6.00%, and the corresponding deemed interest expense of CHF 16,986 thousand was accrued as of December 31, 2022. The nominal amounts (for "A, B and C Series") and the accrued preferred dividend resulted in a long-term debt of CHF 122,449 thousand on December 31, 2022. The movement of the long-term financial liability is illustrated below:

<i>in CHF thousands</i>	Series A shares	Series B shares	Series C shares	Total
Balance as of December 31, 2020	8,179	45,799	-	53,978
Issuance of shares	-	-	56,096	56,096
Transaction costs	-	-	(834)	(834)
Interest	-	2,770	2,226	4,996
FX revaluation	-	-	(734)	(734)
Balance as of December 31, 2021	8,179	48,569	56,754	113,502
Issuance of shares	-	-	2,030	2,030
Transaction costs	-	-	(54)	(54)
Interest	-	2,797	3,546	6,343
FX revaluation	-	-	628	628
Balance as of December 31, 2022	8,179	51,366	62,904	122,449

15. SHARE CAPITAL, SHARE PREMIUM AND TREASURY SHARES

(A) Share capital and premium

As of December 31, 2022, the Company had 3,406,771 shares for CHF 340 thousand. These shares are divided into 2,368,545 common shares of CHF 0.10 each, of which 4,000 will be registered in the commercial register in the first quarter of 2023, and 1,038,226 shares for restricted stock of CHF 0.10 each.

As described in Note 14, due to the characteristics of the instruments issued, the A Series, B Series and C Series preferred shares qualify as financial liability instruments under IAS 32. As a result, they are presented as long-term financial liabilities and are consequently not included in the equity and related premium.

The activities for share capital and share premium accounts in 2020, 2021 and 2022 are as follows:

	<i>number of shares</i>		<i>in CHF thousands</i>	
	Common shares	Restricted stock awards	Share capital	Share premium
Balance as of December 31, 2019	2,315,045	571,783	289	9,476
Issuance of shares	-	80,327	8	149
Transaction costs	-	-	-	(15)
Balance as of December 31, 2020	2,315,045	652,110	297	9,609
Issuance of shares	-	386,116	39	837
Transaction costs	-	-	-	(12)
Balance as of December 31, 2021	2,315,045	1,038,226	335	10,434
Stock options exercised	53,500	-	5	115
Transaction costs	-	-	-	(9)
Balance as of December 31, 2022	2,368,545	1,038,226	340	10,540

(B) Conditional Capital

The conditional share capital at December 31, 2022, amounted to a maximum of CHF 144 thousand split into 1,443,829 common shares with a par value of CHF 0.10 each, in connection with the potential future exercise of options granted to employees and advisors (respectively as of December 31, 2021, to a maximum of CHF 185 thousand split into 1,849,784 common shares with a par value of CHF 0.10 each).

(C) Treasury shares

In December 2017 related to the initial corporate consolidation, the Group acquired 100,000 treasury shares which are held at a cost of CHF 1.00 each.

16. TRADE PAYABLES

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Trade payables	(3,867)	(824)
Total	(3,867)	(824)

Trade payables are non-interest bearing and are normally settled on 60-day terms. Increase in trade payables year over year was primarily due to increase in business and product development activities and to the costs related to the BCA transaction as described under note 2 (E).

17. ACCRUED EXPENSES AND OTHER PAYABLES

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Payroll related accrual	(2,249)	(1,723)
Accrued R&D expense	(4,805)	(730)
Accrued G&A expense	(956)	(592)
Total	(8,011)	(3,045)

The increase in the Payroll related accrual is mainly due to the increase in the headcount. The increase in the accrued Research & Development (R&D) expense compared to the previous year-end is mainly related to the Company's ongoing clinical studies. The increase in the accrued General and Administrative (G&A) expense is primarily due to accrued cost in relation to the BCA as described under note 2 (E).

18. COMMITMENTS AND CONTINGENCIES

Commitments related to Novartis license agreement

In December 2018, Oculis SA entered into an agreement with Novartis, under which Oculis licensed a novel topical anti-TNF alpha antibody, now renamed as OCS-02, for ophthalmic indications. As consideration for the licenses, Oculis SA is obligated to pay non-refundable, up-front license fees, predefined development and commercial milestone payments and royalties on net sales of licensed products. Royalties range from high one digit to low teens, based on sales thresholds. As of December 31, 2019, Oculis SA has paid in full the contractual non-refundable up-front fee of CHF 4,699 thousand. Oculis SA has not reached any milestones or royalties thresholds according to the agreement. If all predefined milestones will be reached, Oculis SA will be obligated to pay additional CHF 89.7 million (\$97.0 million). Oculis SA expects to reach the first milestone payment of CHF 4.6 million (\$5.0 million) in 2024. Royalties are based on net sales of licensed products, depending on the sales volumes reached.

Commitments related to Accure license agreement

On January 29, 2022, the Company entered into a License Agreement with Accure Therapeutics for the exclusive global licensing of its OCS-05 technology. Under this agreement, Oculis licensed a novel neuroprotective drug candidate, now renamed as OCS-05, for ophthalmic and other indications (refer to Note 8). As consideration for the licenses, Oculis SA is obligated to pay non-refundable, up-front license fees, predefined development and commercial milestone payments and royalties on net sales of licensed products. Royalties range from one digit to low teens, based on sales thresholds. As of December 31, 2022, Oculis SA has paid the full contractual non-refundable up-front fee of CHF 3,000 thousand and reimbursed costs in the amount of CHF 483 thousand. Oculis SA has not reached any milestones or royalties thresholds according to the agreement. If all predefined milestones will be reached, Oculis SA will be obligated to pay additional CHF 103.6 million (\$112.1 million). In case of a commercialization, sublicense revenues will be subject to further royalty payments.

Commitments related to Rennes University Collaboration Research agreement

On January 31, 2022, the Company entered into a collaboration research agreement with the Rennes University and CNRS in France. This agreement is for the research of Antisense Oligonucleotide (ASO) to modulate gene expressions. As consideration for the licenses, Oculis SA is obligated to pay non-refundable cost contribution, predefined development and commercial milestone payments and royalties on net sales of licensed products. Royalties are in low one digit range, based on sales thresholds. As of December 31, 2022, Oculis SA has paid the first contractual non-refundable cost contribution of CHF 27 thousand (€27 thousand). Oculis SA has not reached any milestones or royalties thresholds according to the agreement. If all predefined milestones will be reached, Oculis SA will be obligated to pay additional CHF 6.9 million (€7.0 million). In case of a commercialization, sublicense revenues will be subject to further royalty payments.

Commitments related to Sandoz GMP manufacturing agreement

On November 15, 2022, Oculis signed a Letter of Understanding (“LoU”) with Sandoz GmbH with respect to process transfer, scale-up and potential GMP manufacture of Oculis’ recombinant product OCS-02 (“Product”). The parties will negotiate certain definitive agreements such as a Manufacturing and Supply Agreement (“MSA”) for the future manufacturing and supply of the Product and certain related services. The activities under the LoU consist of three work packages (“WP”): Process optimization (WP1), Process Confirmation at Pilot Scale (WP2), and Analytical Method Validation (WP3). In order to start the preparatory work, an advance invoice of CHF 1,871 thousand (€1,890 thousands) was made related to project management fees, 35% of WP1 and 35% of WP3. The total amount of payments committed under this LoU amounts to CHF 7,219 thousand (€7,293 thousands) including raw materials.

Research and development commitments

The Group conducts product research and development programs through collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. Oculis has contractual arrangements with these organizations. As of December 31, 2022, commitments for external research projects total CHF 13,123 thousand (CHF 14,408 thousand, as of December 31, 2021) as detailed in the schedule below. The decrease compared to December 31, 2021, was due to advancements in clinical and technical developments, primarily for OCS-01 phase III clinical trials and OCS-02 CMC activities.

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Within one year	12,145	13,307
Between one and five years	978	1,101
Total	13,123	14,408

Preferred shares redemption option

Per the Series C Shareholders' Agreement, a redemption option exists in April 2025 for a pre-specified qualified condition related to an initial public offering, with amounts equivalent to the sum of investors' Series A, B and C investment, accrued dividends and applicable compounded interests at 0.00%, 6.00% and 8.00% for Series A, B and C shares, respectively, which could lead to a potential cash-outflow. As of December 31, 2022, the sum of amounts due related to the aforementioned redemption option was approximately CHF 135 million, reflecting investment amounts, cumulative accrued dividend and compounded interest for Series A, B and C preferred shares.

The recent Business Combination with EBAC on March 2, 2023 and NASDAQ listing the following day, meets the pre-specified qualified condition, hence the risk of redemption no longer applies. The preferred shares will be transferred to equity including the accrued dividend.

19. RELATED PARTY DISCLOSURES

Key management, including the Board of Directors and the Executive Management compensation were:

<i>in CHF thousands</i>	For the Years Ended December 31,		
	2022	2021	2020
Salaries and other short-term employee benefits	3,506	3,071	2,557
Payroll expenses related to restricted stock	-	951	170
Pension	227	264	293
Share-based compensation	535	251	259
Total	4,268	4,537	3,279

Short-term employee benefits include salaries, bonuses, social security and expense allowances.

