UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934
For the Month of August 2026
(Commission File No. 001-41636)

Oculis Holding AG
(Translation of registrant's name into English)

Bahnhofstrasse 20
CH-6300
Zug, Switzerland
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On August 6, 2026, Oculis Holding AG (the "Registrant") announced its unaudited results for the three and six month periods ended June 30, 2026, which are further described in the Registrant's Unaudited Condensed Consolidated Interim Financial Statements, Management's Discussion and Analysis of Financial Condition and Results of Operations and press release, copies of which are attached hereto as Exhibits 99.1, 99.2 and 99.3, respectively, and are incorporated by reference herein.

The Registrant is also filing updated risk factors, attached hereto as Exhibit 99.4, describing risks and uncertainties that may affect the Registrant and the market price of its securities. These risk factors update and replace the Registrant's previously filed risk factors in its prior U.S. Securities and Exchange Commission ("SEC filings").

The information contained in this Form 6-K, including Exhibits 99.1, 99.2 and 99.4, but excluding Exhibit 99.3, is hereby incorporated by reference into the Registrant's Registration Statements on Form S-8 (File No. 333-271938 and 333-287806) and Form F-3 (File Nos. 333-271063, 333-278409, 333-291426 and 333-294011).

EXHIBIT INDEX

Exhibit	Description
99.1	Unaudited Condensed Consolidated Interim Financial Statements for the Three and Six Months Ended June 30, 2026
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations for the Three and Six Months Ended June 30, 2026
99.3	Press Release Dated August 6, 2026
99.4	Risk Factors

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OCULIS HOLDING AG

Date: August 6, 2026

By: /s/ Sylvia Cheung
Sylvia Cheung
Chief Financial Officer

Oculis Holding AG

Unaudited Condensed Consolidated Interim Financial Statements

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Oculis Holding AG
Unaudited Condensed Consolidated Interim Statements of Financial Position
(in CHF thousands)

	Note	As of June 30, 2026	As of December 31, 2025
ASSETS			
Non-current assets			
Property and equipment		482	534
Intangible assets		13,292	13,292
Right-of-use assets		2,648	2,463
Other non-current assets		847	785
Total non-current assets		**17,269**	**17,074**
Current assets			
Other current assets	6	3,216	4,883
Accrued income	6	1,526	993
Short-term financial assets	8	166,710	131,684
Cash and cash equivalents	8	61,614	81,329
Total current assets		**233,066**	**218,889**
TOTAL ASSETS		**250,335**	**235,963**
EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		679	587
Share premium		605,937	551,731
Reserve for share-based payment	7	38,133	30,387
Actuarial loss on post-employment benefit obligations		(1,595)	(1,634)
Treasury shares	4	(62)	(7)
Cumulative translation adjustments		(419)	(480)
Accumulated losses		(423,336)	(384,514)
Total equity		**219,337**	**196,070**
Non-current liabilities			
Long-term lease liabilities		1,792	1,811
Defined benefit pension liabilities		1,283	1,335
Total non-current liabilities		**3,075**	**3,146**
Current liabilities			
Trade payables		2,683	1,800
Accrued expenses and other payables	10	16,670	19,967
Short-term lease liabilities		751	502
Warrant liabilities	9	7,819	14,478
Total current liabilities		**27,923**	**36,747**
Total liabilities		**30,998**	**39,893**
TOTAL EQUITY AND LIABILITIES		**250,335**	**235,963**

The accompanying notes form an integral part of the Unaudited Condensed Consolidated Interim Financial Statements.

Oculis Holding AG
Unaudited Condensed Consolidated Interim Statements of Loss
(in CHF thousands, except loss per share data)

	Note	For the three months ended June 30,		For the six months ended June 30,	
		2026	**2025**	**2026**	**2025**
Grant income		310	261	519	545
Operating income		**310**	**261**	**519**	**545**
Research and development expenses	5	(15,283)	(14,909)	(29,329)	(29,680)
General and administrative expenses	5	(8,595)	(6,120)	(16,486)	(11,608)
Operating expenses		**(23,878)**	**(21,029)**	**(45,815)**	**(41,288)**
Operating loss		**(23,568)**	**(20,768)**	**(45,296)**	**(40,743)**
Finance income		592	520	959	1,013
Finance expense		(309)	(183)	(482)	(430)
Fair value adjustment on warrant liabilities	9	12,100	(234)	4,117	(12,145)
Foreign currency exchange gain (loss)	2.(D)	1,221	(4,734)	1,788	(6,301)
Finance result		**13,604**	**(4,631)**	**6,382**	**(17,863)**
Loss before tax for the period		**(9,964)**	**(25,399)**	**(38,914)**	**(58,606)**
Income tax benefit (expense)		(6)	24	92	17
Loss for the period		**(9,970)**	**(25,375)**	**(38,822)**	**(58,589)**
Loss per share:					
Basic and diluted loss attributable to equity holders	11	(0.16)	(0.49)	(0.65)	(1.16)

The accompanying notes form an integral part of the Unaudited Condensed Consolidated Interim Financial Statements.

Oculis Holding AG
Unaudited Condensed Consolidated Interim Statements of Comprehensive Loss
(in CHF thousands)

	For the three months ended June 30,		For the six months ended June 30,	
	2026	2025	2026	2025
Loss for the period	**(9,970)**	**(25,375)**	**(38,822)**	**(58,589)**
Other comprehensive income (loss):				
Items that will not be reclassified to Statements of Loss:				
Actuarial gain of defined benefit plans	333	26	39	613
Items that may be reclassified subsequently to loss:				
Foreign currency translation differences	36	(152)	61	(191)
Other comprehensive income (loss) for the period	**369**	**(126)**	**100**	**422**
Total comprehensive loss for the period	**(9,601)**	**(25,501)**	**(38,722)**	**(58,167)**

The accompanying notes form an integral part of the Unaudited Condensed Consolidated Interim Financial Statements.

Oculis Holding AG
Unaudited Condensed Consolidated Interim Statements of Changes in Equity
(in CHF thousands, except share numbers)

		Share capital		Treasury shares							
	Note	Shares	Share capital	Shares	Treasury shares	Share premium	Reserve for share-based payment	Cumulative translation adjustment	Actuarial gain (loss) on post-employment benefit obligations	Accumulated losses	Total
Balance as of January 1, 2025		**44,662,402**	**446**	**(1,000,000)**	**(10)**	**344,946**	**16,062**	**(271)**	**(2,233)**	**(285,557)**	**73,383**
Loss for the period		-	-	-	-	-	-	-	-	(58,589)	(58,589)
Other comprehensive income (loss):											
Actuarial gain on post-employment benefit obligations		-	-	-	-	-	-	-	613	-	613
Foreign currency translation differences		-	-	-	-	-	-	(191)	-	-	(191)
Total comprehensive income (loss) for the period		**-**	**-**	**-**	**-**	**-**	**-**	**(191)**	**613**	**(58,589)**	**(58,167)**
Share-based compensation expense	7	-	-	-	-	-	7,170	-	-	-	7,170
Issuance of ordinary shares related to underwritten offering	4	5,000,000	50	-	-	90,177	-	-	-	-	90,227
Transaction costs related to issuance of ordinary shares	4	-	-	-	-	(7,041)	-	-	-	-	(7,041)
Vesting of earnout shares		1,422,723	14	-	-	(14)	-	-	-	-	-
Issuance of shares to be held as treasury shares		2,500,000	25	(2,500,000)	(25)	-	-	-	-	-	-
Warrants exercised	9	1,817,063	19	-	-	35,863	-	-	-	-	35,882
Stock options exercised and RSUs vested/released	7	433,571	4	-	-	2,507	(869)	-	-	-	1,642
Balance as of June 30, 2025		**55,835,759**	**558**	**(3,500,000)**	**(35)**	**466,438**	**22,363**	**(462)**	**(1,620)**	**(344,146)**	**143,096**
Balance as of January 1, 2026		**58,688,141**	**587**	**(703,703)**	**(7)**	**551,731**	**30,387**	**(480)**	**(1,634)**	**(384,514)**	**196,070**
Loss for the period		-	-	-	-	-	-	-	-	(38,822)	(38,822)
Other comprehensive loss:											
Actuarial gain on post-employment benefit obligations		-	-	-	-	-	-	-	39	-	39
Foreign currency translation differences		-	-	-	-	-	-	61	-	-	61
Total comprehensive loss for the period		**-**	**-**	**-**	**-**	**-**	**-**	**61**	**39**	**(38,822)**	**(38,722)**
Share-based compensation expense	7	-	-	-	-	-	11,644	-	-	-	11,644
Issuance of ordinary shares pursuant to ATM Program	4	-	-	2,250,000	22	47,753	-	-	-	-	47,775
Transaction costs related to the issuance of ordinary shares	4	-	-	-	-	(2,186)	-	-	-	-	(2,186)
Vesting of earnout shares		948,549	9	-	-	(9)	-	-	-	-	-
Issuance of shares to be held as treasury shares	4	7,750,400	77	(7,750,400)	(77)	-	-	-	-	-	-
Warrants exercised	9	186,929	2	-	-	4,177	-	-	-	-	4,179
Stock options exercised and RSUs vested/released	7	362,148	4	-	-	4,471	(3,898)	-	-	-	577
Balance as of June 30, 2026		**67,936,167**	**679**	**(6,204,103)**	**(62)**	**605,937**	**38,133**	**(419)**	**(1,595)**	**(423,336)**	**219,337**

The accompanying notes form an integral part of the Unaudited Condensed Consolidated Interim Financial Statements.

Oculis Holding AG
Unaudited Condensed Consolidated Interim Statements of Cash Flows

(in CHF thousands)

	Note	For the six months ended June 30, 2026	2025
Operating activities			
Loss before tax for the period		**(38,914)**	**(58,606)**
Non-cash adjustments:			
- Financial result		(2,576)	4,679
- Depreciation of property and equipment and right-of-use assets		332	236
- Share-based compensation expense	7	11,644	7,170
- Post-employment loss		(30)	33
- Fair value adjustment on warrant liabilities	9	(4,117)	12,145
Working capital adjustments:			
- Decrease in other current assets	6	1,516	1,420
- Increase in accrued income	6	(533)	(550)
- Decrease in payables and accrued liabilities	10	(2,865)	(2,669)
- Increase in other operating assets		(40)	(55)
Taxes received (paid)		12	(8)
Net cash outflow for operating activities		**(35,571)**	**(36,205)**
Investing activities			
Payment for short-term financial assets, net	8	(34,451)	(25,081)
Interest received		489	583
Payment for intangible assets		-	(1,087)
Payment for purchase of property and equipment		(21)	(139)
Net cash outflow for investing activities		**(33,983)**	**(25,724)**
Financing activities			
Proceeds from sale of shares in public offerings	4	47,775	90,227
Transaction costs related to financing activities	4	(1,051)	(6,107)
Proceeds from exercise of warrants, net	9	1,636	18,858
Proceeds from stock options exercised	7	577	1,642
Principal payment of lease obligations		(231)	(161)
Interest paid		(69)	(23)
Net cash inflow from financing activities		**48,637**	**104,436**
Net increase (decrease) in cash and cash equivalents		**(20,917)**	**42,507**
Cash and cash equivalents, beginning of period	8	81,329	27,708
Effect of foreign exchange rate changes		1,202	(5,950)
Cash and cash equivalents, end of period	8	61,614	64,265
Net cash and cash equivalents variation		**(20,917)**	**42,507**
Supplemental non-cash investing information			
Interest receivable recorded in other current assets		474	428
Supplemental non-cash financing information			
Transaction costs, including stamp duties, recorded in accrued expenses and other payables		1,352	893

The accompanying notes form an integral part of the Unaudited Condensed Consolidated Interim Financial Statements.

1. CORPORATE INFORMATION

Oculis Holding AG (the "*Company*" or "*Oculis*") is a stock corporation (*Aktiengesellschaft*) with its registered office at Bahnhofstrasse 20, CH-6300, Zug, Switzerland. It was incorporated under the laws of Switzerland on October 31, 2022, and controls seven wholly owned subsidiaries. The Company and its wholly-owned subsidiaries form the Oculis Group (the "*Group*"). Unless the context otherwise dictates, a reference to "the Company" "us," "we" or "our" refers to Oculis and its subsidiaries.

Oculis is a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology. Oculis' legacy asset, OCS-01, had topline results announced in May 2026. The primary endpoint of the two Phase 3 trials was not met, and the Company decided not to pursue an FDA NDA regulatory filing for OCS-01 in diabetic macular edema ("*DME*"). Management has assessed and concluded that there is no impairment or significant impact on the financial position of the Company as a result of the OCS-01 DME readout. Oculis shifted focus to its highly differentiated late-stage clinical pipeline with two core product candidates: Privosegtor, a breakthrough neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies including optic neuritis and non-arteritic anterior ischemic optic neuropathy, with the potential to be developed for additional indications in neuro-ophthalmic and neuro-axonal diseases; and Licaminlimab, a novel, topical anti-TNFα in a registrational trial, which is being developed with a genotype-based approach for treating patients with dry eye disease.

The Audit Committee of the Board of Directors approved the issuance of the unaudited interim condensed consolidated financial statements on August 3, 2026.