20. FINANCIAL INSTRUMENTS / RISK MANAGEMENT

Categories of financial instruments:

As indicated in Note 3, all financial assets and liabilities are shown at amortized cost. The following table shows the carrying amounts of financial assets and liabilities:

<i>in CHF thousands</i>	As of December 31,	
	2022	2021
Financial assets		
Financial assets - non-current	50	52
Other current assets (without prepaids)	166	151
Accrued income	912	760
Cash and cash equivalents	19,786	46,277
Total	20,914	47,240

in CHF thousands

Financial liabilities	As of December 31,	
	2022	2021
Trade payables	3,867	824
Accrued expenses and other payables	8,011	3,045
Lease liabilities	633	770
Long-term financial debt related to preferred shares/accrued dividend	122,449	113,502
Total	134,960	118,141

Below is the net debt table of liabilities from financing activities:

in CHF thousands

	Preferred shares	Leasing	Total
Net debt as of December 31, 2020	(53,978)	(833)	(54,811)
Cashflows	(56,096)	147	(55,948)
Interest calculated on Series B & C shares	(4,996)	-	(4,996)
Transaction costs related to 2021	834	-	834
Oculus SA office lease addition/remeasurement	-	(28)	(28)
Interest calculated on leases	-	(49)	(49)
Indexation for the period	-	(26)	(26)
FX revaluation	735	18	753
Net debt as of December 31, 2021	(113,502)	(770)	(114,272)
Cashflows	(2,030)	204	(1,826)
Interest calculated on Series B & C shares	(6,343)	-	(6,343)
Transaction costs related to 2022	54	-	54
Interest calculated on leases	-	(45)	(45)
Indexation for the period	-	(70)	(70)
FX revaluation	(628)	48	(580)
Net debt as of December 31, 2022	(122,449)	(633)	(123,082)

Fair values

Due to their short-term nature, the carrying value of cash and cash equivalents, trade and other receivables and trade and other payables approximates their fair value.

For long-term financial debt, resulting from the issuance of preferred shares as described in Note 14, the fair value can be determined from the similar or identical instruments issued by the Company during 2022. This level 2 value resulted in a fair value of CHF 115,707 thousand compared to a book value of CHF 122,449 thousand. In 2021, these shares had a book value of CHF 113,502 thousand while the fair value was CHF 107,187 thousand.

Risk assessment

Since 2018 the Company implemented an Internal Control System (ICS), which includes a risk assessment. The ultimate responsibility of the risk management is of the Board of Directors and a yearly review takes place during one of the Board of Directors meetings.

Market risk

Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates and equity prices will affect the Company's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return.

Foreign currency risks

In 2020, the Group had all of its grant income and a significant part of its expenses, assets and liabilities denominated in Icelandic Krona (ISK). Starting in 2020, Oculus is also present in the U.S. and France with local currencies in US Dollar and Euro. Starting in 2021, Oculus also reports figures in HKD from its subsidiary in Hong Kong.

The following table demonstrates the sensitivity of reasonably possible changes in ISK, EUR, USD and HKD exchange rate on the Group net result or on equity:

For the Years Ended / As of December 31,					
<i>in CHF thousands</i>	2022		2021		
Change in rate	Impact on loss	Impact on equity	Impact on loss	Impact on equity	
+5% ISK	7	(16)	(101)	125	
-5% ISK	(7)	16	101	(125)	
+5% EUR	(4)	99	(24)	5	
-5% EUR	4	(99)	24	(5)	
+5% USD	7	138	(66)	-	
-5% USD	(7)	(138)	66	-	
+5% HKD	-	(6)	(1)	(174)	
-5% HKD	-	6	1	174	

Interest rate risk

The Company's long-term financial liabilities, which result from the issuance of preferred shares as indicated in Note 14, bear a deemed interest resulting from the preferred dividend, due under certain circumstances, at a fixed rate of 6.00% per year. The other financial instruments of the Group are not bearing interest and are therefore not subject to interest rate risk.

Hedging activities

There are no hedging activities within the Group.

Credit risk

As of December 31, 2022, there is no material credit risk in the Group. The maximum exposure is the carrying amount of cash and other receivables. There is no concentration of credit risk within the Group. Furthermore, there is no significant credit risk on cash and cash equivalents.

Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. Liquidity management is performed by Group finance based on cash flow forecasts which are prepared on a rolling basis and focuses mainly on ensuring that the Group has sufficient cash to meet its operational needs. The Group's liquidity needs have been historically satisfied by issuing preferred shares.

All of the Company's financial instruments, except long-term financial liabilities and the long-term portion of the lease liabilities are due within one year.

<i>in CHF thousands</i>	As of December 31, 2022	Less than one year	Over one year	As of December 31, 2021	Less than one year	Over one year
Trade payables	3,867	3,867	-	824	824	-
Accrued expenses and other payables	8,011	8,011	-	3,045	3,045	-
Long-term financial debt	170,988	-	170,988	167,113	-	167,113
Lease liability	743	149	594	845	199	646
Total	183,609	12,027	171,582	171,827	4,068	167,759

Long-term financial liabilities result from the issuance of preferred shares as indicated in Note 18. They might become due in the case of certain liquidation or exit events within the next year.

Capital management

Since its incorporation, the Group has primarily funded its operations through capital increases, and at the current development stage, the Group frequently raises new funds to finance its projects. Refer to Notes 14 and 15 for further details.

21. LOSS PER SHARE

	For the Years Ended December 31,		
	2022	2021	2020
Net (loss) for the period attributable to Oculis shareholders - in CHF thousands	(38,698)	(18,552)	(14,873)
Loss per share			
Basic and diluted loss for the period attributable to equity holders - in CHF	(12.94)	(6.68)	(5.77)
Weighted-average number of shares used to compute loss per share basic and diluted	2,989,434	2,777,589	2,579,385

Since the Company has a loss for all periods presented, basic net loss per share is the same as diluted net loss per share. We have excluded from our calculation of diluted loss per share all potentially dilutive securities, including (i) share options and (ii) restricted stock awards subject to repurchase, as the inclusion of these awards would have been anti-dilutive.

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	For the Years Ended December 31,		
	2022	2021	2020
Share options issued and outstanding	1,542,108	1,127,585	976,220
Restricted stock subject to repurchase	221,204	416,883	179,608
Total	1,763,312	1,544,468	1,155,828

22. SUBSEQUENT EVENTS

On March 2, 2023, the Company completed its BCA with EBAC, a special purpose acquisition company. Under the BCA and in accordance with applicable law, EBAC transferred into Oculis Holding AG, a public liability company incorporated and existing under the laws of Switzerland.

As a result of the merger, the Company's outstanding common and preferred shares converted into common shares of Oculis Holding AG at the effective exchange ratio. Similarly, the 2018 option plan is replaced by a new 2023 ESOP plan and outstanding options are converted to Oculis Holding AG options at the effective exchange ratio. In addition, existing equityholders of the Company were entitled to receive additional consideration in the form of an aggregate of 4,000,000 newly issued restricted shares of Oculis Holding AG, subject to predefined price targets of Oculis Holding AG shares.

Oculis Holding AG received gross proceeds of approximately CHF 97.4 million (\$103.7 million) comprising CHF 12.0 million (\$12.8 million) of cash held in EBAC's trust account, CHF 85.4 million (\$90.9 million) from PIPE investments and conversion of CLAs into common shares of Oculis Holding AG. The CLAs provided the same economic terms as the other PIPE investors considering a deemed value of CHF 9.40 (\$10.00) per Oculis Holding AG share. EBAC public shareholders exercised their right to redeem their shares of EBAC Class A Common Stock for an amount of CHF 110.4 million (\$117.5 million).

In connection with the BCA, Oculis Holding AG was listed in NASDAQ with the ticker symbol for its Class A common shares "OCS".

There are no further material subsequent events to report and no events out of the ordinary course of business.

DESCRIPTION OF SECURITIES

General

We were incorporated as a stock corporation (*Aktiengesellschaft*) organized under the laws of Switzerland in accordance with articles 620 et seqq. of the CO and registered with the Commercial Register of the Canton of Zug on October 31, 2022. Our corporate legal headquarters is located at Bahnhofstrasse 7, 6300 Zug, Switzerland and is expected to move its headquarters after Closing to EPFL Innovation Park, Bat D 3e Route J-D. Colladon, CH-1015 Lausanne, Switzerland. Neither the Articles of Association nor the operation of law limit the duration of Oculis Holding AG.

Capital Structure of Oculis Holding AG***Issued Share Capital***

Immediately prior to the Business Combination, Oculis Holding AG's share capital was CHF 356,821.68 divided into 35,682,168 fully paid-in registered shares with a nominal value of CHF 0.01 each.

In the context of the Business Combination, Oculis Holding AG increased its share capital in the Commercial Register of the Canton of Zug on the Acquisition Closing Date to CHF 365,273.68, divided into 36,527,368 Ordinary Shares, fully paid-up.

Share Classes

The Articles of Association provide for one class of Ordinary Shares with a nominal value of CHF 0.01 each. Each Ordinary Share will carry one vote in general meetings of Ordinary, and the Ordinary Shares are listed on the Nasdaq Global Market.

Share Capital Increases (General)

Under Swiss law, we may increase our share capital and issue new shares through an ordinary capital increase, an increase by capital band (*Kapitalband*) or a conditional capital increase (*Bedingte Kapitalerhöhung*). In each case, the issue price for each share may not be less than the nominal value of the newly issued share. An ordinary capital increase is approved at a general meeting of shareholders. The required vote is generally the approval of simple majority of the votes cast at the general meeting of shareholders. At least two-thirds of the represented share votes and the absolute majority of the represented nominal value of the shares present in person or represented by proxy is required for capital increases against our equity, against contributions in kind, for the purposes of acquiring assets or the granting of special benefits, or for capital increases where the pre-emptive/subsorption rights of shareholders are limited or excluded. The amount by which the capital can be increased in an ordinary capital increase is unlimited, provided that sufficient contributions are made to cover the capital increase. An ordinary capital increase that has been approved by the shareholders must be executed within six months of shareholder approval. In an ordinary capital increase, holders of Ordinary Shares have pre-emptive rights to obtain newly issued shares in an amount proportional to the nominal value of the shares they already hold, unless such rights are excluded in accordance with Swiss law. For further details on these circumstances, please see the section entitled "*—Pre-emptive Rights and Advance Subscription Rights.*"

Our shareholders can further authorize the Board of directors by way of an amendment of the Articles of Association to increase or decrease the share capital within a capital band in an amount not to exceed 50% of the share capital registered in the commercial register for a period of five years without further shareholder approval. To create a capital band, a resolution of the general meeting of shareholders passed by a supermajority of at least two-thirds of the represented share votes and the absolute majority of the represented nominal value of the shares present in person or represented by proxy is required. Additional information regarding capital band is set forth below in the section entitled "*—Capital band.*"

Under Swiss law, conditional share capital is used to issue new shares in the context of employee benefit and incentive plans, debt instruments with conversion rights or warrants granted to creditors or options and warrants issued to third parties. To create conditional capital, a resolution of the general meeting of shareholders passed by a supermajority of at least two-thirds of the represented share votes and the absolute majority of the represented nominal value of the shares present in person or represented by proxy is required. The requirements for a conditional capital increase are set forth below in the section entitled “—*Conditional Share Capital*.”

Capital band

Under the Articles of Association, the Board of directors is authorized to increase the share capital, at any time until March 2, 2028, at the latest, by a maximum amount of CHF 178,410.84 by issuing a maximum of 17,841,084 fully paid-up shares with a nominal value of CHF 0.01 each (Ordinary Shares). Such increase of the share capital (i) by means of an offering underwritten by a financial institution, a syndicate of financial institutions or another third party or third parties, followed by an offer to the then-existing shareholders of the Oculis Holding AG, and (ii) in partial amounts, are permissible.

The Board of directors may determine the time of the issuance, the issue price, the manner in which the new shares have to be paid up, the date from which the shares carry the right to dividends, the conditions for the exercise of the pre-emptive rights and the allotment of pre-emptive rights that have not been exercised. The Board of directors may allow the pre-emptive rights that have not been exercised to expire, or it may place such shares or the pre-emptive rights of which have not been exercised, at market conditions or use them otherwise in the interest of Oculis Holding AG.

The Board of directors is authorized to withdraw or limit the pre-emptive rights of the shareholders with respect to the shares to be issued under the capital band and to allot them to individual shareholders or third parties:

1. if the issue price of the new registered shares is determined by reference to the market price;
2. for the acquisition of an enterprise, part of an enterprise or participations, or for the financing or refinancing of any of such acquisition, or in the event of share placement for the financing or refinancing of such placement;
3. for purposes of broadening the shareholders of our constituency in certain financial or investor markets, for purposes of the participation of strategic partners, or in connection with the listing or registration of new registered shares on domestic or foreign stock exchanges;
4. for purposes of granting an over-allotment option (Greenshoe) or an option to subscribe additional shares to the respective initial purchaser(s) or underwriter(s) in a placement or sale of registered shares;
5. for raising of capital (including private placements) in a fast and flexible way, which probably could not be achieved without the exclusion of the statutory pre-emptive right of the existing shareholders;
6. for other valid grounds in the sense of article 652b para. 2 CO; or
7. following a shareholder or a group of shareholders acting in concert having accumulated shareholdings in excess of 15% of the share capital registered in the commercial register without having submitted to the other shareholders a takeover offer recommended by the Board of directors, or for the defense of an actual, threatened or potential takeover bid, in relation to which the Board of directors, upon consultation with an independent financial adviser retained by it, has not recommended to the shareholders acceptance on the basis that the Board of directors has not found the takeover bid to be financially fair to the shareholders.

The authorization to withdraw or limit the pre-emptive rights is limited to the above listed items and exclusively linked to the particular available capital band (*Kapitalband*) set out in the Articles of Association. If the period to increase our share capital within the capital band lapses without having been used by the Board of directors, the authorization to withdraw or to limit the pre-emptive rights lapses simultaneously with such capital.

Conditional Share Capital

Conditional Share Capital in Connection with Employee Benefit Plans

Under the Articles of Association, our share capital may be increased by an amount not exceeding CHF 78,355.44 through the issue of a maximum of 7,835,544 fully paid up registered shares, each with a nominal value of CHF 0.01 (Ordinary Shares), in connection with the exercise of option rights or other equity-linked instruments granted to any employee of Oculis Holding AG or a subsidiary, and any consultant, members of the Board of directors, or other person providing services to us or a subsidiary.

Shareholders' subscription rights are excluded with regard to these shares. These new registered shares may be issued at a price below the current market price. The Board of directors shall determine the other conditions of issue including the issue price of the Ordinary Shares.

Conditional Share Capital for new Bonds and Similar Debt Instruments

Under the Articles of Association, our share capital may be increased by an amount not exceeding CHF 50,000 through the issuance from time to time of a maximum of 5,000,000 fully paid up registered shares, each with a par value of CHF 0.01 (Ordinary Shares), in connection with the exercise of convertible rights and/or option rights or warrants, which have been granted or will be granted in connection with new bonds and similar debt instruments, including convertible loans of Oculis SA which were issued prior to the date of the Business Combination in accordance with the Convertible Loan Agreements, that have been issued by us or our subsidiaries.

Shareholders' advance subscription rights and subscription rights are excluded with regard to the new registered shares. These new registered shares may be issued at a price below the current market price. The Board shall determine the other conditions of issue including the issue price of the Ordinary Shares.

Conditional Share Capital for EBAC Public Warrants

Under the Articles of Association, our share capital may be increased by an amount not exceeding CHF 44,032.94 through the issuance, from time to time, of a maximum of 4,403,294 fully paid up registered shares, each with a par value of CHF 0.01 (Ordinary Shares), in connection with the exercise of warrants granted through the exercise of conversion and/or option rights, which were assumed from, and allocated by, EBAC, on the basis of the Warrant Assignment and Assumption Agreement.

Shareholders' advance subscription rights and subscription rights are excluded with regard to the new registered shares. These new registered shares may be issued at a price below the current market price. The Board shall determine the other conditions of issue including the issue price of the Ordinary Shares.

Participation Certificates and Profit-sharing Certificates

As of the date of this proxy statement/prospectus, we have neither participation certificates (*Partizipationsscheine*) nor profit-sharing certificates (*Genussscheine*) outstanding.

Treasury Shares

As of the date of this proxy statement/prospectus, we may hold Ordinary Shares in treasury. Under Swiss law, a stock company may only hold 10% of its own shares in treasury and up to 20% under special circumstances.

Pre-emptive Rights and Advance Subscription Rights

Swiss law provides that any share issue, whether for cash or non-cash consideration, is subject to the prior approval at a general meeting of shareholders. Shareholders are granted certain pre-emptive rights (*Bezugsrechte*) to subscribe for new issues of shares and advance subscription rights (*Vorwegzeichnungsrechte*) to subscribe for warrants, convertible bonds or similar debt instruments with option rights in proportion to the nominal amount of

shares held. Pursuant to the Articles of Association, a resolution adopted at a general meeting by a majority of two-thirds of the votes represented at the meeting is required to repeal, limit or suspend pre-emptive rights.

Warrants

Pursuant to the Business Combination Agreement and Warrant Assignment and Assumption Agreement, the Company has assumed and issued 4,403,294 Warrants. Each Warrant entitles the registered holder to purchase one Ordinary Share at a price of \$11.50 per share, subject to adjustment as discussed below, exercisable at any time commencing 30 days after the completion of the Business Combination, provided that we have an effective registration statement under the Securities Act covering the issuance of the Ordinary Shares issuable upon exercise of the Warrants. Pursuant to the Warrant Assignment and Assumption Agreement, a warrant holder may exercise its Warrants only for a whole number of Ordinary Shares. This means only a whole public warrant may be exercised at a given time by a Warrant holder. The Warrants will expire on March 2, 2028 (i.e. five years after the completion of the Business Combination), at 5:00 p.m. Eastern Time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any Ordinary Shares pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act covering the issuance of the Ordinary Shares issuable upon exercise of the Warrants is then effective and a current prospectus relating thereto is current, subject to us satisfying our obligations described below with respect to registration, or a valid exemption from registration is available, including in connection with a cashless exercise permitted as a result of a notice of redemption described below under the section entitled “*Redemption of warrants when the price per Ordinary Share equals or exceeds \$10.00.*” No Warrant will be exercisable for cash or on a cashless basis, and we will not be obligated to issue any shares to holders seeking to exercise their warrants, unless the issuance of the shares upon such exercise is registered or qualified under the securities laws of the state of the exercising holder, or an exemption is available. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a Warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless.

We agreed to file with the SEC this registration statement covering the issuance, under the Securities Act, of the Ordinary Shares issuable upon exercise of the Warrants, and we will use our commercially reasonable efforts to cause this registration statement to become effective within 60 business days, and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the Warrants in accordance with the provisions of the Warrant Assignment and Assumption Agreement. Notwithstanding the above, if the Ordinary Shares are, at the time of any exercise of a warrant, not listed on a national securities exchange such that they satisfy the definition of a “covered security” under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of Warrants who exercise their warrants to do so on a “cashless basis” in accordance with Section 3(a)(9) of the Securities Act and, in the event we so elect, we will not be required to file or maintain in effect a registration statement, but will use commercially reasonable efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. In such event, each holder would pay the exercise price by surrendering the Warrants for that number of Ordinary Shares equal to the lesser of (i) the quotient obtained by dividing (A) the product of the number of Ordinary Shares underlying the Warrants, *multiplied* by the excess of the “fair market value” (defined below) less the exercise price of the warrants by (B) the fair market value and (ii) 0.361. The “*fair market value*” as used in this proxy statement/prospectus shall mean the volume weighted average price of the Ordinary Shares for the 10 trading days ending on the trading day prior to the date on which the notice of exercise is received by the warrant agent.