2. BASIS OF PREPARATION AND CHANGES TO THE COMPANY'S ACCOUNTING POLICIES

(A) Going concern

The Company's accounts are prepared on a going concern basis. The Board of Directors believes that based on the Company's current cash, cash equivalents and investments, the Company has the ability to meet its financial obligations for at least the next 12 months.

The Company is a late clinical-stage company and is exposed to all the risks inherent to establishing a business, 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 preclinical and clinical development; (iv) successfully obtain regulatory approval and commercialize its products; and (v) attract and retain key personnel. The Company's success is subject to its ability to raise capital to support its current and future operations. To date, the Company has financed its cash requirements primarily through the sale of equity shares. 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 of its 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.

(B) Material accounting policies

Due to their short-term nature, the carrying value of cash and cash equivalents, short-term financial assets, other current assets excluding prepaid expenses, accrued income, lease liabilities, trade payables, accrued expenses and other payables approximates their fair value. There have been no material changes to the accounting policies that were applied by the Company in its audited consolidated financial statements as of and for the year ended December 31, 2025, included in Form 20-F filed with the U.S. Securities and Exchange Commission ("*SEC*") on March 4, 2026 and available at www.sec.gov.

(C) Statement of compliance

These unaudited condensed consolidated interim financial statements as of June 30, 2026 and for the three and six months ended June 30, 2026 and 2025, have been prepared in accordance with International Accounting Standard ("*IAS"*) 34 - *Interim Financial Reporting*. They do not include all of the information required for a complete set of financial statements prepared in accordance with IFRS Accounting Standards ("*IFRS*") as issued by the International Accounting Standards Board ("*IASB*"). In the opinion of the Company, the accompanying unaudited condensed consolidated interim financial statements present a fair statement of its financial information for the interim periods reported.

(D) Functional currency

The unaudited condensed consolidated interim financial statements of the Group are expressed in Swiss Francs ("*CHF*"), which is the Company's functional and the Group's presentation currency. The functional currency of the Company's subsidiaries is the local currency except for Oculis ehf, the Company's Icelandic subsidiary, whose functional currency is CHF. Included in the Company's finance result are foreign currency exchange gains of CHF 1.2 million and CHF 1.8 million for the three and six months ended June 30, 2026, respectively, arising from favorable fluctuations of the U.S. dollar against the Swiss Franc, impacting the valuation of the Company's cash and short-term financial assets balances.

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 average monthly exchange rates. The exchange differences arising on translation for consolidation are recognized in other comprehensive income.

3. SUMMARY OF MATERIAL ACCOUNTING POLICIES, CRITICAL JUDGMENTS AND ACCOUNTING ESTIMATES

(A) Critical judgments and accounting estimates

In preparing these unaudited condensed consolidated interim financial statements, the critical accounting estimates, assumptions and judgments made by management in applying the Company's accounting policies and the key sources of estimation uncertainty were the same as those applied and discussed in the audited consolidated financial statements for the year ended December 31, 2025.

(B) New accounting standards, interpretations, and amendments adopted by the Company

There are no new IFRS Accounting Standards, amendments to standards or interpretations that are mandatory for the financial year beginning on January 1, 2026, that have a material impact in the interim period. In April 2024, the IASB issued IFRS 18 - *Presentation and Disclosure in Financial Statements*. The standard, which will replace IAS 1, impacts the presentation of primary financial statements and notes, including the statement of profit and loss where companies will be required to present separate categories of income and expense for operating, investing, and financing activities with prescribed subtotals for each new category. It also requires disclosure of management defined performance measures, if applicable, and includes new requirements for aggregation and disaggregation of financial information. The standard is effective for annual reporting periods beginning on or after January 1, 2027, and requires retrospective application. While IFRS 18 will not change recognition criteria or measurement bases, it may have a significant impact on the presentation of information in the financial statements, in particular the profit and loss statement. Based on current analysis, the impact on the consolidated financial statements is expected to be limited to presentation and disclosure changes.

To date, the following potential impacts have been identified:

- Items of income and expenses presented in the consolidated income statement will be grouped into the new categories: operating, investing, financing, and income tax expense/benefit;
- an additional mandatory subtotal for "income (loss) before financing and income taxes" will be presented;
- the enhanced principles on aggregation and disaggregation, and the useful "structured summary" concept, may require some changes to line items presented in the primary financial statements, however the change is not expected to be significant;
- certain new or enhanced disclosures will be required for management-defined performance measures (MPMs), if deemed applicable, and a reconciliation for each line item in the consolidated income statement between the restated amounts and the amounts previously published upon transition of IAS 1 to IFRS 18; and
- there will also be a minor impact on the presentation of the consolidated statement of cash flows as the starting point for the cash flow statement will be the "operating income (loss)" subtotal.

The Company intends to adopt IFRS 18 for the reporting period commencing January 1, 2027. Preparatory activities are underway to ensure readiness for adoption.

4. FINANCING ACTIVITY

The Company's historical financing activities, including equity offerings, private placements, and debt arrangements, are described in detail in Note 5 to the consolidated financial statements included in the Company's Annual Report on Form 20-F for the year ended December 31, 2025, filed with the SEC on March 4, 2026.

During the six months ended June 30, 2026, in connection with the Company's existing at-the-market offering program (the "*ATM Program*"), the Company issued 7,750,400 ordinary shares out of its existing capital band with a nominal value of CHF 0.01 held as treasury shares. The Company sold 2,250,000 ordinary shares under the ATM Program for gross proceeds of CHF 47.8 million, or $61.3 million. The Company had CHF 2.2 million of transaction costs that were offset against the proceeds and have been recorded as a reduction of share premium during the first half of 2026.

On November 3, 2025, the Company closed offerings of an aggregate of 5,432,098 ordinary shares at a price of $20.25 (CHF 16.33) per share for total gross proceeds of $110.0 million (CHF 88.7 million) before deducting underwriting discounts and commissions and offering expenses. The Company issued 2,635,801 shares out of the Company's existing capital band and 2,796,297 shares previously held in treasury.

On July 31, 2025, the Company amended its existing loan facility with Kreos Capital VII (UK) Limited (the "*Lender*"), which are funds and accounts managed by BlackRock, Inc. (the "*Amended Loan Agreement*"). The Amended Loan Agreement is structured to provide the EUR equivalent of up to CHF 75.0 million in borrowing capacity (which may be increased to up to CHF 100.0 million), comprising tranches 1 ("*Loan 1*"), 2 ("*Loan 2*") and 3 ("*Loan 3*" and together with Loan 1 and Loan 2, the "*Loan*"), in the amounts of the EUR equivalents of CHF 25.0 million each, as well as an additional loan of the EUR equivalent of up to CHF 25.0 million. Pursuant to the Amended Loan Agreement, the Company is subject to a non-utilization fee of 0.75% per annum of any undrawn amount under tranches 1 and 2. No amounts were drawn under the Amended Loan Agreement during the six months ended June 30, 2026 and 2025.

In conjunction with the Loan, the Company entered into an amended warrant (the "*Amended BlackRock Warrant*") with Kreos Capital VII Aggregator SCSp, an affiliate of the Lender (the "*Holder*"), under which the Holder can purchase up to 494,259 of the Company's ordinary shares, at a price per ordinary share equal to $12.17 (CHF 9.84) with respect to 361,011 shares from the prior warrant agreement, and $18.64 (CHF 15.07) with respect to the remaining 133,248 shares. At signing, the Amended BlackRock Warrant was immediately exercisable for 59,310 ordinary

shares. Following the drawdown of each of Loan 1, Loan 2 and Loan 3, the Amended BlackRock Warrant will become exercisable for additional amounts of ordinary shares ratably based on the amounts of Loan 1, Loan 2 and Loan 3 that are drawn. The Amended BlackRock Warrant had not been exercised in part or in full as of June 30, 2026.

In February 2025, the Company closed an underwritten follow-on offering of 5,000,000 ordinary shares at a price of $20.00 (CHF 18.05) per share, for total gross proceeds of $100.0 million (CHF 90.2 million). In connection with this offering, the Company incurred $7.5 million (CHF 6.8 million) of transaction costs during the six months ended June 30, 2025 that are presented as a reduction of share premium within the statement of changes in equity.

5. OPERATING EXPENSES

Operating expenses

The tables below show the breakdown of the operating expenses by category:

	For the three months ended June 30,					
	Research and development expenses		General and administrative expenses		Total operating expenses	
	2026	2025	2026	2025	2026	2025
Personnel expenses	**6,277**	**4,834**	**5,583**	**3,730**	**11,860**	**8,564**
Payroll and related expenses	3,051	2,319	2,166	1,705	5,217	4,024
Share-based compensation	3,226	2,515	3,417	2,025	6,643	4,540
Other operating expenses	**9,006**	**10,075**	**3,012**	**2,390**	**12,018**	**12,465**
External service providers	8,302	9,756	1,966	1,701	10,268	11,457
Other operating expenses	599	238	973	657	1,572	895
Depreciation expense	105	81	73	32	178	113
Total operating expenses	**15,283**	**14,909**	**8,595**	**6,120**	**23,878**	**21,029**

	For the six months ended June 30,					
	Research and development expenses		General and administrative expenses		Total operating expenses	
	2026	2025	2026	2025	2026	2025
Personnel expenses	**11,656**	**9,182**	**10,235**	**6,587**	**21,891**	**15,769**
Payroll and related expenses	5,757	4,766	4,490	3,833	10,247	8,599
Share-based compensation expense	5,899	4,416	5,745	2,754	11,644	7,170
Other operating expenses	**17,673**	**20,498**	**6,251**	**5,021**	**23,924**	**25,519**
External service providers	16,444	19,943	4,496	3,768	20,940	23,711
Other operating expenses	1,034	398	1,618	1,174	2,652	1,572
Depreciation expense	195	157	137	79	332	236
Total operating expenses	**29,329**	**29,680**	**16,486**	**11,608**	**45,815**	**41,288**

Total operating expenses increased for the three and six months ended June 30, 2026 compared to the prior year periods. The increase for the three months ended June 30, 2026 was primarily driven by a CHF 2.5 million increase in general and administrative expense. The increase for the six months ended June 30, 2026 was driven by a CHF 4.9 million increase in general and administrative expenses, partially offset by a CHF 0.4 million decrease in research and development expenses. The increases in general and administrative costs were primarily driven by personnel costs, specifically share-based compensation expense due to increased headcount and increased grant value for awards granted during the three and six months ended June 30, 2026 as compared to the same periods in the prior year. The year-to-date decrease in research and development expense was primarily due to a decrease in external service provider expense as OCS-01 DIAMOND-1 and DIAMOND-2 trials in diabetic macular edema were completed, for which the Company announced topline results in May 2026.

6. OTHER CURRENT ASSETS AND ACCRUED INCOME

The table below shows the breakdown of other current assets by category:

	As of June 30, 2026	As of December 31, 2025
Prepaid general and administrative expenses	2,409	2,492
Prepaid clinical and technical development expenses	486	1,590
VAT, interest and tax-related receivables	321	801
Total	**3,216**	**4,883**

The decrease in prepaid general and administrative expenses as of June 30, 2026 compared to prior year end was due to capitalized transaction costs associated with the Company's ATM Program that were reclassified to a reduction of share premium as a result of ordinary share sales under the program during the six months ended June 30, 2026.

The table below shows the movement of accrued income for the six months ended June 30, 2026 and 2025:

	2026	2025
Balance as of January 1,	**993**	**629**
Accrued income recognized during the period	519	545
Foreign exchange revaluation	14	5
Balance as of June 30,	**1,526**	**1,179**

Accrued income is generated by incentives for research and development offered by the Icelandic government in the form of tax credits for innovation companies. These tax credits are either used to reduce the Company's income tax liability or, if the credits exceed the tax due, they are paid out in cash. The tax credit is subject to companies having a research project approved as eligible for tax credit by the Icelandic Center for Research (*Rannís*).

7. SHARE-BASED COMPENSATION

2023 Employee Stock Option and Incentive Plan

On March 2, 2023, the Company adopted the 2023 Employee Stock Option and Incentive Plan ("*2023 ESOP*") which allows for the grant of equity incentives, including share-based options, stock appreciation rights ("*SARs*"), restricted stock units ("*RSUs*") and other awards. The 2023 ESOP lays out the details for the equity incentives for talent acquisition and retention purposes. Each grant of share-based options made under the 2023 ESOP entitles the grantee to acquire ordinary shares with payment of the exercise price in cash. The Company intends to settle any options, RSUs and SARs granted only in ordinary shares. Following the Company's Annual General Meeting on May 13, 2026, the total conditional share capital available for issuance under the 2023 ESOP was increased to 12,677,700 ordinary shares.

Option awards and SARs

The fair value of option awards and SARs is determined using the Black-Scholes option-pricing model. The weighted average grant date fair value for options and SARs granted during the six months ended June 30, 2026 was CHF 14.30 or $18.17 per share. The weighted average grant date fair value for options and SARs granted during the six months ended June 30, 2025 was CHF 12.48 or $14.47 per share.

The following assumptions were used in the Black-Scholes option pricing model for determining the value of options and SARs granted during the six months ended June 30, 2026 and 2025:

	For the six months ended June 30,	
	2026	2025
Weighted average share price at the date of grant[(1)]	$26.82 (CHF 21.11)	$18.68 (CHF 16.11)
Range of expected volatilities (%)[(2)]	68.01 - 86.38	89.91 - 91.39
Range of expected terms (years)[(3)]	5.50 - 6.25	6.25
Range of risk-free interest rates (%)[(4)]	3.75 - 4.37	3.94 - 4.26
Dividend yield (%)	0.00	0.00

[(1)] The equity award exercise price is denominated in USD.
[(2)] The expected volatility was derived from the historical stock volatilities of the Company, as well as comparable peer public companies within the Company's industry.
[(3)] The expected term represents the period that share-based awards are expected to be outstanding.
[(4)] The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected terms.

The following table summarizes the Company's stock option and SAR activity under the 2023 ESOP for the six months ended June 30, 2026 and 2025:

	2026			2025		
	Number of awards	Weighted average exercise price (CHF)	Range of expiration dates	Number of awards	Weighted average exercise price (CHF)	Range of expiration dates
Outstanding as of January 1,	**5,163,946**	**8.32**	**2028 - 2035**	**4,687,054**	**6.82**	**2028 - 2034**
Options granted	1,116,899	21.11	2036	1,035,131	16.11	2035
Forfeited[(1)]	(91,746)	13.18	2033 - 2036	(297,978)	8.31	2033 - 2034
Exercised[(1)]	(72,750)	8.05	2028 - 2034	(335,581)	5.02	2033 - 2034
Outstanding as of June 30,	**6,116,349**	**10.22**	**2028 - 2036**	**5,088,626**	**8.48**	**2028 - 2035**

[(1)] Forfeited amount includes earnout options forfeited during the six month periods ended June 30, 2026 and 2025. No SARs had been exercised or forfeited during the six months ended June 30, 2026 and 2025.

The number of options and SARs that were exercisable at June 30, 2026 and 2025 were 3,306,692 and 2,236,218, respectively. Excluding earnout options, which have an exercise price of CHF 0.01, options outstanding as of June 30, 2026 have exercise prices ranging from CHF 1.54 to CHF 24.69. The weighted average remaining contractual life of options and SARs outstanding as of June 30, 2026 and December 31, 2025 was seven years.

Restricted stock units

Each RSU granted under the 2023 ESOP entitles the grantee to one ordinary share upon vesting of the RSU. The Company intends to settle all RSUs granted in equity. The fair value of RSUs is determined by the closing stock price on the date of grant and the related compensation cost is amortized over the vesting period of the award using the graded method. RSUs have time-based vesting conditions ranging from one to four years. The following is a summary of RSU activity for the six months ended June 30, 2026 and 2025:

	2026			2025		
	Number of awards	Weighted average grant date fair value (CHF)	Range of expiration dates	Number of awards	Weighted average grant date fair value (CHF)	Range of expiration dates
Outstanding as of January 1,	**1,007,636**	**13.93**	**2034 - 2035**	**467,478**	**9.81**	**2034**
RSUs granted	766,262	21.20	2036	646,741	16.16	2035
RSUs vested/released	(289,398)	13.78	2034 - 2036	(97,990)	9.55	2034
Outstanding as of June 30,	**1,484,500**	**17.22**	**2034 - 2036**	**1,016,229**	**14.31**	**2034 - 2035**

Share-based compensation expense

The total share-based compensation expense recognized in the statement of loss amounted to CHF 6.6 million and CHF 11.6 million for the three and six months ended June 30, 2026, respectively, including CHF 3.2 million and CHF 5.4 million recognized during the three and six months ended June 30, 2026, respectively, related to RSUs outstanding. Total share-based compensation recognized in the statement of loss was CHF 4.5 million and CHF 7.2 million for the three and six months ended June 30, 2025, respectively, including CHF 1.7 million and CHF 2.6 million recognized during the three and six months ended June 30, 2025, respectively, related to RSUs outstanding. The reserve for share-based payment increased from CHF 30.4 million as of December 31, 2025 to CHF 38.1 million as of June 30, 2026.

Earnout options

As a result of the Company's 2023 business combination agreement with European Biotech Acquisition Corp ("*BCA*"), certain pre-BCA Oculis equity holders received consideration in the form of 3,793,995 earnout shares and 369,737 earnout options with an exercise price of CHF 0.01. Vesting of earnout shares and options was based on the achievement of post acquisition-closing volume weighted average share price targets of Oculis of $15.00, $20.00 and $25.00, in each case, for any 20 trading days within any consecutive 30 trading day period commencing after the acquisition closing date and ending on or prior to March 2, 2028. The price targets of $15.00, $20.00 and $25.00 were met in November 2024, February 2025 and February 2026, respectively, resulting in an aggregate of 3,793,995 earnout shares vesting and certain earnout options becoming exercisable. As of June 30, 2026, 211,148 earnout options were exercisable.

8. CASH AND CASH EQUIVALENTS, AND SHORT-TERM FINANCIAL ASSETS

The table below shows the breakdown of the cash and cash equivalents and short-term financial assets by currencies:

	Cash and cash equivalents		Short-term financial assets	
By currency	**As of June 30, 2026**	**As of December 31, 2025**	**As of June 30, 2026**	**As of December 31, 2025**
Swiss Franc	5,852	45,716	143,000	126,000
US Dollar	51,916	33,766	13,182	1,031
Euro	3,702	539	6,458	4,653
Other	144	1,308	4,070	-
Total	**61,614**	**81,329**	**166,710**	**131,684**

Cash and cash equivalents consist primarily of cash balances held at commercial banks. Short-term financial assets consist of fixed term bank deposits with maturities between three and six months.

9. WARRANT LIABILITIES

The following table summarizes the Company's outstanding warrant liabilities by warrant type as of June 30, 2026 and 2025:

	2026			2025		
	BCA Warrants	Amended BlackRock Warrant	Total Warrant Liabilities	BCA Warrants	BlackRock Warrant	Total Warrant Liabilities
Balance as of January 1,	**13,881**	**597**	**14,478**	**19,390**	**461**	**19,851**
Fair value (gain) loss on warrant liability	(3,824)	(293)	(4,117)	12,145	-	12,145
Exercise of public and private warrants	(2,542)	-	(2,542)	(16,886)	-	(16,886)
Balance as of June 30,	**7,515**	**304**	**7,819**	**14,649**	**461**	**15,110**

The BCA warrants represent public and private placement warrants assumed from European Biotech Acquisition Corp. as part of the BCA ("*BCA Warrants*"). The fair value of the public BCA Warrants, which are traded on Nasdaq, is based on the quoted Nasdaq market prices at the end of the reporting period for such warrants. Since the private placement BCA Warrants have identical terms to the public BCA Warrants, the Company determined that the fair value of each private placement BCA Warrant is equivalent to that of each public BCA Warrant. The public BCA Warrants are included in Level 1 and the private placement BCA Warrants in Level 2 of the fair value hierarchy. BCA Warrants are classified as short-term liabilities given that the Company cannot defer the settlement for at least 12 months.

The Company's Amended BlackRock Warrant, described in Note 4, is classified as a liability because its exercise prices are fixed in USD, which is not the functional currency of the Company and therefore it does not meet the requirements to be classified as equity under IFRS. The fair value of the Amended BlackRock Warrant is determined using the Black-Scholes option-pricing model and is included in Level 3 of the fair value hierarchy.

The following assumptions were used in the Black-Scholes option-pricing model for determining the fair value of the Amended BlackRock Warrant as of June 30, 2026 and December 31, 2025:

	June 30, 2026	December 31, 2025
Share price on valuation date	$13.87 (CHF 11.22)	$19.97 (CHF 15.83)
Range of expected volatility (%)[(1)]	67.90 - 68.92	82.52 - 85.13
Range of expected term (years)[(2)]	2.46 - 3.05	2.71 - 3.29
Range of risk-free interest rate (%)[(3)]	4.14 - 4.15	3.53 - 3.58
Dividend yield (%)	0.00	0.00

[(1)] The expected volatility was derived from the historical stock volatilities of the Company, as well as comparable peer public companies within the Company's industry.
[(2)] The expected term represents the period that the Amended BlackRock Warrant is expected to be outstanding.
[(3)] The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected terms.

For the three and six months ended June 30, 2026, the Company recognized fair value gains of CHF 12.1 million and CHF 4.1 million, respectively, which were attributable to the decreasing market price of outstanding public warrants during the period. For the three and six months ended June 30, 2025, the Company recognized fair value losses of CHF 0.2 million and CHF 12.1 million, respectively, which were attributable to the increasing market price of outstanding public warrants during the period.

In the event of exercise, warrant liabilities are reduced by the fair value on the date of exercise. The resulting fair value adjustment and cash received are recorded to share premium within the Statements of Changes in Equity. The movement of the warrant liability during the six months ended June 30, 2026 and 2025 is illustrated below:

	2026		2025	
	Warrant liabilities	Number of outstanding warrants	Warrant liabilities	Number of outstanding warrants
Balance as of January 1,	**14,478**	**2,104,906**	**19,851**	**4,018,384**
Fair value (gain) loss on warrant liability	(4,117)	-	12,145	-
Exercise of public and private warrants	(2,542)	(186,929)	(16,886)	(1,817,063)
Balance as of June 30,	**7,819**	**1,917,977**	**15,110**	**2,201,321**

10. ACCRUED EXPENSES AND OTHER PAYABLES

The table below shows the breakdown of the accrued expenses and other payables by category:

	As of June 30, 2026	As of December 31, 2025
Product development related expenses	10,478	13,156
Personnel related expenses	3,684	4,491
General and administration related expenses	1,161	1,385
Other payables	1,347	935
Total	**16,670**	**19,967**

The decrease in accrued personnel related expenses during the year was primarily related to the payout of bonus amounts accrued as of December 31, 2025. The decrease in product development-related accrued expenses as of June 30, 2026 relative to the prior year-end primarily reflects the timing of invoices and advancements of clinical trials.

11. LOSS PER SHARE

As of June 30, 2026, the Company had 61,732,064 ordinary shares issued and outstanding with a share price of $13.87 or CHF 11.22. The following table sets forth the loss per share calculations for the three and six months ended June 30, 2026 compared to the three and six months ended June 30, 2025.

	For the three months ended June 30,		For the six months ended June 30,	
	2026	2025	2026	2025
Net loss for the period attributable to Oculis shareholders	(9,970)	(25,375)	(38,822)	(58,589)
Loss per share				
Weighted-average number of shares used to compute basic and diluted loss per share	61,270,798	52,288,911	60,096,277	50,297,119
Basic and diluted net loss per share for the period, in CHF	**(0.16)**	**(0.49)**	**(0.65)**	**(1.16)**

Since the Company has a loss for all periods presented, basic net loss per share is the same as diluted net loss per share. Potentially dilutive securities that were not included in the diluted loss per share calculations because they would be anti-dilutive were as follows:

	As of June 30, 2026	As of June 30, 2025
Share options issued and outstanding	5,904,745	4,870,628
Earnout options	211,604	217,998
Share and earnout options issued and outstanding	6,116,349	5,088,626
Restricted stock units subject to future vesting	1,484,500	1,016,229
Public warrants	1,706,968	2,006,301
Private warrants	151,699	151,699
Amended BlackRock Warrant	59,310	43,321
Earnout shares	-	948,549
Total	**9,518,826**	**9,254,725**

12. RELATED PARTY DISCLOSURES

Compensation of key management, including the Board of Directors and the executive management team, was as follows:

	For the three months ended June 30,		For the six months ended June 30,	
	2026	2025	2026	2025
Salaries, cash compensation and other short-term benefits	1,650	1,305	3,184	3,060
Pension	146	130	298	235
Share-based compensation expense	4,971	3,322	8,377	4,844
Total	**6,767**	**4,757**	**11,859**	**8,139**

Salaries, cash compensation and other short-term benefits include social security and board member fees.

The number of key management individuals reported as receiving compensation in the table above increased from 9 to 10 for the six months ended June 30, 2026 as compared to the six months ended June 30, 2025. The number of individuals receiving compensation for service on the Board of Directors as reported in the table above was 4 for both periods presented.

13. SUBSEQUENT EVENTS

There are no material subsequent events.

Exhibit 99.2

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The Unaudited Condensed Consolidated Interim Financial Statements as of and for the three and six months ended June 30, 2026 are included as Exhibit 99.1 to this Report on Form 6-K submitted to the Securities and Exchange Commission ("SEC"). We also recommend that you read our discussion and analysis of financial condition and results of operations together with the audited financial statements and notes thereto for the year ended December 31, 2025 and the section entitled "Risk Factors" included as Exhibit 99.4 to the Report on Form 6-K to which this exhibit is attached and our subsequent filings with the SEC. The following discussion and analysis contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (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. As discussed in the below section titled "Cautionary Note Regarding Forward-Looking Statements," all forward-looking statements included in this discussion and analysis are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. The terms "Company," "Oculis," "we," "our" or "us" as used herein refer to Oculis Holding AG and its consolidated subsidiaries unless otherwise stated or indicated by context.

The Unaudited Condensed Consolidated Interim Financial Statements as of and for the three and six months ended June 30, 2026 were prepared in accordance with IFRS Accounting Standards ("IFRS"), specifically International Accounting Standard ("IAS") 34- Interim Financial Reporting, as issued by the International Accounting Standards Board ("IASB") and are presented in Swiss Francs (CHF) unless otherwise indicated. Amounts, aside from share data, are presented in thousands unless otherwise indicated.