We will not redeem the Warrants as described above unless a registration statement under the Securities Act covering the issuance of the Ordinary Shares issuable upon exercise of the warrants is then effective and a current prospectus relating to those Ordinary Shares is available throughout the 30-days redemption period. If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is, at the time of the call, a significant premium to the Warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Warrants, each warrant holder will be entitled to exercise his, her or its

warrants prior to the scheduled redemption date. However, the price of the Ordinary Shares may fall below the \$18.00 redemption trigger price (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a Warrant as described under the heading “—Redeemable Warrants—Warrants—Anti-dilution Adjustments”) as well as the \$11.50 (for whole shares) warrant exercise price after the redemption notice is issued.

Redemption of Warrants when the price per Ordinary Share equals or exceeds \$10.00. Once the warrants become exercisable, we may redeem the outstanding Warrants:

- in whole and not in part;
- at \$0.10 per warrant upon a minimum of 30 days’ prior written notice of redemption provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares based on the redemption date and the “fair market value” of the Ordinary Shares, except as otherwise described below;
- if, and only if, the Reference Value equals or exceeds \$10.00 per share (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a warrant as described under the heading “—Redeemable Warrants—Warrants—Anti-dilution Adjustments”) for any 20 trading days within the 30-trading day period ending three trading days before we send the notice of redemption to the warrant holders; and
- if the Reference Value is less than \$18.00 per share (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a warrant, as described under the heading “—Redeemable Warrants—Warrants—Anti-dilution Adjustments”) the Private Placement Warrants must also be concurrently called for redemption on the same terms as the outstanding Warrants, as described above.

During the period beginning on the date the notice of redemption is given, holders may elect to exercise their Warrants on a cashless basis. The numbers in the table below represent the number of Ordinary Shares that a warrant holder will receive upon such cashless exercise in connection with a redemption by us pursuant to this redemption feature based on the “fair market value” of the Ordinary Shares on the corresponding redemption date (assuming holders elect to exercise their warrants and such warrants are not redeemed for \$0.10 per warrant), determined for these purposes based on volume weighted average price of the Ordinary Shares during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of warrants, and the number of months that the corresponding redemption is sent to the holders of warrants, each as set forth in the table below. We will provide its warrant holders with the final fair market value no later than one business day after the 10-trading days period described above ends.

Redemption of Warrants when the price per Ordinary Share equals or exceeds \$18.00. Once the Warrants become exercisable, we may redeem the warrants (except as described herein with respect to the Private Placement Warrants):

- in whole and not in part;
- at a price of \$0.01 per warrant;
- upon not less than 30 days’ prior written notice of redemption to each warrant holder; and
- if, and only if, the last reported sale price of the Ordinary Shares for any 20 trading days within a 30-trading days period ending on the third trading day prior to the date on which we send the notice of redemption to the warrant holders (such price, the “Reference Value”) equals or exceeds \$18.00 per share (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a warrant as described under the heading “—Redeemable Warrants—Public Shareholders’ Warrants—Anti-dilution Adjustments”).

This redemption feature is structured to allow for all of the outstanding Warrants to be redeemed when the Ordinary Shares are trading at or above \$10.00 per share, which may be at a time when the trading price of the Ordinary Shares is below the exercise price of the warrants. We have established this redemption feature to provide itself with the flexibility to redeem the Warrants without the Warrants having to reach the \$18.00 per share threshold set forth above under the heading “—Redemption of Warrants when the price per Ordinary Share equals or exceeds \$18.00.”

Holders choosing to exercise their warrants in connection with a redemption pursuant to this feature will, in effect, receive a number of shares for their warrants based on an option pricing model with a fixed volatility input as of the date of this proxy statement/prospectus. This redemption right provides us with an additional mechanism by which to redeem all of the outstanding Warrants, and therefore have certainty as to our capital structure as the warrants would no longer be outstanding and would have been exercised or redeemed. We will be required to pay the applicable redemption price to warrant holders if we choose to exercise this redemption right and it will allow us to quickly proceed with a redemption of the Warrants if we determine it is in its best interest to do so. As such, we would redeem the Warrants in this manner when we believe it is in its best interest to update its capital structure to remove the Warrants and pay the redemption price to the warrant holders.

Redemption Date (period to expiration of warrants)	Fair Market Value of Ordinary Shares								
	≤\$10.00	\$11.00	\$12.00	\$13.00	\$14.00	\$15.00	\$16.00	\$17.00	≥\$18.00
60 months	0.261	0.281	0.297	0.311	0.324	0.337	0.348	0.358	0.361
57 months	0.257	0.277	0.294	0.310	0.324	0.337	0.348	0.358	0.361
54 months	0.252	0.272	0.291	0.307	0.322	0.335	0.347	0.357	0.361
51 months	0.246	0.268	0.287	0.304	0.320	0.333	0.346	0.357	0.361
48 months	0.241	0.263	0.283	0.301	0.317	0.332	0.344	0.356	0.361
45 months	0.235	0.258	0.279	0.298	0.315	0.330	0.343	0.356	0.361
42 months	0.228	0.252	0.274	0.294	0.312	0.328	0.342	0.355	0.361
39 months	0.221	0.246	0.269	0.290	0.309	0.325	0.340	0.354	0.361
36 months	0.213	0.239	0.263	0.285	0.305	0.323	0.339	0.353	0.361
33 months	0.205	0.232	0.257	0.280	0.301	0.320	0.337	0.352	0.361
30 months	0.196	0.224	0.250	0.274	0.297	0.316	0.335	0.351	0.361
27 months	0.185	0.214	0.242	0.268	0.291	0.313	0.332	0.350	0.361
24 months	0.173	0.204	0.233	0.260	0.285	0.308	0.329	0.348	0.361
21 months	0.161	0.193	0.223	0.252	0.279	0.304	0.326	0.347	0.361
18 months	0.146	0.179	0.211	0.242	0.271	0.298	0.322	0.345	0.361
15 months	0.130	0.164	0.197	0.230	0.262	0.291	0.317	0.342	0.361
12 months	0.111	0.146	0.181	0.216	0.250	0.282	0.312	0.339	0.361
9 months	0.090	0.125	0.162	0.199	0.237	0.272	0.305	0.336	0.361
6 months	0.065	0.099	0.137	0.178	0.219	0.259	0.296	0.331	0.361
3 months	0.034	0.065	0.104	0.150	0.197	0.243	0.286	0.326	0.361
0 months	—	—	0.042	0.115	0.179	0.233	0.281	0.323	0.361

As stated above, we can redeem the Warrants when the Ordinary Shares are trading at a price starting at \$10.00, which is below the exercise price of \$11.50, because it will provide certainty with respect to its capital structure and cash position while providing warrant holders with the opportunity to exercise their warrants on a cashless basis for the applicable number of shares. If we choose to redeem the Warrants when the Ordinary Shares are trading at a price below the exercise price of the warrants, this could result in the warrant holders receiving fewer Ordinary Shares than they would have received if they had chosen to exercise their warrants for Ordinary Shares if and when such Ordinary Shares were trading at a price higher than the exercise price of \$11.50.

No fractional Ordinary Shares will be issued upon exercise. If, upon exercise, a holder would be entitled to receive a fractional interest in a share, we will round down to the nearest whole number of the number of Ordinary Shares to be issued to the holder. If, at the time of redemption, the Warrants are exercisable for a security other than the Ordinary Shares pursuant to the Warrant Assignment and Assumption Agreement (for instance, if we are not the surviving company after completion of a business combination), the warrants may be exercised for such security. At such time as the Warrants become exercisable for a security other than the Ordinary Shares, we (or the surviving company, as applicable) will use its commercially reasonable efforts to register under the Securities Act the security issuable upon the exercise of the warrants.

Redemption Procedures. A holder of a Warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would

beneficially own in excess of 9.8% (or such other amount as a holder may specify) of the Ordinary Shares issued and outstanding immediately after giving effect to such exercise.

Anti-dilution Adjustments. If the number of issued and outstanding Ordinary Shares is increased by a capitalization or share dividend payable in Ordinary Shares, or by a split-up of Ordinary Shares or other similar event, then, on the effective date of such capitalization or share dividend, split-up or similar event, the number of Ordinary Shares issuable on exercise of each Warrant will be increased in proportion to such increase in the issued and outstanding Ordinary Shares. A rights offering made to all or substantially all holders of Ordinary Shares entitling holders to purchase Ordinary Shares at a price less than the “historical fair market value” (as defined below) will be deemed a share dividend of a number of Ordinary Shares equal to the product of (i) the number of Ordinary Shares actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Ordinary Shares) and (ii) one *minus* the quotient of (a) the price per Ordinary Share paid in such rights offering and (b) the historical fair market value. For these purposes, (i) if the rights offering is for securities convertible into or exercisable for Ordinary Shares, in determining the price payable for Ordinary Shares, there will be taken into account any consideration received for such rights payable upon exercise or conversion and (ii) “*historical fair market value*” means the volume weighted average price of Ordinary Shares during the 10 trading days period ending on the trading day prior to the first date on which the Ordinary Shares trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

If the number of issued and outstanding Ordinary Shares is decreased by a consolidation, combination, reverse share sub-division or reclassification of Ordinary Shares or other similar event, then, on the effective date of such consolidation, combination, reverse share sub-division, reclassification or similar event, the number of Ordinary Shares issuable on exercise of each warrant will be decreased in proportion to such decrease in issued and outstanding Ordinary Shares. Whenever the number of Ordinary Shares purchasable upon the exercise of the Warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (i) the numerator of which will be the number of Ordinary Shares purchasable upon the exercise of the warrants immediately prior to such adjustment and (ii) the denominator of which will be the number of Ordinary Shares so purchasable immediately thereafter.