Company Overview

We are a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology, headquartered in Switzerland with operations in Switzerland, the U.S. and Iceland. Our highly differentiated late-stage clinical pipeline focuses on two core product candidates: Privosegtor, a breakthrough neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies like optic neuritis (*"ON"*) and non-arteritic anterior ischemic optic neuropathy (*"NAION"*), with the potential to be developed for additional indications in neuro-ophthalmic and neuro-axonal diseases, and Licaminlimab, a novel, topical anti-TNFα in a registrational trial, which is being developed with a genotype-based approach for treating patients with dry eye disease (*"DED"*).

Recent Developments

We completed our OCS-01 DIAMOND Stage 2 program, which included two global pivotal Phase 3 clinical trials, DIAMOND-1 and DIAMOND-2, for the treatment of diabetic macular edema (*"DME"*). The topline results from the DIAMOND trials were announced in May of 2026. The primary endpoint, mean change in best corrected visual acuity early treatment diabetic retinopathy study (BCVA ETDRS) letter score at Week 52, was not met in both trials. The secondary endpoint of retinal thickness, as measured by OCT, showed a substantial and persistent reduction with OCS-01 vs. vehicle at all visits in DIAMOND-2 and at all visits except Week 52 in DIAMOND-1. The key secondary endpoint of the proportion of patients with ≥15-letter gain in BCVA was not met in both trials. OCS-01 was well tolerated, with no unexpected adverse events observed, and the overall safety profile was consistent with that of previous trials. Based on the results, at this time, we do not plan to pursue an FDA regulatory filing for OCS-01 in DME.

Privosegtor, a novel small molecule peptoid that penetrates blood-brain and retinal barriers, was selected by high-throughput screening for neurotrophic and neuroprotective properties. Following a successful meeting with the FDA in the third quarter of 2025, we advanced Privosegtor into the PIONEER registrational program for ON and NAION. PIONEER-1 is currently in the global site initiation and activation phase, with PIONEER-2 planned to follow later in the year; both trials will evaluate Privosegtor for the treatment of ON. The third trial in the PIONEER program, PIONEER-3, will evaluate Privosegtor after the acute onset of NAION and is expected to follow after PIONEER-1 and -2. Privosegtor was granted PRIME (PRIority MEdicines) designation by the European Medicines Agency, a highly selective process to provide early and proactive support to developers of promising medicines that may offer a major therapeutic advantage over existing treatments or provide benefits to patients without treatment options. This follows the recent granting of Breakthrough Therapy designation for Privosegtor for the treatment of ON by the FDA, reinforcing global regulatory support for this unique neuroprotective asset. In May 2026, we received written agreement from the FDA under a Special Protocol Assessment (SPA) regarding PIONEER-1 to confirm that the design and planned analysis of the PIONEER-1 study are adequate to address the objectives necessary to support a future NDA submission, subject to a successful trial outcome and FDA review of the complete submission. In August 2026, the FDA's Division of Neurology provided guidance that no additional preclinical studies will be required ahead of an Investigational New Drug (IND) submission for Privosegtor in acute MS relapses, cross-referencing the data from the open ON IND residing in the Division of Ophthalmology. Constructive FDA feedback also supports the proposed clinical development strategy and regulatory pathway, which will include MS patients with both optic neuritis and other relapses, such as ambulatory relapses, in future trials. Oculis anticipates an IND submission for the treatment of acute MS relapses in the fourth quarter of 2026.

Licaminlimab is a next-generation biologic treatment being evaluated for ocular inflammation, specifically as a treatment for DED. We are actively enrolling patients in the PREDICT-1 genotype-based registrational trial in dry eye disease (DED) evaluating Licaminlimab as a precision medicine treatment. All planned trial sites have been activated and >45% patients have been randomized. With Licaminlimab PREDICT-1 trial site activations complete and a third of patients enrolled, we expect to report topline results around year-end.

Components of Results of Operations

Revenue

We have not generated any revenue from product sales 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 and 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 near 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*. Capitalization does not result in amortization until the related product is approved for commercialization, where a finite useful economic life can be more reliably determined. To date, all capitalized research and development intangible assets remain unamortized.

Research and development expenses include:

- personnel-related expenses, including salaries, related benefits and equity-based compensation expense, for employees and third-party consultants 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*"), as well as clinical trial investigative sites and consultants that conduct our clinical trials;
- costs related to contract manufacturing organizations that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as costs of acquiring and manufacturing non-clinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to non-clinical studies and other scientific development services;
- costs related to compliance with quality and regulatory requirements; and
- costs related to formulation research, intellectual property expenses, facilities, overhead, depreciation and amortization of laboratory equipment and other expenses.

For the three and six months ended June 30, 2026 and 2025, no research and development costs were capitalized by the Company.

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 ongoing and 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.

General and administrative expenses

General and administrative expenses consist primarily of internal and external costs related to executive management, finance and accounting functions, legal, business development, corporate insurance, corporate and investor communications, pre-commercial and other administrative functions and operating costs.

Finance income (expense)

Finance income (expense) consists primarily of interest income on fixed term deposits.

Fair value adjustment on warrant liabilities

Fair value adjustment on warrant liabilities reflects the changes in fair value of the Company's warrant instruments. The fair value is dependent on the change in the underlying market price of the public and private placement warrants, the change in the Black-Scholes fair value of the warrant issued to Kreos Capital VII Aggregator SCSp (the "*Amended BlackRock Warrant*"), and the number of outstanding warrants at the reporting date. The fair value of the public and private placement warrants is, in general, directly correlated with the market price of our public warrants. Assuming the number of outstanding warrants remains constant, we would expect a fair value loss due to an increase in the market price of the warrants, and a fair value gain due to a decrease in the market price of the warrants. The fair value of the Amended BlackRock Warrant is dependent on the change in the Black-Scholes fair value and the number of outstanding warrants at the reporting date.

Foreign currency exchange gain (loss)

Foreign currency exchange gains and losses consist of currency exchange differences that arise from transactions denominated in currencies other than Swiss Francs.

Income tax benefit (expense)

We are subject to corporate Swiss federal, cantonal and communal taxation, respectively, in Switzerland, Canton of Zug, and Commune of Zug, as well as in the Canton of Vaud and Commune of Lausanne. We are also subject to taxation in other jurisdictions in which we operate, in particular the United States, France, Hong Kong 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 seven years and can offset our losses carried forward against future taxes owed. As of December 31, 2025, we had tax loss carry-forwards totaling CHF 106.9 million. There is no certainty that we will make sufficient profits to be able to utilize tax loss carry-forwards in full and no deferred tax assets have been recognized in the financial statements.

A. Operating Results

Comparison of the Three Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the periods presented:

	For the three months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Grant income	310	261	49	19%
Operating income	**310**	**261**	**49**	**19%**
Research and development expenses	(15,283)	(14,909)	(374)	3%
General and administrative expenses	(8,595)	(6,120)	(2,475)	40%
Operating expenses	**(23,878)**	**(21,029)**	**(2,849)**	**14%**
Operating loss	**(23,568)**	**(20,768)**	**(2,800)**	**13%**
Finance income	592	520	72	14%
Finance expense	(309)	(183)	(126)	69%
Fair value adjustment on warrant liabilities	12,100	(234)	12,334	(5271%)
Foreign currency exchange gain (loss)	1,221	(4,734)	5,955	126%
Finance result	**13,604**	**(4,631)**	**18,235**	**394%**
Loss before tax for the period	**(9,964)**	**(25,399)**	**15,435**	**(61%)**
Income tax benefit (expense)	(6)	24	(30)	(125%)
Loss for the period	**(9,970)**	**(25,375)**	**15,405**	**(61%)**

Grant income

Grant income for both the three months ended June 30, 2026 and 2025 was CHF 0.3 million, and is dependent upon the Icelandic government making such reimbursement available for qualified 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

	For the three months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Personnel expenses	**6,277**	**4,834**	**1,443**	**30%**
Payroll and related expenses	3,051	2,319	732	32%
Share-based compensation	3,226	2,515	711	28%
Other operating expenses	**9,006**	**10,075**	**(1,069)**	**(11%)**
External service providers	8,302	9,756	(1,454)	(15%)
Other operating expenses	599	238	361	152%
Depreciation expense	105	81	24	30%
Total research and development expenses	**15,283**	**14,909**	**374**	**3%**

Research and development expense was CHF 15.3 million for the three months ended June 30, 2026, compared to CHF 14.9 million for the three months ended June 30, 2025. The modest increase of CHF 0.4 million, or 3%, was primarily due to increased personnel costs due to increased headcount and share-based compensation expense resulting from new equity grants and increased grant value for awards granted in 2026. This was partially offset by a decrease in external service providers, primarily driven by the DIAMOND-1 and DIAMOND-2 trials of OCS-01 in DME, which concluded during the second quarter of 2026, partially offset by an increase in PIONEER-1 clinical expenses.

The table below represents the breakdown of research and development expenses by project:

	For the three months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Privosegtor (OCS-05)	7,128	2,282	4,846	212%
Licaminlimab (OCS-02)	3,719	1,893	1,826	96%
OCS-01	3,776	10,054	(6,278)	(62%)
Other development projects	660	680	(20)	(3%)
Total	**15,283**	**14,909**	**374**	**3%**

During the three months ended June 30, 2026 and 2025, the increase in research and development expenses was primarily due to an increase in OCS-05 program expenses related to the PIONEER-1 trial, partially offset by a decrease in external service provider expense for OCS-01 driven by the conclusion of the DIAMOND-1 and DIAMOND-2 trials in DME during the second quarter of 2026.

General and administrative expenses

	For the three months ended June 30,			
	2026	2025	Change	% Change
Personnel expenses	**5,583**	**3,730**	**1,853**	**50%**
Payroll and related expenses	2,166	1,705	461	27%
Share-based compensation	3,417	2,025	1,392	69%
Other operating expenses	**3,012**	**2,390**	**622**	**26%**
External service providers	1,966	1,701	265	16%
Other operating expenses	973	657	316	48%
Depreciation expense	73	32	41	128%
Total general and administrative expenses	**8,595**	**6,120**	**2,475**	**40%**

General and administrative expenses were CHF 8.6 million for the three months ended June 30, 2026, compared to CHF 6.1 million for the three months ended June 30, 2025. The increase of CHF 2.5 million, or 40%, was primarily driven by an increase in share-based compensation expense due to new equity grants and increased grant value for equity awards granted in 2026.

Finance income and Finance expense

	For the three months ended June 30,			
	2026	2025	Change	% Change
Finance income	592	520	72	14%
Finance expense	(309)	(183)	(126)	69%
Total finance income	**283**	**337**	**(54)**	**(16%)**

We realized net finance income of CHF 0.3 million for both the three months ended June 30, 2026 and 2025, which is primarily comprised of interest income from our short-term bank deposits, offset by amortization of transaction costs in connection with BlackRock loan related fees.

Fair value adjustment on warrant liabilities

	For the three months ended June 30,			
	2026	2025	Change	% Change
Fair value adjustment on warrant liabilities	12,100	(234)	12,334	(5271%)

We realized a fair value gain on warrant liabilities of CHF 12.1 million for the three months ended June 30, 2026, primarily due to a decrease in the market price of the BCA warrants ("*BCA Warrants*") during the period and a fair value loss of CHF 0.2 million for the three months ended 2025, primarily due to an increase in the market price of the BCA Warrants during the period. The public and private placement warrants were assumed from European Biotech Acquisition Corp. as part of the 2023 business combination agreement.

Foreign currency exchange gain (loss)

	For the three months ended June 30,			
	2026	2025	Change	% Change
Foreign currency exchange gain (loss)	1,221	(4,734)	5,955	(126%)

We recognized a foreign currency exchange gain of CHF 1.2 million for the three months ended June 30, 2026, compared to a loss of CHF 4.7 million for the three months ended June 30, 2025. The foreign currency exchange gain (loss) reflects fluctuations of the U.S. dollar against the Swiss Franc impacting our cash and short-term financial assets balances and currency transaction activities, which were favorable in 2026 due to a strengthening U.S. dollar as compared to the same period in 2025.