In addition, if (i) we issue additional Ordinary Shares or equity-linked securities for capital raising purposes in connection with the completion of the Business Combination at an issue price or effective issue price of less than \$9.20 per ordinary share (with such issue price or effective issue price to be determined in good faith by the Board) (the “*Newly Issued Price*”), (ii) the aggregate gross proceeds from such issuances represent more than 60% of the total equity proceeds, and interest thereon, available for the funding of the Business Combination on the date of the completion of the Business Combination (net of redemptions), and (iii) the volume weighted average trading price of the Ordinary Shares during the 20 trading day period starting on the trading day prior to the day on which we consummate the Business Combination (such price, the “*Market Value*”) is below \$9.20 per share, the exercise price of the Warrants will be adjusted (to the nearest cent) to be equal to 115% of the higher of the Market Value and the Newly Issued Price, the \$18.00 per share redemption trigger prices described above under “—*Redemption of Warrants when the price per Ordinary Share equals or exceeds \$18.00*” and “—*Redemption of Warrants when the price per Ordinary Share equals or exceeds \$10.00*” will be adjusted (to the nearest cent) to be equal to 180% of the higher of the Market Value and the Newly Issued Price, and the \$10.00 per share redemption trigger price described above under “—*Redemption of Warrants when the price per Ordinary Share equals or exceeds \$10.00*” will be adjusted (to the nearest cent) to be equal to the higher of the Market Value and the Newly Issued Price.

In case of any reclassification or reorganization of the issued and outstanding Ordinary Shares (other than those described above or that solely affects the par value of such Ordinary Shares), or in the case of any merger or consolidation of Oculis Holding AG with or into another corporation (other than a merger or consolidation in which we are a continuing corporation and that does not result in any reclassification or reorganization of our issued and outstanding Ordinary Shares), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of Oculis Holding AG as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the warrants and in lieu of the Ordinary Shares immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares, stock or other equity securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Warrants would

have received if such holder had exercised their warrants immediately prior to such event. However, if such holders are entitled to exercise a right of election as to the kind or amount of securities, cash or other assets receivable upon such merger or consolidation, then the kind and amount of securities, cash or other assets for which each warrant will become exercisable will be deemed to be the weighted average of the kind and amount received per share by such holders in such merger or consolidation that affirmatively make such election, and if a tender, exchange or redemption offer has been made to and accepted by such holders under circumstances in which, upon completion of such tender or exchange offer, the maker thereof, together with members of any group (within the meaning of Rule 13d-5(b)(1) under the Exchange Act) of which such maker is a part, and together with any affiliate or associate of such maker (within the meaning of Rule 12b-2 under the Exchange Act) and any members of any such group of which any such affiliate or associate is a part, own beneficially (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the issued and outstanding Ordinary Shares, the holder of a warrant will be entitled to receive the highest amount of cash, securities or other property to which such holder would actually have been entitled as a shareholder if such warrant holder had exercised the warrant prior to the expiration of such tender or exchange offer, accepted such offer and all of the Ordinary Shares held by such holder had been purchased pursuant to such tender or exchange offer, subject to adjustment (from and after the consummation of such tender or exchange offer) as nearly equivalent as possible to the adjustments provided for in the Warrant Assignment and Assumption Agreement. Additionally, if less than 70% of the consideration receivable by the holders of Ordinary Shares in such a transaction is payable in the form of ordinary shares in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the Warrant properly exercises the warrant within 30 days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the Warrant Assignment and Assumption Agreement based on the per share consideration *minus* the Black-Scholes Warrant Value (as defined in the Warrant Assignment and Assumption Agreement) of the Warrant.

The Warrants will be issued in registered form under the Warrant Assignment and Assumption Agreement. The Warrant Assignment and Assumption Agreement provides that the terms of the Warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correcting any mistake, including to conform the provisions of the Warrant Assignment and Assumption Agreement to the description of the terms of the warrants and the Warrant Assignment and Assumption Agreement set forth in this proxy statement/prospectus or defective provision or (ii) adding or changing any provisions with respect to matters or questions arising under the Warrant Assignment and Assumption Agreement as the parties to the Warrant Assignment and Assumption Agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the warrants.

The warrant holders do not have the rights or privileges of holders of Ordinary Shares and any voting rights until they exercise their Warrants and receive Ordinary Shares. After the issuance of Ordinary Shares upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by shareholders.

We have agreed that, subject to applicable law, any action, proceeding or claim against it arising out of or relating in any way to the Warrant Assignment and Assumption Agreement will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. This provision applies to claims under the Securities Act but does not apply to claims under the Exchange Act or any claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Dividends

General

Dividends may be paid only if we have sufficient distributable profit from previous years or sufficient free reserves to allow the distribution of a dividend. Swiss law requires that we retain at least 5% of its annual net profit as general reserves for so long as these reserves amount to less than 20% of its paid-in nominal share capital.

Annual Profit Distribution

Under Swiss law, dividends are proposed by the Board and require the approval at a meeting of shareholders. Our auditors must also confirm that the dividend proposal conforms to law and the Articles of Association. Dividends that have not been collected by shareholders within five years after the due date accrue to us.

For a description of certain tax considerations, including withholding taxes, in relation to dividend payments, please see the section entitled “*Material Tax Consideration—Material Swiss Tax Considerations.*”

Payment

The Board determines the date on which the dividend entitlement starts. Dividends are usually due and payable shortly after the shareholders have passed the resolution approving the payment, but shareholders may also resolve at an annual general meeting to pay dividends in quarterly or other instalments.

Capital Reduction

Distributions out of issued share capital (i.e., the aggregate nominal value of our issued shares) are not allowed and may be made only by way of a share capital reduction. Such a capital reduction requires a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders or the introduction of a capital band (*Kapitalband*) pursuant to which the Board is empowered to make such resolution. The resolution of the shareholders must be recorded in a public deed and a special audit report must confirm that claims of our creditors remain fully covered despite the reduction in our share capital recorded in the Commercial Register. Our share capital may be reduced below CHF 100,000 only if and to the extent that at the same time the statutory minimum share capital of CHF 100,000 is re-established by sufficient new, fully paid-up capital. Upon approval or before the general meeting of the capital reduction, the Board must give public notice of the capital reduction resolution in the Swiss Official Gazette of Commerce (“*SOGC*”) and notify creditors that they may request, within thirty (30) days of the third publication, satisfaction of or security for their claims. The reduction of our share capital may be implemented only after expiration of this time limit.

Repurchases of Shares

Swiss law limits our right to purchase and hold our own shares. We may purchase our own shares only if and to the extent that: (i) We have freely distributable reserves in the amount of the purchase price; and (ii) the aggregate nominal value of all Ordinary Shares held by us does not exceed 10% of our share capital (or up to 20% under certain specific circumstances). Furthermore, according to Swiss accounting rules, we need to reflect the amount of the purchase price of the acquired Ordinary Shares as a negative position through the creation of a special reserve on its balance sheet. We may face negative tax consequences, if we hold more than 10% of our Shares for more than six years.

Ordinary Shares held by us or our subsidiaries do not carry any voting rights at general meetings of shareholders, but are entitled to the economic benefits, including dividends, pre-emptive rights (*Bezugsrechte*) in the case of share capital increases and advance subscription rights (*Vorwegzeichnungsrechte*) and in the case of issuance of debt instruments with option rights applicable to the Ordinary Shares generally.

Form and Transfer of Shares

Form of the Shares

Ordinary Shares may be issued as ordinary uncertificated securities within the meaning of article 973c CO (*Wertrechte*) and/or global certificates. In accordance with article 973c CO, we maintain a register of uncertificated securities (*Wertrechtbuch*). We may create intermediated securities (*Bucheffekten*) for Ordinary Shares.

Upon its registration with the share register, a shareholder may at any time request that we issue a written confirmation of the Ordinary Shares held by such shareholder. However, the shareholder has no right to request the printing and delivery of share certificates nor the conversion of Ordinary Shares issued in one form into another form. We may, however, at any time print and deliver certificates for registered (single certificates or global

certificates) and, with the consent of the shareholder, delete without replacement issued share certificates, which have been returned to it. We may convert Ordinary Shares from one form into another form at any time and without the approval of the shareholders. We shall bear the cost associated with any such conversion.

Transfer of Shares

Ordinary Shares in uncertificated form (*Wertrechte*) may only be transferred by way of assignment. Ordinary Shares or the beneficial interest in Ordinary Shares, as applicable, credited in a securities account may only be transferred when a credit of the relevant intermediated securities to the acquirer's securities account is made in accordance with applicable rules. For certain registration and voting right restrictions on the Ordinary Shares, please see the section entitled "*Registration and Voting Right Restrictions*."

Share Register

We maintain a share register (*Aktienbuch*) (the "*Share Register*") in which the owners of the Ordinary Shares are registered with name, address and nationality (in case of legal entities the registered office). In relation to Oculis Holding AG, only those shareholders registered in the Share Register are recognized as shareholders.

Pursuant to article 4 of the Articles of Association, acquirers of Ordinary Shares are, upon request and presentation of evidence of the transfer, registered as shareholders with voting rights in the Share Register if they explicitly declare to hold Ordinary Shares in their own name and for their own account.

The Board shall implement the necessary directions for maintaining the Share Register and it may issue corresponding regulations or guidelines. The Board may delegate such tasks.

In the invitation to the general meeting, the Board shall announce the record date for registration in the Share Register that is relevant with respect to the right to attend and vote.

We have the right to delete entries in the Share Register retroactively as of the date of the entry if the registration has been made on the basis of false information. We may give the relevant shareholder or nominee, in advance, the opportunity to be heard. The relevant shareholder or nominee must be informed of the deletion without delay.

Registration and Voting Right Restrictions

The Articles of Association contain the following registration restrictions:

1. *Regulatory Registration and Voting Right Restrictions.* According to article 4 of the Articles of Association, the Board may refuse the registration of an acquirer of Ordinary Shares in the Share Register as a shareholder with voting rights or cancel an already occurred registration of Ordinary Shares with voting rights from the Share Register, if (a) the number of Ordinary Shares held or acquired directly or indirectly or acting in concert with third parties or as an organized group by such acquirer exceeds 15% of the total number of voting rights of Oculis Holding AG pursuant to the entry in the commercial register, and (b) such acquirer has not submitted prior to the acquisition of such Ordinary Shares an orderly tender offer to all shareholders with a minimum price of the higher of (i) the volume weighted average price of the last 60 trading days prior to the publication of the tender offer, or (ii) the highest price paid by such acquirer in the 12 months preceding to the publication of the tender offer.

Those associated through capital, voting power, joint management, beneficial ownership or in any other way, or joining for the acquisition of shares shall be regarded as one acquirer for the purposes of article 4 of the Articles of Association. Acquirers who do not meet the legal or regulatory requirements according to article 4 of the Articles of Association shall be entered in the Share Register as shareholder without voting rights for Ordinary Shares exceeding the limit of 15%. In case of an already occurred registration, Ordinary Shares exceeding the limit of 3% will be cancelled from the Share Register as Ordinary Shares with voting rights and instead be registered as Ordinary Shares without voting rights. The Board may enact regulations governing the details of such registration restriction. Nominees do not constitute acquirers within the

meaning of article 4 of the Articles of Association. After hearing the person concerned, we may cancel the registrations in the Share Register if those registrations were based on false information of the acquirer. In addition, according to article 4 of the Articles of Association, the Board may refuse the exercise of voting rights of a shareholder in excess of 15% of the total number of voting rights of Oculis Holding AG pursuant to the entry in the commercial register, if such shareholder does not meet the legal or regulatory requirements according to article 4 of the Articles of Association

2. *Registration and Voting Right Restrictions for Ordinary Shares held through Nominees.* The registration and voting right restrictions in connection with the regulatory registration and voting right restrictions described above are also applicable to Ordinary Shares held through nominees. Accordingly, article 4 of the Articles of Association provides that, if, any beneficial owner should as a result of such registration of a nominee being made or upheld, directly or indirectly, formally, constructively or beneficially own, or otherwise control or alone or together with third parties, hold a number of shares exceeding 3% of the total number of voting rights of Oculis Holding AG pursuant to the entry in the commercial register and the nominee does not, expressly declare in the registration application that it is holding the shares on its own account, and the nominee does not confirm in writing that it is willing to disclose the names, addresses and shareholdings of the persons on whose account they hold 0.5% or more of the share capital, the Board may refuse to register (or cancel an already occurred registration of) the nominee holding Ordinary Shares for the account of such beneficial owner with respect to any Ordinary Shares in excess of such restriction. The Board may make the registration with voting rights of the Ordinary Shares held by a nominee subject to conditions, limitations and reporting requirements and may impose or adjust such conditions, limitations and requirements once registered and may enter into agreements with nominees in this regard.

Further, the voting right restrictions pursuant to article 4 of the Articles of Association as set out above also apply to Ordinary Shares, which are held by a nominee for the account of a person exceeding the threshold of 15% (regulatory voting right restrictions).

Apart from the registration and voting rights restrictions as described above, there are no restrictions on the transferability of the Ordinary Shares in the Articles of Association.

General Meetings of Shareholders

Convocation of Meetings

Under Swiss law and article 10 of the Articles of Association, an annual general meeting of shareholders must be held each year within six months after the end of the business year. Extraordinary meetings of shareholders may be convened when required.

General meetings of shareholders must be convened by the board of directors at least 20 days before the date of the meeting. The general meeting of shareholders is convened by way of a notice appearing in our official publication medium, currently the SOGC. Registered shareholders may also be informed by ordinary mail or e-mail. The notice of a general meeting of shareholders must state the items on the agenda, the proposals to be acted upon and, in case of elections, the names of the nominated candidates. Except in the limited circumstances listed below, a resolution may not be passed at a general meeting without proper notice. This limitation does not apply to proposals to convene an extraordinary general meeting of shareholders or to initiate a special investigation. No previous notification is required for proposals concerning items included in the agenda or for debates that do not result in a vote.

In addition, one or several shareholders that represent at least 5% of the share capital may also request to convene a general meeting. Shareholders representing at least 0.5% of the share capital may request items to be put on the agenda, provided the request is submitted to the Board at least 70 calendar days in advance of the relevant general meeting. Convocation requests and requests for inclusion of agenda items need to be submitted to the Board in written form, indicating the agenda items and proposals. Swiss law and the Articles of Association do not prescribe that a particular quorum of shareholders is required for general meetings of shareholders to be validly held.

No resolutions may be passed on motions concerning agenda items which have not been duly announced, except for motions to convene an extraordinary general meeting, to initiate a special audit or to elect auditors upon a

shareholders' request. No prior notice is required to submit motions relating to items already on the agenda and to discuss matters on which no resolution is to be taken.

The general meeting will be chaired by the chairman of the Board, or, in his or her absence, by another member of the Board as appointed by the Board. If no member of the Board is present, the general meeting shall appoint the chairperson of the meeting.

Representation of Shareholders

Each shareholder may have its shares represented in the general meeting by itself or by a third person who does not need to be a shareholder by means of written proxy or by the independent proxy. The general meeting annually elects an independent proxy. The independent proxy's term of office begins at the day of election and ends at the end of the following annual general meeting. Re-election is possible. If we do not have an independent proxy, the Board shall appoint the independent proxy for the next general meeting of shareholders.

Quorum and Majority Requirements at General Meetings of Shareholders

Except where the law or the Articles of Association provide otherwise, the general meeting passes its resolutions and performs elections with the absolute majority of the votes cast, excluding any abstentions, blank or invalid votes. The chairperson of the general meeting determines the voting procedure.

According to article 19 of the Articles of Association, a resolution of the general meeting passed with at least two-thirds of the votes represented at the meeting and the absolute majority of the nominal values of the Ordinary Shares represented at the meeting is required for:

1. the amendment of the purpose of the Company;
 2. the consolidation of shares, insofar as this does not require the consent of all shareholders concerned;
 3. the increase of the share capital against contributions in kind or by offsetting against a receivable and the granting of special benefits;
 4. the limitation or withdrawal of subscription rights;
 5. the introduction of conditional capital, the creation of reserve capital pursuant to article 12 of the Swiss Banking Act or the introduction of a capital band;
 6. the conversion of participation certificates into shares;
 7. the restriction of the transferability of registered shares;
 8. the creation of shares with privileged voting rights;
 9. the change of currency of the share capital;
 10. the introduction of the casting vote of the Chairman in the General Assembly;
 11. the introduction of a provision in the Articles of Association to hold general meetings outside of Switzerland;
 12. the change of the registered office of the Company;
 13. the introduction of an arbitration clause in the Articles of Association;
 14. the delisting of the Ordinary Shares;
 15. the dissolution of the Company;
 16. the merger, de-merger or conversion of the Company(subject to mandatory law);
 17. the alleviating or withdrawal of restrictions upon the transfer of registered shares;
 18. the conversion of registered shares into bearer shares and vice versa; and
-

19. the amendment or elimination of the provisions of articles 4, 19 and 31 of the Articles of Association.

Provisions of the Articles of Association which require higher majorities for the passing of certain resolutions than provided by law can only be adopted and removed with that same proposed majority.

Voting Rights

In principle, each Ordinary Share entitles a holder to one vote in our general meeting, irrespective of nominal value of such share (please see the section entitled “*Comparison of Shareholder Rights—Voting Rights*” for details on certain exceptions under Swiss law).

The Ordinary Shares are not divisible. The right to vote and the other rights of share ownership may only be exercised by shareholders (including any nominees) who are entered in the Share Register prior to the applicable cut-off date to be determined by the Board. Those entitled to vote in the general meeting may be represented by the independent proxy holder (annually elected by the general meeting of shareholders), by its legal representative or by another person with written authorization to act as proxy. The chairman of the general meeting has the power to decide whether to recognize a power of attorney. Only shareholders registered in the Share Register with voting rights are entitled to vote in a Ordinary Shareholders’ meeting.

Inspection of Books and Records

The annual report and the auditors’ report shall be made available for inspection by the shareholders at the registered office of the Company at the latest 20 days prior to the annual general meeting. Provided that the annual report and the auditors’ report have not been made available electronically before the annual general meeting, each shareholder may demand a timely delivery of these documents. The notice to the shareholders must refer to this right. Furthermore, each shareholder may within one year after the annual general meeting demand the delivery of the auditors’ report and the annual report in the form approved by the annual general meeting, provided that they have not been made available electronically.

Under Swiss law, a shareholder may also, upon request submitted to the Company, inspect the minutes of general meetings.

At general meetings, shareholders may further request information from the Board regarding the business and operations of the Company and may request information from our auditors regarding the performance and results of their examination of our financial statements. We may refuse to provide certain requested information to a shareholder if, in our opinion, the disclosure of the requested information would reveal confidential business secrets or infringe other protected interests.

Shareholders representing at least 5% of the share capital or votes have the right to inspect the company’s books. The board of directors must grant the inspection insofar as it is necessary for the exercise of shareholders’ rights and the disclosure would not reveal confidential business secrets or infringe other protected interests. Upon inspection of the books, the shareholders may make notes.