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the periods presented:

	For the six months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Grant income	519	545	(26)	(5%)
Operating income	**519**	**545**	**(26)**	**(5%)**
Research and development expenses	(29,329)	(29,680)	351	(1%)
General and administrative expenses	(16,486)	(11,608)	(4,878)	42%
Operating expenses	**(45,815)**	**(41,288)**	**(4,527)**	**11%**
Operating loss	**(45,296)**	**(40,743)**	**(4,553)**	**11%**
Finance income	959	1,013	(54)	(5%)
Finance expense	(482)	(430)	(52)	12%
Fair value adjustment on warrant liabilities	4,117	(12,145)	16,262	(134%)
Foreign currency exchange gain (loss)	1,788	(6,301)	8,089	(128%)
Finance result	**6,382**	**(17,863)**	**24,245**	**(136%)**
Loss before tax for the period	**(38,914)**	**(58,606)**	**19,692**	**(34%)**
Income tax benefit (expense)	92	17	75	441%
Loss for the period	**(38,822)**	**(58,589)**	**19,767**	**(34%)**

Grant income

Grant income for both the six months ended June 30, 2026 and 2025 was CHF 0.5 million. The grant income is dependent upon the Icelandic government making such reimbursement available for qualified 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

	For the six months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Personnel expenses	**11,656**	**9,182**	**2,474**	**27%**
Payroll and related expenses	5,757	4,766	991	21%
Share-based compensation	5,899	4,416	1,483	34%
Other operating expenses	**17,673**	**20,498**	**(2,825)**	**(14%)**
External service providers	16,444	19,943	(3,499)	(18%)
Other operating expenses	1,034	398	636	160%
Depreciation expense	195	157	38	24%
Total research and development expenses	**29,329**	**29,680**	**(351)**	**(1%)**

Research and development expense was CHF 29.3 million for the six months ended June 30, 2026, compared to CHF 29.7 million for the six months ended June 30, 2025. The modest decrease of CHF 0.4 million, or 1%, was primarily due to a decrease in external service providers, driven by the DIAMOND-1 and DIAMOND-2 trials of OCS-01 in DME, which concluded during the second quarter of 2026. This was partially offset by an increase in PIONEER-1 clinical expenses, and by increased personnel costs primarily due to share-based compensation expense resulting from new equity grants and increased grant value for awards granted in 2026.

The table below represents the breakdown of research and development expenses by project:

	For the six months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Privosegtor (OCS-05)	12,597	3,739	8,858	237%
Licaminlimab (OCS-02)	4,826	3,716	1,110	30%
OCS-01	10,512	20,766	(10,254)	(49%)
Other development projects	1,394	1,459	(65)	(4%)
Total	**29,329**	**29,680**	**(351)**	**(1%)**

During the six months ended June 30, 2026 and 2025, the decrease in research and development expenses was primarily due to a decrease in external service provider expense for OCS-01 driven by the conclusion of the DIAMOND-1 and DIAMOND-2 trials in DME during the second quarter of 2026, partially offset by an increase in OCS-05 program expenses for the PIONEER-1 trial.

General and administrative expenses

	For the six months ended June 30,			
	2026	2025	Change	% Change
Personnel expenses	**10,235**	**6,587**	**3,648**	**55%**
Payroll and related expenses	4,490	3,833	657	17%
Share-based compensation	5,745	2,754	2,991	109%
Other operating expenses	**6,251**	**5,021**	**1,230**	**24%**
External service providers	4,496	3,768	728	19%
Other operating expenses	1,618	1,174	444	38%
Depreciation expense	137	79	58	73%
Total general and administrative expenses	**16,486**	**11,608**	**4,878**	**42%**

General and administrative expenses were CHF 16.5 million for the six months ended June 30, 2026, compared to CHF 11.6 million for the six months ended June 30, 2025. The increase of CHF 4.9 million, or 42%, was primarily driven by an increase in share-based compensation expense due to new equity grants and increased grant value for equity awards granted in 2026.

Finance income and Finance expense

	For the six months ended June 30,			
	2026	2025	Change	% Change
Finance income	959	1,013	(54)	(5%)
Finance expense	(482)	(430)	(52)	12%
Total finance income	**477**	**583**	**(106)**	**(18%)**

We realized net finance income of CHF 0.5 million and CHF 0.6 million for the six months ended June 30, 2026 and 2025, respectively, which is primarily comprised of interest income from our short-term bank deposits, offset by amortization of transaction costs in connection with BlackRock loan related fees.

Fair value adjustment on warrant liabilities

	For the six months ended June 30,			
	2026	2025	Change	% Change
Fair value adjustment on warrant liabilities	4,117	(12,145)	16,262	(134%)

We realized a fair value gain on warrant liabilities of CHF 4.1 million for the six months ended June 30, 2026, primarily due to a decrease in the market price of the BCA Warrants during the period and a fair value loss of CHF 12.1 million for the six months ended June 30, 2025, primarily due to an increase in the market price of the BCA Warrants during the period.

Foreign currency exchange gain (loss)

	For the six months ended June 30,			
	2026	2025	Change	% Change
Foreign currency exchange gain (loss)	1,788	(6,301)	8,089	(128%)

We recognized a foreign currency exchange gain of CHF 1.8 million for the six months ended June 30, 2026, compared to a loss of CHF 6.3 million for the six months ended June 30, 2025. The foreign currency exchange gain (loss) reflects fluctuations of the U.S. dollar against the Swiss Franc impacting our cash and short-term financial assets balances and currency transaction activities, which were favorable in 2026 due to a strengthening U.S. dollar as compared to the same period in 2025.

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 in the near future. We incurred a loss of CHF 38.8 million and a cash outflow from operations of CHF 35.6 million for the six months ended June 30, 2026. We had a total of CHF 228.3 million, or $282.3 million, in cash, cash equivalents and short-term financial assets as of June 30, 2026.

On March 4, 2026, we entered into an amended and restated sales agreement with Leerink Partners LLC with respect to an at-the-market offering program (the "*ATM Program*") under which we may offer and sell, from time to time at our sole discretion, ordinary shares having an aggregate offering price of up to $100.0 million (CHF 80.9 million) through Leerink Partners LLC as our sales agent. In the first half of 2026, 2,250,000 ordinary shares were sold under the ATM Program for gross proceeds of CHF 47.8 million, or $61.3 million. We have recognized CHF 2.2 million of transaction costs that were offset against the proceeds and recorded as a reduction of share premium for the six months ended June 30, 2026.

On November 3, 2025, we closed concurrent underwritten and registered direct offerings for the issuance and sale of an aggregate of 5,432,098 ordinary shares at a price per share of $20.25 (CHF 16.33) for total gross proceeds of $110.0 million (CHF 88.7 million) before deducting underwriting discounts and commissions and offering expenses.

On July 31, 2025 we amended our existing loan facility with Kreos Capital VII (UK) Limited (the "*Lender*"), which are funds and accounts managed by BlackRock, Inc. (the "*Amended Loan Agreement*"). The Amended Loan Agreement is structured to provide the EUR equivalent of up to CHF 75.0 million in borrowing capacity (which may be increased to up to CHF 100.0 million), comprising tranches 1, 2 and 3, in the amounts of the EUR equivalents of CHF 25.0 million each, as well as an additional loan of the EUR equivalent of up to CHF 25.0 million, which may be made available by the Lender to us if mutually agreed in writing between us and the Lender.

On February 18, 2025, we closed an underwritten offering for the issuance and sale of 5,000,000 ordinary shares at a price of $20.00 or CHF 18.05 per share, for total gross proceeds of CHF 90.2 million or $100.0 million before deducting underwriting discounts and commissions and offering expenses.

We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to invest in the development of our product candidates through additional research and development activities, including clinical trials, and prepare for potential commercialization. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term financial assets will be sufficient to fund our operations and capital expenditures for at least 12 months from the date of this Report without additional capital or drawdown from our loan facility. 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 or our portfolio or if we consider acquisitions or other strategic transactions, including licensing transactions.

Cash Flows

The following table summarizes our sources and uses of cash and cash equivalents for each of the periods presented:

	For the six months ended June 30,			
	2026	**2025**	**Change**	**% Change**
Net cash outflow for operating activities	(35,571)	(36,205)	634	(2%)
Net cash outflow for investing activities	(33,983)	(25,724)	(8,259)	32%
Net cash inflow from financing activities	48,637	104,436	(55,799)	(53%)
Increase (decrease) in cash and cash equivalents	**(20,917)**	**42,507**	**(63,424)**	**(149%)**

Total cash, cash equivalents and short-term investments were CHF 228.3 million as of June 30, 2026, which represents an increase of CHF 15.3 million from CHF 213.0 million at December 31, 2025. The increase was primarily due to proceeds from the ATM sales, partially offset by ongoing operating expenses.

Operating Activities

For the six months ended June 30, 2026, operating activities used CHF 35.6 million of cash, primarily consisting of a loss before tax of CHF 38.9 million and working capital adjustments of CHF 1.9 million, partially offset by non-cash adjustments of CHF 5.3 million. Working capital adjustments consisted of a CHF 2.9 million timing related decrease in payables and accrued liabilities and a CHF 0.5 million increase in accrued income related to Icelandic government research and development cost reimbursements, partially offset by a CHF 1.5 million decrease in other current assets related to capitalized transaction costs associated with our ATM Program that were reclassed to share premium as a result of the ATM sales during the six months ended June 30, 2026. Non-cash adjustments primarily consisted of CHF 11.6 million of share-based compensation expense, partially offset by a CHF 4.1 million fair value adjustment gain on warrant liabilities and CHF 2.6 million of financial result comprised primarily of foreign exchange losses on U.S. dollar liquid asset balances during the period and interest income.

For the six months ended June 30, 2025, operating activities used CHF 36.2 million of cash, primarily consisting of a loss before tax of CHF 58.6 million and working capital adjustments of CHF 1.9 million, partially offset by non-cash adjustments of CHF 24.3 million. Working capital adjustments consisted of a CHF 2.7 million decrease in payables and accrued liabilities, partially offset by a CHF 1.4 million decrease in other current assets. Non-cash adjustments primarily consisted of a CHF 12.1 million fair value adjustment loss on warrant liabilities, CHF 7.2 million of share-based compensation expense and CHF 4.7 million of financial result comprised primarily of foreign exchange losses on U.S. dollar cash balances during the period and interest income.

Investing Activities

For the six months ended June 30, 2026, the Company recorded cash outflow for investing activities of CHF 34.0 million, primarily driven by CHF 34.5 million for investments in current fixed term bank deposits, net of maturities.

For the six months ended June 30, 2025, the Company recorded cash outflow for investing activities of CHF 25.7 million, primarily driven by CHF 25.1 million for investments in current fixed term bank deposits, net of maturities, as well as a CHF 1.1 million milestone payment pursuant to our licensing agreement with Accure Therapeutics SL (the "*Accure Agreement*").

Financing Activities

For the six months ended June 30, 2026, net cash provided by financing activities was CHF 48.6 million which consisted primarily of CHF 46.7 million of net proceeds received from the issuance and sale of shares from the ATM Program, CHF 1.6 million received from the exercise of warrants and CHF 0.6 million of proceeds from the exercise of stock options.

For the six months ended June 30, 2025, net cash provided by financing activities was CHF 104.4 million, which consisted primarily of CHF 84.1 million of net proceeds received from the issuance and sale of shares in the February 2025 underwritten offering, CHF 18.9 million received from the exercise of warrants and CHF 1.6 million of proceeds from the exercise of stock options.

Future Funding Requirements

Product development is 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.

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.

If we obtain regulatory approval for one or more of our product candidates, we have the options of seeking strategic partnerships or commercializing such products ourselves. If we decide to pursue direct commercialization, we expect to incur significant expenses to develop our commercialization capabilities to support product sales, medical affairs, market access, and marketing and distribution activities, either alone or in collaboration with others. As a result, we may need substantial additional funding to support our continuing operations and pursue our growth strategy.

Until such time, if ever, when 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 funding. 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 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, such as the Amended Loan Agreement we entered into in July 2025, 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 third parties rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangements 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.

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, and prepare for potential commercialization. In addition, we will continue to incur additional costs associated with operating as a dual-listed public company, including significant legal, accounting, investor relations and other expenses. Our expenses will also increase 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, maintain outsourced manufacturing or 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 high quality personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a dual-listed public company; and
- defend against any product liability claims or other lawsuits.

Material Cash Requirements for Known Contractual Obligations and Commitments

We have certain payment obligations under existing 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. The next milestone under the Accure Agreement, which we expect to become payable in the second half of 2026, would trigger a payment of CHF 2.1 million ($2.6 million).

The majority of our near-term cash needs relate to our clinical and chemistry, manufacturing and controls (CMC) projects. We have conducted research and development programs through collaboration arrangements that include, among others, arrangements with universities, CROs and clinical research sites. 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.

C. Critical Accounting Policies and Accounting Estimates

There have been no material changes to the key estimates, assumptions and judgments from those disclosed in our audited financial statements and notes thereto for the year ended December 31, 2025, included in our Annual Report on Form 20-F filed with the SEC on March 4, 2026. Refer to Note 2 to our Unaudited Condensed Consolidated Interim Financial Statements included elsewhere in this Report on Form 6-K for further details on the most material accounting policies applied in the preparation of our consolidated financial statements and our critical accounting estimates and judgments.

D. Risk Factors

We have filed updated risk factors as Exhibit 99.4 to the Report on Form 6-K to which this exhibit is attached. Please refer to the risk factors described therein, as well as any described in our subsequent SEC filings.