Special Investigations

If the shareholders’ inspection and information rights as outlined above prove to be insufficient, any shareholder may propose to the general meeting that specific facts be examined by a special commissioner in a special investigation. If the general meeting approves the proposal, the Company or any shareholder may, within 30 calendar days after the general meeting, request the court at our registered office to appoint a special commissioner. If the general meeting rejects the request, one or more shareholders representing at least 5% of the share capital or voting rights may request, within three months after the general meeting, a court to appoint a special commissioner as described in the Articles of Association. Such court will issue such order if the petitioners can demonstrate that the Board, any member thereof or an officer of the Company infringed the law or the Articles of Association and thereby damaged the Company or the shareholders. If admitted, the costs of the investigation by such court would generally be allocated to the Company and only in exceptional cases to the petitioners.

Notices

Official publications of the Company shall be made in the SOGC. The Board may designate additional means of publication.

Notices to the shareholders shall be made by official publications of the Company. Notices to shareholders may also be made by mail or email to the addresses recorded in the Share Register.

Takeover Regulation and Mandatory Bids

Swiss law provides for certain rules and protections of shareholders of domestic listed companies. Because the Ordinary Shares will be listed exclusively on the Nasdaq Global Market, however, several of these rules do not apply to us as if we were a company listed in Switzerland. In particular, the Swiss rules under the Swiss Financial Market Infrastructure Act on disclosure of shareholdings and the tender offer rules under the Swiss Financial Market Infrastructure Act, including mandatory tender offer requirements and regulations regarding voluntary tender offers, which are typically available in relation to Swiss-listed companies, do not apply to us because we will not be listed in Switzerland.

Compulsory Acquisitions; Appraisal Rights

Business combinations and other transactions that are governed by the Switzerland's Federal Act on Mergers, Demergers, Transformations and the Transfer of Assets of October 3, 2003, as amended (the "*Swiss Merger Act*") (i.e., mergers, demergers, transformations and certain asset transfers) are binding on all shareholders. A statutory merger or demerger requires approval of two-thirds of the shares represented at a General Meeting of shareholders and the absolute majority of the nominal value of the shares represented.

If a transaction under the Swiss Merger Act receives all of the necessary consents, all shareholders are compelled to participate in such a transaction.

Swiss stock corporations may be acquired by an acquirer through the direct acquisition of the shares of the Swiss stock corporation. The Swiss Merger Act provides for the possibility of a so-called "cash-out" or "squeeze-out" merger with the approval of holders of 90% of the issued shares. In these limited circumstances, minority shareholders of the corporation being acquired may be compensated in a form other than through shares of the acquiring corporation (for instance, through cash or securities of a parent corporation of the acquiring corporation or of another corporation). For business combinations effected in the form of a statutory merger or demerger and subject to Swiss law, the Swiss Merger Act provides that if equity rights have not been adequately preserved or compensation payments in the transaction are unreasonable, a shareholder may request a competent court to determine a reasonable amount of compensation.

In addition, under Swiss law, the sale of "all or substantially all" of our assets may require the approval of two-thirds of the voting rights represented at a general meeting of shareholders and the absolute majority of the nominal value of the shares represented. Whether a shareholder resolution is required depends on the particular transaction, including whether the following test is satisfied:

- a core part of our business is sold without which it is economically impracticable or unreasonable to continue to operate the remaining business;
 - Our assets, after the divestment, are not invested in accordance with its corporate purpose as set forth in the Articles of Association; and
-

- the proceeds of the divestment are not earmarked for reinvestment in accordance with our corporate purpose (as set forth in the Articles of Association), but instead are intended for distribution to our shareholders or for financial investments unrelated to its corporate purpose.
- Our assets, after the divestment, are not invested in accordance with its corporate purpose as set forth in the Articles of Association; and
- the proceeds of the divestment are not earmarked for reinvestment in accordance with our corporate purpose (as set forth in the Articles of Association), but instead are intended for distribution to our shareholders or for financial investments unrelated to its corporate purpose.

Duration and Liquidation

Under Swiss law, unless the duration of a company is limited by its articles of association, a company may be dissolved at any time by way of liquidation, or, in the case of a merger with the Swiss Merger Act (*Fusionsgesetz*), based on a resolution of a general meeting of shareholders, which must be passed by a majority as provided by Swiss law or the relevant company's articles of association, as the case may be. The Articles of Association do not limit the duration of the Company and provide that the majority required for the general meeting to resolve on the liquidation of the Company is set at two-thirds of the votes represented at the general meeting and the absolute majority of the nominal values of the shares represented at the meeting.

Dissolution and liquidation by court order is also possible if, among other things, (i) the Company becomes bankrupt or (ii) shareholders holding at least 10% of the Company's share capital so request for important reasons. Under Swiss law, any surplus arising out of a liquidation (after settlement of all the claims of the Company's creditors) is distributed in proportion to the paid-up nominal value of shares held. This surplus is subject to Swiss federal withholding tax, except if paid out of reserves from qualifying capital contributions (*Reserven aus Kapitaleinlagen*).

Comparison of Swiss and Delaware Shareholder Rights The Swiss laws applicable to Swiss corporations and their shareholders differ from laws applicable to U.S. corporations and their shareholders. The following table summarizes significant differences in shareholder rights pursuant to the provisions of the Swiss CO, by which our Company is governed, and the Delaware General Corporation Law applicable to companies incorporated in Delaware and their shareholders. Please note that this is only a general summary of certain provisions applicable to companies in Delaware and Switzerland.

Delaware Corporate Law

Swiss Corporate Law

Mergers and similar arrangements

Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such

Under Swiss law, with certain exceptions, a merger or a demerger of the corporation or a sale of all or substantially all of the assets of a corporation must be approved by two-thirds of the voting rights represented at the respective general meeting of shareholders as well as the majority of the par value of shares represented at such general meeting of shareholders. A shareholder of a Swiss corporation participating in a statutory merger or demerger pursuant to the Swiss Merger Act (*Fusionsgesetz*) can file a lawsuit against the surviving company. If the

shareholder would otherwise receive in the transaction. The Delaware General Corporation Law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary, of which it owns at least 90.0% of each class of capital stock without a vote by the shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights..

consideration is deemed “inadequate,” such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that such shareholder receives the fair value of the shares held by such shareholder. Swiss law also provides that if the merger agreement provides only for a compensation payment, at least 90% of all members in the transferring legal entity who are entitled to vote shall approve the merger agreement.

Shareholders' suits

Class actions and derivative actions generally are available to shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys’ fees incurred in connection with such action.

Class actions and derivative actions as such are not available under Swiss law. Nevertheless, certain actions may have a similar effect. A shareholder is entitled to bring suit against directors, officers or liquidators for breach of their duties and claim the payment of the company’s losses or damages to the corporation and, in some cases, to the individual shareholder. Likewise, an appraisal lawsuit won by a shareholder may indirectly compensate all shareholders. In addition, to the extent that U.S. laws and regulations provide a basis for liability and U.S. courts have jurisdiction, a class action may be available.

Under Swiss law, the prevailing party is generally entitled to recover a limited amount of attorneys’ fees incurred in connection with such action. The court has discretion to permit the shareholder who lost the lawsuit to recover attorneys’ fees incurred to the extent that he or she acted in good faith.

Shareholder vote on board and management compensation

Under the Delaware General Corporation Law, the board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws.

Pursuant to Swiss law, the general meeting of shareholders has the non-transferable right, amongst others, to vote separately and bindingly on the aggregate amount of compensation of the members of the board of directors, of the executive committee and of the advisory boards

Annual vote on board renewal

Unless directors are elected by written consent in lieu of an annual meeting, directors are elected in an annual meeting of shareholders on a date and at a time designated by or in the manner provided in the bylaws. Re-election is possible.

The general meeting of shareholders elects the members of the board of directors, the chairperson of the board of directors and the members of the compensation committee individually and annually for a term of office until the end of the following general meeting of shareholders. Re-election is possible.

Classified boards are permitted.

Indemnification of directors and executive officers and limitation of liability

The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors and officers of the corporation for monetary damages for breach of a fiduciary duty as a director or officer, except no provision in the certificate of incorporation may eliminate or limit:

- the liability of a director or officer for any breach of the duty of loyalty to the corporation or its shareholder
- the liability of a director or officer for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- a director's statutory liability for unlawful payment of dividends or unlawful share purchase or redemption;
- the liability of a director or officer for any transaction from which the director or officer derived an improper personal benefit; or
- the liability of an officer in any action by or in the right of the corporation..

A Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any proceeding, other than an action by or on behalf of the corporation, because the person is or was a director or officer, against liability incurred in connection with the proceeding if the director or officer acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation; and the director or officer, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Unless ordered by a court, any foregoing indemnification is subject to a determination that the director or officer has met the applicable standard of conduct:

- by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum;
- by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum;
- by independent legal counsel in a written opinion if there are no eligible directors or if the eligible directors so direct; or
- by the shareholders

Moreover, a Delaware corporation may not indemnify a director or officer in connection with any proceeding in which the director or officer has been adjudged to be liable to the corporation unless and only to the extent that the court determines that, despite the adjudication of liability

Under Swiss corporate law, an indemnification by the corporation of a director or member of the executive committee in relation to potential personal liability is not effective to the extent the director or member of the executive committee intentionally or negligently violated his or her corporate duties towards the corporation (certain scholars advocate that at least a grossly negligent violation is required to exclude the indemnification). Furthermore, the general meeting of shareholders may discharge (release) the directors and members of the executive committee from liability for their conduct to the extent the shareholders have knowledge of the relevant facts of a potential claim. Such discharge is effective only with respect to claims of the company and of those shareholders who approved the discharge or who have since acquired their shares in full knowledge of the discharge. Most violations of corporate law are regarded as violations of duties towards the corporation rather than towards the shareholders. In addition, indemnification of other controlling persons is not permitted under Swiss corporate law, including shareholders of the corporation.

The articles of association of a Swiss corporation may also set forth that the corporation shall indemnify and hold harmless, to the extent permitted by the law, the directors and executive managers out of assets of the corporation against threatened, pending or completed actions. Also, a corporation may enter into and pay for directors' and officers' liability insurance, which may cover negligent acts as well

but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity for those expenses which the court deems proper

Directors' fiduciary duties

A director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components:

- the duty of care; and
- the duty of loyalty.

The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself or herself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction.

The duty of loyalty requires that a director act in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use his or her corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties.

Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction and that the transaction was of fair value to the corporation.

The board of directors of a Swiss corporation manages the business of the corporation, unless responsibility for such management has been duly delegated to the executive committee based on organizational rules. However, there are several non-transferable duties of the board of directors:

- the overall management of the corporation and the issuing of all necessary directives;
- determination of the corporation's organization;
- the organization of the accounting, financial control and financial planning systems as required for management of the corporation;
- the appointment and dismissal of persons entrusted with management and the representation of the corporation;
- overall supervision of the persons entrusted with managing the corporation, in particular with regard to compliance with the law, articles of association, bylaws and internal directives;
- compilation of the annual report, preparation for the general meeting of the shareholders, the compensation report and implementation of its resolutions;
- the filing an application for a debt restructuring moratorium and notification of the court in the event that the company is over-indebted; and
- the filing of the compensation report.

The members of the board of directors must perform their duties with all due diligence and safeguard the interests of the corporation in good faith. They must afford the shareholders equal treatment in equal circumstances.

The duty of care requires that a director act in good faith, with the care that an ordinarily prudent director would exercise under like circumstances.

The duty of loyalty requires that a director safeguard the interests of the corporation and requires that directors act in the interest of the corporation and, if necessarily, put aside their personal interests. The members of the board of directors and the executive committee are required to immediately and fully inform the board of directors about their conflicts of

interests. If there is a risk of a conflict of interest, the board of directors must take appropriate measures to ensure that the interests of the company are duly taken into account.

The burden of proof for a violation of these duties is with the corporation or with the shareholder bringing a suit against the director.

The Swiss Federal Supreme Court has established a doctrine that restricts its review of a business decision if the decision has been made after proper preparation, on an informed basis, and without conflicts of interest.

Shareholder action by written consent

A Delaware corporation may, in its certificate of incorporation, eliminate the right of shareholders to act by written consent.

Shareholders of a Swiss corporation may exercise their voting rights in a general meeting of shareholders.

Shareholders may also exercise their rights by instructing an independent proxy, who is elected by the general meeting or the board of directors. The instruction of such (independent) proxies may occur in writing or electronically. The articles of association of a Swiss corporation may also provide for the possibility for shareholders to attend a general meeting electronically (virtual or hybrid general meeting) and cast their vote electronically.

Shareholder proposals

A shareholder of a Delaware corporation has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

At any general meeting of shareholders any shareholder may put proposals to the meeting if the proposal is part of an agenda item. No resolution may be taken on proposals relating to the agenda items that were not duly notified.

Unless the articles of association provide for a lower threshold or for additional shareholders' rights:

- shareholders jointly representing at least 5% of the share capital or voting rights may demand that a general meeting of shareholders be called for specific agenda items and specific proposals; and
 - shareholders jointly representing at least 0.5% of the share capital or voting rights of the share capital or the voting rights may demand that an agenda item including a specific proposal, or a proposal with respect to an existing agenda item, be put on the agenda for a scheduled general meeting of shareholders, provided such request is made with appropriate lead time.
-

Any shareholder can propose candidates for election as directors or make other proposals within the scope of an agenda item without prior written notice.

In addition, any shareholder is entitled, at a general meeting of shareholders and without advance notice, to (i) request information from the board of directors on the affairs of the company (note, however, that the right to obtain such information is limited), (ii) request information from the auditors on the methods and results of their audit, (iii) request that the general meeting of shareholders resolve to convene an extraordinary general meeting, or (iv) request that the general meeting of shareholders resolve to appoint an examiner to carry out a special examination (“*Sonderuntersuchung*”).

Cumulative voting

Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation’s certificate of incorporation provides for it.

Cumulative voting is not permitted under Swiss corporate law. Pursuant to Swiss law, shareholders can vote for each proposed candidate, but they are not allowed to cumulate their votes for single candidates.

An annual individual election of (i) all members of the board of directors, (ii) the chairperson of the board of directors, (iii) the members of the compensation committee, (iv) the election of the independent proxy for a term of office of one year (i.e. until the following annual general meeting of shareholders), as well as the vote on the aggregate amount of compensation of the members of the board of directors, of the executive committee and of the members of any advisory board, is mandatory for listed companies. Re-election is permitted.

Removal of directors

A Delaware corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.

A Swiss corporation may remove, with or without cause, any director at any time with a resolution passed by a majority of the shares represented at a general meeting of shareholders. The articles of association may provide that a larger majority is required.

Transactions with interested shareholders

The Delaware General Corporation Law generally prohibits a Delaware corporation from engaging in certain business combinations with an “interested shareholder” for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15.0% or more of the corporation’s outstanding voting shares within the past three years.

No such rule applies to a Swiss corporation.

Dissolution; Winding-up

Unless the board of directors of a Delaware corporation approves the proposal to dissolve, dissolution must be approved by shareholders holding 100.0% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

A dissolution of a Swiss corporation requires the approval by two-thirds of the voting rights represented at the respective general meeting of shareholders as well as the majority of the par value of shares represented at such general meeting of shareholders. The articles of association may provide that a larger majorities are required.

Variation of rights of shares

A Delaware corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.

The general meeting of shareholders of a Swiss corporation may resolve that preference shares be issued or that existing shares be converted into preference shares with a resolution passed by a majority of the shares represented at the general meeting of shareholders.

Where a company has issued preference shares, further preference shares conferring preferential rights over the existing preference shares may be issued only with the consent of both a special meeting of the adversely affected holders of the existing preference shares and of a general meeting of all shareholders, unless otherwise provided in the articles of association. Shares with preferential voting rights are not regarded as preference shares for voting on such items.

Amendment of governing documents

A Delaware corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.

The articles of association of a Swiss corporation may be amended with a resolution passed by a majority of the shares represented at a general meeting of shareholders, unless otherwise provided by law or in the articles of association.

There are a number of resolutions, such as an amendment of the stated purpose of the corporation, the introduction of a capital band and conditional capital and the introduction of shares with preferential voting rights that require the approval by two-thirds of the votes and a majority of the par value of the shares represented at such general meeting of shareholders. The articles of association may increase these voting thresholds.

Inspection of books and records

Shareholders of a Delaware corporation, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation.

Shareholders of a Swiss corporation holding in the aggregate at least 5% of the nominal share capital or voting rights have the right to inspect books and records, subject to the safeguarding of the company's business secrets and other interests warranting protection. A shareholder is only entitled to receive information to the extent required to exercise his or her rights as a shareholder. The board of directors has to decide on an inspection request within four months after receipt of such request. Denial of the request will need to be justified in writing. If the board of directors denies an inspection request, shareholders may request the order of an inspection by the court within thirty days. A shareholder's right to inspect the share register is limited to the right to inspect his or her own entry in the share register.

Payment of dividends

The board of directors may approve a dividend without shareholder approval. Subject to any restrictions contained in its certificate of incorporation, the board may declare and pay dividends upon the shares of its capital stock either:

- out of its surplus; or
- in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year.

Shareholder approval is required to authorize capital stock in excess of that provided in the charter. Directors may issue authorized shares without shareholder approval.

Dividend (including interim dividend) payments and repayment of capital contributions (but not the nominal share capital) are subject to the approval of the general meeting of shareholders. The board of directors may propose to shareholders that a dividend shall be paid but cannot itself authorize the distribution.

Payments out of a corporation's share capital (in other words, the aggregate par value of the corporation's shares) in the form of dividends are not allowed and may be made only by way of a formal share capital reduction or a capital reduction within the capital band. Dividends may be paid only from the profits of the previous business year or brought forward from previous or current business years or if the corporation has distributable reserves, each as evidenced by the corporation's audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and the articles of association have been deducted.

Creation and issuance of new shares

The creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

All creation of shares require a shareholders' resolution. The creation of a capital band or conditional share capital requires at least two-thirds of the voting rights represented at the general meeting of shareholders and a majority of the par value of shares represented at such meeting.

The board of directors may create and issue or cancel shares out of the capital band during a period of up to five years by a maximum amount of 50% of the current share capital.

Shares may be created and issued by the board of directors out of conditional share capital through the exercise of options or of conversion rights that the board of directors may grant to shareholders, creditors of bonds or similar debt instruments, employees, directors of the company or another group company or third parties.

**Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Sylvia Cheung, certify that:

1. I have reviewed this annual report on Form 20-F of Oculis Holding AG (the “*Company*”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [Intentionally omitted];
 - (c) Evaluated the effectiveness of the Company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company’s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: March 28, 2023

By: /s/ Sylvia Cheung

Sylvia Cheung

Chief Financial Officer

(Principal Financial Officer)

**Certification by the Principal Executive Officer and Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report on Form 20-F of Oculis Holding AG (the “*Company*”) for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “*Report*”), I, Riad Sherif, Chief Executive Officer of the Company and Sylvia Cheung, Chief Financial Officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each hereby certifies that, to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2023

/s/ Riad Sherif

Chief Executive Officer
(Principal Executive Officer)

/s/ Sylvia Cheung

Chief Financial Officer
(Principal Financial Officer)