Cautionary Note Regarding Forward-Looking Statements

Some of the statements in this Report on Form 6-K constitute forward-looking statements that do not directly or exclusively relate to historical facts. You should not place undue reliance on such statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Forward-looking statements include information concerning our possible or assumed future results of operations, including descriptions of our business strategy. These statements are often, but not always, made through the use of words or phrases such as “believe,” “anticipate,” “could,” “may,” “would,” “should,” “intend,” “plan,” “potential,” “predict,” “will,” “expect,” “estimate,” “project,” “positioned,” “strategy,” “outlook” and similar expressions. All such forward looking statements involve estimates and assumptions that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from the results expressed in the statements. 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. Among the key factors that could cause actual results to differ materially from those projected in the forward-looking statements are the following:

- our financial performance;
- the ability to maintain the listing of our ordinary shares and warrants on the Nasdaq Global Market and the Nasdaq Iceland Main Market;
- timing and expected outcomes of clinical trials, preclinical studies, regulatory submissions and approvals, as well as commercial outcomes;
- timing of expected milestones in connection with our in-licensed assets;
- 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 partner or commercialize our pipeline of product candidates;
- our ability to establish and maintain arrangements for the manufacture of our 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 cash runway, 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 any macroeconomic factors and other global events on our business;
- changes in applicable laws or regulations;
- our ability to maintain our status as a “foreign private issuer”; 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 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.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Report. And while we believe such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

Exhibit 99.3

Oculis Reports Q2 2026 Financial Results and Provides Company Update

- *Company pivot to neuro-ophthalmology continues with Privosegtor positioned as lead late-stage asset through the registrational PIONEER program with expansion potential in acute multiple sclerosis (MS) relapses following positive FDA pre-IND feedback*
- *Enrollment progressing as planned in the PREDICT-1 genotype-based registrational trial of Licaminlimab in dry eye disease with all planned sites activated and >45% patients randomized*
- *Cash, cash equivalents, and short-term investments of $282.3 million as of June 30, 2026, providing cash runway into 2H 2029*

ZUG, Switzerland, August 6, 2026 -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) (Oculis), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology, today announced results for the second quarter ended June 30, 2026, and provided an overview of the Company's progress.

Riad Sherif, M.D., Chief Executive Officer of Oculis, stated, "We continue to advance and expand the Privosegtor neuroprotection franchise, with PIONEER-1 on track in global site activations and positive regulatory momentum supporting our development strategy in acute multiple sclerosis relapses. Given the considerable unmet need for neuroprotective treatments, these achievements reinforce both our strategy to pivot to neuro-ophthalmology by exploring the clinical potential of Privosegtor and the substantial opportunity across multiple neuro-ophthalmic and neuro-axonal diseases. In parallel, with Licaminlimab PREDICT-1 genotype-based trial planned site activations complete and over 45% of patients enrolled, we expect to report topline results around year-end. With a strong balance sheet, we are well positioned to execute on our strategy, advance our registrational programs and deliver on upcoming value-driving milestones."

Recent Development Highlights and Upcoming Milestones:

Privosegtor:

- The PIONEER-1 registrational trial is designed to investigate Privosegtor as a neuroprotective treatment for patients with optic neuritis (ON) across a broad population, including those with and without multiple sclerosis (MS). As established under a Special Protocol Assessment (SPA) agreement with the FDA, the primary endpoint is defined as the proportion of patients achieving at least a 15-letter gain from baseline in low-contrast visual acuity (LCVA) at Month 3, a clinically meaningful visual function endpoint in ON. The primary analysis will be conducted at Month 3, and patients will be followed through Month 12 to assess Privosegtor's long-term safety and tolerability. Site activation is actively progressing across the U.S., Europe, Australia, and Canada, with an execution focus and priority on building a robust, multidisciplinary network connecting emergency room physicians,

ophthalmologists, and neurologists. This integrated approach aims to optimize operational flows from patient identification to treatment, capitalizing on peak enrollment opportunities during the fall, winter, and spring to align with the natural seasonality of the disease.

- The FDA's Division of Neurology provided guidance that no additional preclinical studies will be required ahead of an Investigational New Drug (IND) submission for Privosegtor in acute MS relapses, cross-referencing the data from the open ON IND residing in the Division of Ophthalmology. Constructive FDA feedback also supports the proposed clinical development strategy and regulatory pathway, which will include MS patients with both optic neuritis and other relapses, such as ambulatory relapses, in future trials. It also supports a primary endpoint as early as 3 months, with the same 3mg/kg dose administered daily for 5 days as in PIONEER-1. Oculis anticipates an IND submission for the treatment of acute MS relapses in the fourth quarter of 2026.
- MS is a chronic immune-mediated disease of the central nervous system affecting approximately 2.8 million people worldwide, including around 850,000 in the U.S. alone.[1-3] There are two main types of MS: relapsing-remitting MS (RRMS) and progressive MS. While progressive MS remains a significant unmet medical need, RRMS is the most common type, representing ~85% of patients at initial diagnosis.[2] Despite available therapies, relapses still persist for many patients, with an estimated 170,000 MS relapses occurring each year in the U.S.[4,5] During an acute relapse, neurologists commonly use a short course of high-dose corticosteroids to reduce inflammation and shorten the episode, as is standard of care in optic neuritis. However, corticosteroids do not influence the frequency of future relapses or long-term disability, and recovery from relapses is often incomplete. There are currently no neuroprotective therapies approved for MS relapses, and there remains an urgent unmet medical need for treatments that can prevent central nervous system damage.
- The Company will host an R&D Day in Q4 to share key updates on Privosegtor's ongoing clinical development in optic neuritis and acute MS relapses.

Licaminlimab:

- Oculis is actively enrolling patients in the PREDICT-1 genotype-based registrational trial in dry eye disease (DED) evaluating Licaminlimab as a precision medicine treatment. All planned trial sites have been activated and >45% patients have been randomized. The PREDICT-1 trial is a randomized, multi-center, double-masked, vehicle-controlled study that plans to enroll ~160 patients of whom approximately 2/3 will have the specified TNFR1 genotype. The primary endpoint is the change from baseline to Day 29 in the global ocular discomfort severity score in patients with the specified TNFR1 genotype. The same outcome measure will be evaluated in the overall study population as a key secondary endpoint. While measurements of dry eye symptoms are inherently subjective, this precision medicine approach is designed to identify patients more likely to benefit from Licaminlimab.
- In the U.S., approximately 10 million diagnosed patients suffer from moderate to severe DED.[6,7] Current disease management relies on a trial-and-error therapeutic approach, with a minority (~13%) of patients experiencing sustained relief,[8] leading to an 85-90% discontinuation rate within the first 6 months,[9] underscoring the significant unmet need for a targeted, effective treatment approach. If approved,

Licaminlimab has the potential to transform the current DED treatment paradigm by providing a precision medicine approach with high efficacy, rapid onset of action, and a comfort level similar to artificial tears.

OCS-01

- Following the DIAMOND topline results announcement in May, at this time Oculis does not plan to pursue an FDA regulatory filing for OCS-01 in DME.

Q2 2026 Financial Highlights:

As of June 30, 2026, Oculis held cash, cash equivalents and short-term investments of CHF 228.3 million or $282.3 million, compared to CHF 213.0 million or $268.7 million as of December 31, 2025. The increase reflects proceeds from sales of ordinary shares year-to-date under the Company's existing at-the-market offering program, offset by operating expenses. Research and development expenses were CHF 15.3 million or $19.3 million for the three months ended June 30, 2026, compared to CHF 14.9 million or $18.1 million in the same period in 2025. General and administrative expenses were CHF 8.6 million or $10.9 million for the three months ended June 30, 2026, compared to CHF 6.1 million or $7.4 million in the same period in 2025. The increase in operating expenses was primarily driven by headcount-related costs, including share-based compensation expenses, to support and execute the Company's development strategies. The Company's net loss was CHF 38.8 million or $49.3 million for the six months ended June 30, 2026, compared to CHF 58.6 million or $67.9 million for the same period in 2025. The decrease was primarily due to the fair value gain on warrant liabilities in 2026 driven by decreased market value as well as a favorable foreign currency fluctuation resulting from favorable U.S. dollar versus Swiss Franc for U.S. dollar denominated transactions and assets, compared to a weaker U.S. dollar against the Swiss Franc in the prior year period.

Key Upcoming Events:

Medical Conferences

- Asia-Pacific Vitreo-Retina Society (APVRS) Congress; Aug. 28-30, Queensland, Australia
- The Retina Society 59th Annual Scientific Meeting; Sep. 23-26, Los Angeles, California, U.S.
- EURETINA 26th Annual Congress; Oct. 1-4, Vienna, Austria
- MS Toronto 2026 – 10th Joint ACTRIMS-ECTRIMS Meeting; Oct. 21-23, Toronto, Canada

Investor Conferences

- Stifel Biotech Summer Summit; Aug. 10-12, Newport, Rhode Island, U.S.
- JPM Aspen Summit; Aug. 24-26, Aspen, Colorado, U.S.
- Pareto Healthcare Conference; Sep. 2, Stockholm, Sweden
- Wells Fargo Healthcare Conference; Sep. 8-10, Boston, Massachusetts, U.S.
- HCW Annual Global Investment Conference; Sep. 14-16, New York, New York, U.S.
- Baird 2026 Global Healthcare Conference; Sep. 15, New York, New York, U.S.

- Leerink Biopharma Summit; Sep. 23-25, Healdsburg, California, U.S.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of June 30, 2026	As of December 31, 2025
ASSETS		
Non-current assets		
Property and equipment	482	534
Intangible assets	13,292	13,292
Right-of-use assets	2,648	2,463
Other non-current assets	847	785
Total non-current assets	**17,269**	**17,074**
Current assets		
Other current assets	3,216	4,883
Accrued income	1,526	993
Short-term financial assets	166,710	131,684
Cash and cash equivalents	61,614	81,329
Total current assets	**233,066**	**218,889**
TOTAL ASSETS	**250,335**	**235,963**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	679	587
Share premium	605,937	551,731
Reserve for share-based payment	38,133	30,387
Actuarial loss on post-employment benefit obligations	(1,595)	(1,634)
Treasury shares	(62)	(7)
Cumulative translation adjustments	(419)	(480)
Accumulated losses	(423,336)	(384,514)
Total equity	**219,337**	**196,070**
Non-current liabilities		
Long-term lease liabilities	1,792	1,811
Defined benefit pension liabilities	1,283	1,335
Total non-current liabilities	**3,075**	**3,146**
Current liabilities		
Trade payables	2,683	1,800
Accrued expenses and other payables	16,670	19,967
Short-term lease liabilities	751	502
Warrant liabilities	7,819	14,478
Total current liabilities	**27,923**	**36,747**
Total liabilities	**30,998**	**39,893**
TOTAL EQUITY AND LIABILITIES	**250,335**	**235,963**

Condensed Consolidated Statements of Loss (Unaudited)

(Amounts in CHF thousands, except per share data)	For the three months ended June 30,		For the six months ended June 30,	
	2026	**2025**	**2026**	**2025**
Grant income	310	261	519	545
Operating income	**310**	**261**	**519**	**545**
Research and development expenses	(15,283)	(14,909)	(29,329)	(29,680)
General and administrative expenses	(8,595)	(6,120)	(16,486)	(11,608)
Operating expenses	**(23,878)**	**(21,029)**	**(45,815)**	**(41,288)**
Operating loss	**(23,568)**	**(20,768)**	**(45,296)**	**(40,743)**
Finance income	592	520	959	1,013
Finance expense	(309)	(183)	(482)	(430)
Fair value adjustment on warrant liabilities	12,100	(234)	4,117	(12,145)
Foreign currency exchange gain (loss)	1,221	(4,734)	1,788	(6,301)
Finance result	**13,604**	**(4,631)**	**6,382**	**(17,863)**
Loss before tax for the period	**(9,964)**	**(25,399)**	**(38,914)**	**(58,606)**
Income tax benefit (expense)	(6)	24	92	17
Loss for the period	**(9,970)**	**(25,375)**	**(38,822)**	**(58,589)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.16)	(0.49)	(0.65)	(1.16)

About Oculis
Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology. Oculis' highly differentiated late-stage clinical pipeline focuses on two core product candidates. Privosegtor is a breakthrough neuroprotective candidate in the PIONEER program, which consists of studies intended to support registration plans for treatment of optic neuropathies, including optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION). Privosegtor also has potential to be developed for additional indications in other neuro-ophthalmic and neuro-axonal diseases. Licaminlimab is a novel, topical anti-TNFα in a registrational trial, and is being developed with a genotype-based approach for treating patients with dry eye disease (DED). Headquartered in Switzerland with operations in the U.S., Iceland and Switzerland, Oculis is led by an experienced management team with a successful track record and supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

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Cautionary Statement Regarding Forward Looking Statements
This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of the Company's product candidates, including the potential of Privosegtor to become the first neuroprotective therapy for ON and other neuro-ophthalmic and neurological indications such as MS, including the potential to improve long-term outcomes for patients with these diseases, and the potential for Licaminlimab to redefine the treatment paradigm in dry eye disease with a precision medicine approach; the initiation, timing, progress and results of current and future clinical trials, including the planned IND submission for Privosegtor in acute MS relapses and the progress and timing of the PREDICT-1 trial of Licaminlimab and the PIONEER trials of Privosegtor; Oculis' research and development programs, regulatory and business strategy; expected milestones; statements about market opportunity; and statements about cash runway, are forward-looking. All forward-looking statements are based on estimates and assumptions that, while considered reasonable by Oculis and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Oculis' control. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. All forward-looking statements are subject to risks, uncertainties and other factors that may cause actual results to differ

materially from those that we expected and/or those expressed or implied by such forward-looking statements. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of Oculis, including those set forth in the Risk Factors exhibit to Oculis' Form 6-K filed on August 6, 2026 and any other documents filed with the SEC. Copies of these documents are available on the SEC's website, www.sec.gov. Oculis undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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Oculis Holding AG

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. Set forth below is a summary list of the principal risk factors as of the date of the filing of this Report on Form 6-K:

- We have a 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 not yet received any marketing approvals or commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.
- We depend significantly on our clinical-stage product candidates, Privosegtor and Licaminlimab, 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 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.
- The manufacture of Licaminlimab, a biologic, is highly complex, costly and requires substantial lead time to produce.
- 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 agencies.
- 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.
- 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 approvals for Licaminlimab, Privosegtor, 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 product candidates 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 Licaminlimab and Privosegtor. 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 product candidates, 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 agencies 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.

Risk Factors

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

We have a 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 late clinical stage biopharmaceutical company specializing in novel therapeutics to treat neuro-ophthalmic, ophthalmic and neurological diseases. We commenced operations in October 2003 and formed Oculis SA 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 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 our pre-commercial stage 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 99.0 million and CHF 85.8 million for the fiscal years ended December 31, 2025 and 2024, respectively, and a net loss of CHF 38.2 million for the six months ended June 30, 2026. As of June 30, 2026, we had accumulated losses of CHF 422.7 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, maintain outsourced manufacturing or establish and operate a manufacturing facility;
- continue our development and research 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 high quality personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a dual-listed public company; and
- defend against any product liability claims or other lawsuits.

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 our ordinary shares to decline.

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, nonclinical 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 a sustainable 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 high quality 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 U.S. Food and Drug Administration ("*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 agencies 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 our ordinary shares, all or any of which may adversely affect our viability.

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 June 30, 2026, we had CHF 228.3 million in cash, cash equivalents and short-term financial assets. Although we believe that our existing cash, cash equivalents and short-term financial assets 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, cash equivalents and short-term financial assets 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 foresee.

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 beyond amounts available to us under our Amended Loan Agreement (as defined below) with BlackRock. 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 committee members, 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 committee members 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 committee members 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, medical, clinical and regulatory 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 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 June 30, 2026, we had 67 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.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

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, global conflicts, wars, the U.S. financial markets, foreign exchange rates, the impact of trade policies including the implementation of tariffs, capital and exchange controls, unstable global credit markets and financial conditions, 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. We could also be affected by current or future tariffs or other restrictive trade measures between the United States and other countries, and any retaliatory tariffs by those other countries. If our activities, or those of our current or future service providers, manufacturers, suppliers and other partners, fall within the scope of any of these or other tariffs, our costs may increase significantly.

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. 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.

In addition, our available cash, cash equivalents and investments (short-term financial assets) 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, cash equivalents or investments; however, we can provide no assurances that access to our operating cash or invested cash, cash equivalents or investments 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.

If our information technology systems or those of third parties with whom we work or provide our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share

(collectively, process) proprietary, confidential, and sensitive data, including personal information, intellectual property, trade secrets, protected health information, and data we collect about trial participants in connection with clinical trials (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent, difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors, such as nation-state actors, engage in cyber-attacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and product development programs.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by generative artificial intelligence ("*AI*"), and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and could lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, contract research organizations, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have (and may in the future) experienced delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. 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.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, clinical trial patients, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of clinical trial data); financial loss; and other similar harms. Security incidents and attendant material consequences may delay the development of future product candidates, deter new customers from using our products in the future, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally,

our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We, and the third parties with whom we work, are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

The global data protection landscape is rapidly evolving, and our data processing activities subject us to numerous data privacy and security obligations, such as U.S. and foreign laws, regulations, industry standards, external and internal privacy and security policies, contractual requirements, and other requirements governing the processing of personal information, including information that we collect about trial participants 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 or that of third parties with whom we work 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 or a third party with whom we work to comply with applicable obligations related to data privacy and security could result in negative publicity, government investigations, enforcement actions, and claims by third parties, any of which could have a material adverse effect on our business, results of operations and financial condition.

In the United States, numerous federal, state and local laws and regulations, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws) that govern the collection, processing, use, disclosure, and protection of health-related and other personal information apply to our operations and the operations of the third parties with whom we work. For example, in the United States, the Health Insurance Portability and Accountability Act of 1996 ("*HIPAA*"), as amended by the Health Information Technology for Economic and Clinical Health Act ("*HITECH*"), 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 ("*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.

In addition, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal information, including sensitive personal information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the

California Consumer Privacy Act of 2018 ("*CCPA*") applies to the personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials and PHI, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Further, we are subject to international data protection laws and regulations, including the European Union's General Data Protection Regulation (*"EU GDPR"*) and the United Kingdom's GDPR ("*UK GDPR*") (collectively, "*GDPR*"), which imposes strict requirements for processing personal data of individuals located in the European Economic Area ("*EEA*") and United Kingdom ("*UK*"), including clinical trial data, as well as potential fines for noncompliant companies. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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.

Our employees and personnel use AI and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to

increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future.

In addition, legislative proposals and present laws and regulations regulate the use of cookies and other tracking technologies, electronic communications, and marketing. For example, in the EEA and the UK, regulators are increasingly focusing on compliance with requirements related to the targeted advertising ecosystem. European regulators have issued significant fines in certain circumstances where the regulators alleged that appropriate consent was not obtained in connection with targeted advertising activities. It is anticipated that the ePrivacy Regulation and national implementing laws will replace the current national laws implementing the ePrivacy Directive, which could increase our exposure to regulatory enforcement action, increase our compliance costs, and adversely affect our business.

In Europe, the Network and Information Security Directive ("*NIS2*") regulates resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2 may lead up to administrative fines of a maximum of 10 million Euros or up to 2% of the total worldwide revenue of the preceding fiscal year.

The Swiss Federal Act on Data Protection (*"FADP"*) 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.

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

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

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to varying applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our

efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation (including class-action claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans or restrictions on processing personal information, orders to destroy or not use personal information, imprisonment of company officials, and/or adverse publicity, and could negatively affect our operating results and business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, have in the past and may in the future contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with applicable data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, interrupt or stop our business operations (including, as relevant, our clinical trials), limit our ability to develop or commercialize our products, and result in adverse publicity that could materially 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 potential future strategic transaction depends on various risks and uncertainties. For example, assets we acquire may be subject to existing or potential liabilities, including unknown, contingent or undisclosed obligations, such as intellectual property disputes, contractual restrictions, regulatory non-compliance or prior clinical or manufacturing deficiencies that could delay or impair development or commercialization of our product candidates. We may also encounter conflicts in economic or business interests with joint ventures or investee companies, as well as difficulties integrating acquired personnel, technologies and operations into our existing business, including challenges in retaining key employees. Our management's time and focus may be diverted from operating our business to managing strategic alliances, joint ventures or acquisition integration efforts, which could disrupt our operations. In addition, such transactions may result in increased expenses and reductions in our cash available for operations and other uses or possible write-offs or impairment charges.

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.

With respect to existing in-licensed or future 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.

The terms of our loan facility place restrictions on our operating and financial flexibility.

On July 31, 2025, we entered into an amended and restated agreement for our loan facility (the *"Amended Loan Agreement"*) with Kreos Capital VII (UK) Limited (*"Kreos"* or the *"Lender"*), which are funds and accounts managed by BlackRock, Inc., that replaced the prior loan agreement between the Company and the Lender previously entered into on May 29, 2024. The Amended Loan Agreement is structured to provide the EUR equivalent of up to CHF 75.0 million in borrowing capacity (which may be increased to up to the EUR equivalent of CHF 100.0 million), comprising tranches 1, 2 and 3, in the amounts of the EUR equivalents of CHF 25.0 million each, as well as an additional loan of the EUR equivalent of up to CHF 25.0 million, which may be made available by the Lender to us if mutually agreed in writing by us and the Lender. See Note 5 of our consolidated financial statements for additional information about the Amended Loan Agreement.

The Amended Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants, events of default and other provisions and conditions that are customarily required for similar financings. Failure to maintain compliance with covenants under the Amended Loan Agreement would result in an event of default under the Amended Loan Agreement, which could result in enforcement action, including acceleration of amounts due under the Amended Loan Agreement. In the event there is an acceleration of our liabilities under the Amended Loan Agreement as a result of an event of default or otherwise, we may not have sufficient funds or may be unable to arrange for additional financing to repay the liabilities or to make any accelerated payments, and the Lender could seek to enforce security interests in the collateral securing the Amended Loan Agreement, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, our obligations in connection with the Amended Loan Agreement could have additional significant adverse consequences, including, among other things:

- restricting our activities, including limitations on transferring certain of our assets, engaging in certain transactions, terminating certain agreements, incurring certain additional indebtedness, creating certain liens, paying cash dividends or making certain other distributions and investments;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry;
- placing us at a possible competitive disadvantage compared to our competitors who have a smaller amount of debt (if we decide to draw down on the loan) or competitors with comparable debt at more favorable interest rates; and
- limiting our ability to borrow additional amounts for working capital, capital expenditures, research and development (*"R&D"*) efforts, acquisitions, debt service requirements, execution of our business strategy and other purposes.

Any of these factors could materially and adversely affect our business, financial condition and results of operations.

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 Privosegtor, Licaminlimab and any other product candidate we may develop or acquire in the future. The clinical and commercial success of our product candidates depends on a number of factors, including the following:

- As we advance our Privosegtor development program, we are shifting our main focus towards the treatment of neuro-ophthalmic and neurological diseases, and we may not be successful in this transition.
- Our innovations to the treatments of neuro-ophthalmic, ophthalmic and neurological diseases are unproven, and we do not know whether we will be able to successfully develop our product candidates targeting these diseases and their symptoms. In particular, our Privosegtor development program centers on neuroprotection which is an unproven approach to the treatment of neuro-ophthalmic and neurological diseases.
- 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 FDA and non-U.S. regulatory agencies 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 agencies.
- Our business depends on the successful development and commercialization of Privosegtor, Licaminlimab and our other pipeline product candidates. To the extent these product candidates are not commercially successful, our business, financial condition, and results of operations may be adversely affected.
- Even if approved, 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 Licaminlimab, a biologic, and certain of our other product candidates is complex and highly regulated, and there are particular risks associated with manufacturing the products to commercial scale, including our reliance on third parties. Therefore, we may 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.

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 we overestimate the sizes of 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 for 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, and such publications and studies usually involve assumptions and estimates. 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 and assumptions and estimates that we believe to be reasonable, we cannot guarantee that such information is accurate or complete. The potential market opportunities of our product candidates are difficult to precisely estimate, particularly for indications where there are not analogous products currently available.

In addition, some of our market opportunity data is based on the incidence of the disease and price ranges of current treatments. The actual market opportunity for any of our product candidates that receive approval may be based on a smaller patient population and different pricing. Further, we are developing Licaminlimab in DED, focused on patients with a specific biomarker. If our estimates of the DED patient population with the biomarker are not accurate, the market for the product, if approved, could be smaller than we expect. 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, 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 commercial partners' 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 and supply chain logistics;
- 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 optic neuropathies and other neuro-ophthalmic and neurological diseases with Privosegtor is unproven, and we do not know whether we will be able to successfully develop Privosegtor.

Privosegtor is intended to prevent or reverse nerve damage (*"neuroprotection"*) in neuro-ophthalmic and neurological diseases in which patients lose vision due to nerve damage. There are currently no FDA-approved neuroprotective therapies. Our future success partially depends on the successful development of Privosegtor which is based on this novel therapeutic approach. Although Privosegtor achieved positive results in the Phase 2 ACUITY trial in optic neuritis ("*ON*") announced in January 2025, we have not yet demonstrated efficacy and safety for Privosegtor in a pivotal trial. We are now evaluating Privosegtor in the PIONEER program for ON and also plan to explore its potential in non-arteritic anterior ischemic optic neuropathy ("*NAION*") and other neurological diseases including acute multiple sclerosis relapses. In our PIONEER clinical trials and any future clinical trials, Privosegtor may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess, and the positive results from the Phase 2 ACUITY trial may not be replicated in future clinical trials. Part of our strategy is to explore whether the potential neuroprotection of Privosegtor may also extend to other neurological diseases. Even if Privosegtor is successful in ON, it may fail to show benefit in NAION and other neuropathological or neurological

indications for which we do not yet have clinical data. If we are unsuccessful in our development efforts, we may not be able to advance the development and commercialization of Privosegtor.

Our approach to the treatment of retinal disease with OCS-01 is unproven, and we have not yet decided whether we will continue development or consider other strategic alternatives for the program.

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. We evaluated OCS-01 for the treatment of DME and announced negative results for our DIAMOND-1 and DIAMOND-2 clinical trials in May 2026. Although at this time we do not plan to pursue an NDA in DME with the FDA, we have not yet decided our plan for the OCS-01 program overall. We may consider further development in other indications or other geographies, or we may choose to consider strategic alternatives that would allow a third party to further explore the potential of OCS-01. If we choose to further develop OCS-01, the drug may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. If we are unsuccessful in such development efforts, we may not be able to advance the development and commercialization of OCS-01. If instead we choose to consider other alternatives for the program, we cannot guarantee that we will be able to identify and execute a transaction on beneficial terms or at all.

Our approach to use Licaminlimab for the treatment of dry eye disease ("DED") 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 Licaminlimab.

Licaminlimab is in development for treating DED. One of our strategies for Licaminlimab is to develop it for patients identified with a biomarker to predict patients that may respond well to Licaminlimab treatment. There are currently no FDA-approved therapies that treat DED using this "precision medicine" approach. If we choose to utilize this biomarker strategy, then our future success partially depends on both the successful development of Licaminlimab and either identification or development of a companion diagnostic that can screen patients for the biomarker, if we are able to demonstrate that patients with that biomarker are likely to respond well to Licaminlimab treatment. We have not yet demonstrated efficacy and safety for Licaminlimab in patients with or without a biomarker in a pivotal trial or obtained marketing approval. The registrational trial for Licaminlimab, PREDICT-1, may not demonstrate in patients with or without the biomarker any or all of the pharmacological benefits we believe it may possess. Even if the results of the PREDICT-1 trial are positive, we will need to ensure its commercial viability including in terms of manufacturing and implementing a precision medicine strategy. If we are unsuccessful in our development efforts, we may not be able to advance the development and commercialization of Licaminlimab.

We have not yet 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, Phase 2 and Phase 3 clinical trials for our product candidates. We have not yet demonstrated an ability to 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 clinical-stage product candidates, Privosegtor and Licaminlimab, which are being developed for the treatment of multiple diseases. If we are unable to complete the 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 Privosegtor, which we are initially developing for the treatment of ON, and Licaminlimab, which we are developing for the treatment of DED.

To date, we have invested a significant portion of our efforts and financial resources in the development of our product candidates. Despite consultation with regulatory agencies, no assurance can be provided that the FDA or non-U.S. regulatory agencies would consider our ongoing and planned registrational trials for Privosegtor and Licaminlimab to be sufficient to serve as the basis for approval in their respective indications, with such a final determination only made by the FDA or non-U.S. regulatory agencies 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 Privosegtor, Licaminlimab and any other product candidates we develop or acquire.

The success of our product candidates will depend on many factors, including:

- successfully and timely completing preclinical studies, nonclinical studies and clinical trials that demonstrate to the satisfaction of the FDA, the European Medicines Agency (*"EMA"*), the European Commission, or comparable non-U.S. regulatory agencies 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 agencies, including the specific indication for which the product may be approved;
- whether we are required by the FDA or similar non-U.S. regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of our product candidates;
- 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 agencies 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;
- 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 and any required nonclinical studies may not satisfy the requirements of the FDA or non-U.S. regulatory agencies.

The results from the prior preclinical studies and clinical trials for our product candidates may not necessarily be predictive of the results of future clinical trials. For example, despite achieving positive results in Stage 1 of our DIAMOND program evaluating OCS-01 for the treatment of DME, Stage 2 of the program did not achieve the primary or key secondary endpoints of the DIAMOND-1 and DIAMOND-2 trials. At this time, we do not plan to pursue an NDA for OCS-01 in DME with the FDA.

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 in the future, as we did with our OCS-01 DIAMOND trials in DME. 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. For example, in January 2025, we announced topline data in our Phase 2 ACUITY trial of Privosegtor in ON. Although Privosegtor met the primary safety endpoint and key secondary efficacy endpoints, there is no guarantee that these results will be replicated in our PIONEER development program, or that positive results in ON will translate to positive results in other indications for which we do not have clinical data. Similarly, in 2024, we announced results from the RELIEF Phase 2b trial in which a treatment effect in favor of Licaminlimab versus vehicle was observed on multiple signs of DED in the full trial population and, consistent with the previous Phase 2 symptom trial, the treatment effects were more pronounced in the specific genotype population. There is no guarantee that these results, in the full trial population or in the population with the biomarker, will be replicated in our PREDICT-1 clinical trial.

We also may be required by the FDA or non-U.S. regulatory agencies to conduct nonclinical studies to support marketing applications. For example, Privosegtor is a new molecular entity (“NME”) and as such, we are required to conduct, and have begun conducting, nonclinical studies to support a potential future marketing application. These nonclinical studies may yield unexpected safety, toxicology or pharmacology findings that could prompt regulators to request additional data, impose new requirements or delay review of or negatively impact our submission. Any inability to complete these nonclinical studies on our planned timelines or the emergence of any unforeseen results could adversely affect our ability to obtain marketing approval for the product candidate. Even at advanced stages of development, regulatory agencies may determine that our nonclinical package is insufficient, which could lead to substantial delays, increased costs or the need for further studies before commercialization, or could result in failing to achieve marketing authorization altogether.

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 agencies may disagree with our trial designs or our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory agencies 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 agency. Furthermore, any of these regulatory agencies 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 the Phase 2a clinical trial of Licaminlimab for the treatment of DED and the Phase 2 ACUITY trial of Privosegtor, making it difficult to predict whether the favorable results from such trials will be repeatable in larger, more advanced clinical trials such as the PIONEER program and PREDICT-1 trial. 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 agencies would consider our completed and planned clinical trials and any required nonclinical studies used for an NDA submission or comparable foreign submissions 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 agencies 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 or nonclinical studies 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 trials or studies 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, 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 (*"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, vary, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements.

Regulatory agencies, IRBs, ethics committees or data safety monitoring boards may, at any time, recommend the temporary or permanent discontinuation of our clinical trials, request that we vary clinical trials or 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 Good Clinical Practices (*"GCPs"*) and other applicable non-U.S. regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, non-U.S. regulatory agencies, IRBs and ethics committees 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 agencies, 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, vary 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.

Our product candidates may cause undesirable side effects 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.

Unforeseen side effects varying in severity (from minor reactions to death) and frequency (infrequent or prevalent) from Licaminlimab or Privosegtor or any other product candidate we develop 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 agencies 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 agencies.

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 Licaminlimab or Privosegtor or any other product candidate we develop are associated with serious adverse events ("*SAEs*") or other undesirable side effects in clinical trials or have characteristics that are unexpected, we may need or choose 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.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended, varied or terminated, and the FDA or comparable non-U.S. regulatory agencies 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 agencies 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, varied or terminated, and the FDA or comparable regulatory agencies 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 regulatory approval, a number of potentially negative consequences could result, including but not limited to, regulatory agencies suspending, withdrawing or varying approvals of such product, regulatory agencies 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 will require that we regularly report certain information, including information about adverse events that may have been caused or contributed to 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 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 our 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 approval or commercialization of the particular product candidate, or result in volatility in the price of our 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 agencies, 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 IND or a clinical trial application (*"CTA"*) will result in regulatory agencies allowing clinical trials to begin in a timely manner, if at all.

Any difficulties we experience relating to the initiation or completion of patient visits in clinical trials 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. Many factors can cause delays in clinical trials and enrollment of patients, 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 approval, or a positive ethics committee opinion 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 agencies, or any other regulatory authority concerns about risk to patients of the technology broadly; or if a 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, particularly in our trials that are focused on indications in which patient enrollment is event-driven;
- delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and clinical trial 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 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 regulatory agencies, 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 agencies may suspend, vary 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 regulatory agencies 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 certain non-U.S. regulatory agencies 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 and

certain non-U.S. regulatory agencies may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or such non-U.S. regulatory agency 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 agencies 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 agency 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 agency 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 clinical trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates in a timely manner or at all.

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 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 will continue to play a significant role in the conduct of our current and planned clinical trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies and have limited ability to control certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and good laboratory practice (*"GLP"*) requirements, which are regulations and guidelines enforced by the FDA and comparable non-U.S. regulatory agencies. Regulatory agencies 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 agencies may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot provide assurance of the outcome of any such inspections or audits. In addition, our clinical trials generally must be conducted with product produced under current good manufacturing practice ("*cGMP*") regulations. Our failure to comply with these regulations and policies may require us to repeat or terminate clinical trials, which would delay the regulatory approval process, and adversely affect our operations.

Even if our CROs and clinical trial sites comply with applicable GCP, GLP and GMP requirements, they may otherwise not meet our requirements for our clinical trials on the timelines and with the cost we expect, or at all. We have limited ability beyond our contractual rights to oversee and enforce the standards, timelines and costs we expect for our clinical trials. If any of our CROs, clinical trial sites or other third party vendors fail to

meet expectations, it could result in significant delays in our clinical trial timelines, overrun of costs or quality problems, any of which could ultimately jeopardize the conduct and outcome of the clinical trial.

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 also serve as scientific advisors or consultants to us 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 agencies, 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 agencies.

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 (*"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 agencies, 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 not 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 or the competent equivalent foreign authority to impose civil or criminal penalties;
- begin proceedings to suspend, vary or withdraw regulatory approval;
- issue an import alert;
- total or partial suspension of production, distribution or manufacturing for our ongoing clinical studies or trials;
- refuse to approve pending applications (including supplements to approved applications) submitted by us;
- ask us to initiate a product recall;
- suspend licenses;
- impose fines; or
- refer a case to the U.S. Department of Justice or the competent equivalent foreign authority 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 suspended, varied or withdrawn, the value of us and our operating results will be adversely affected. The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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

A key element of our strategy is to develop and potentially commercialize additional product candidates beyond our current portfolio, or expand our product candidates into additional indications. We intend to do so by investing exploring potential strategic alliances for the development or acquisition of new products or technologies 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 also plan to evaluate our product candidates in additional indications. For example, we are currently evaluating Privosegtor in optic neuropathies, but we believe it may also have potential in other neurological indications such as acute multiple sclerosis relapse. Even if we are successful in developing a product candidate in a given indication, we may fail to successfully develop it in other indications, which could limit the potential value of the product candidate. The factors above which could cause us to be unsuccessful in developing new product candidates also apply to expansion into additional indications.

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, and expanding product candidates into additional indications, 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 not to 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. For example, following our announcement of negative topline results from our DIAMOND clinical trials in May 2026, at this time we do not plan to pursue an FDA regulatory filing for OCS-01 in DME. If we terminate a program in which we have invested significant resources, such as OCS-01 in DME, 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 Privosegtor and Licaminlimab 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 Licaminlimab and Privosegtor 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, competent agencies of EU member states 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 and other non-U.S. regulatory authority requirements, including complying with cGMPs on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EU or other regulatory agencies, 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, European Commission, EMA or other regulatory agencies, 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.

In the event that we need to change our CMOs, our clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Various steps in the manufacture of our product candidates may need to be sole-sourced. In accordance with cGMP, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future CMOs may be difficult for us and could be costly, which could result in our inability to manufacture our product candidates for an extended period of time and

therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our CMOs, we may incur significantly higher costs to manufacture our product candidates.

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

Manufacturing Licaminlimab, 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 Licaminlimab 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 Licaminlimab 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 Licaminlimab. In the future, if the proposed manufacturing plans to reduce Licaminlimab costs do not succeed when producing Licaminlimab at commercial scale, we may not be able to proceed with Licaminlimab 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 Licaminlimab or Privosegtor, if approved, will depend significantly on attaining broad adoption and use of the products by physicians and patients for approved indications, and 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 agencies-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 or comparable foreign 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 approvals for Licaminlimab, Privosegtor, 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 agencies. 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. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the

Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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 educate adequate numbers of physicians about 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.

Licaminlimab

The DED market is already served by multiple approved products, such as cyclosporine ophthalmic emulsion and solution, lifitegrast ophthalmic solution, loteprednol etabonate ophthalmic suspension, varenicline solution and perfluorohexyloctane ophthalmic solution. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. This, as well as the emerging development of generics, may make it difficult to educate these parties on the benefits of switching to Licaminlimab. Companies that we are aware are commercializing or are developing therapeutics for DED include large companies with significant financial resources, such as Abbvie (Allergan), Bausch + Lomb, Alcon, Sun Pharmaceuticals, Harrow and Viatris, among others. In addition, over the counter products are currently available for the treatment of DED which may impact sales of our products.

Privosegtor

There are no currently approved neuroprotective treatments for optic neuritis and NAION, with significant unmet needs remaining. We are aware of companies that are commercializing or developing therapeutics for neuro-ophthalmic disorders, including companies with significant financial resources such as Amgen and Dompé, among others. With respect to acute multiple sclerosis relapses, we are aware of companies developing therapeutics for prevention of disease activity that may eventually influence relapse recovery, such as Sanofi, Roche, Novartis and other leading biotech companies, and these companies have significant financial resources to pursue such programs.

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 or biosimilar products. For example, a generic version of Restasis® to treat DED received FDA approval and was launched in 2022. Generic and biosimilar 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 and biosimilar products could have a material adverse impact on our ability to successfully commercialize Licaminlimab for DED, Privosegtor in optic neuropathies and other neurological indications, 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 ("*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 have limited 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 non-renewal 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. We, or our contract manufacturers, or any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of EU member states, or other comparable foreign regulatory agencies, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection to be noncompliant with cGMP regulations. 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 shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation 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 develop do, and will, compete with other product candidates and products for access to manufacturing facilities, particularly in the United States. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing our products or product candidates. There are also a limited number of U.S. manufacturers that could meet our requirements, and demand for capacity with such manufacturers is high, particularly in light of tariffs that could apply to products sold in the United States but manufactured elsewhere.

Any performance failure on the part of our 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 product candidates 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 Privosegtor and Licaminlimab. 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 Accure and Novartis, that we depend on for rights to Privosegtor and Licaminlimab, 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 Accure and Novartis on net product sales of Privosegtor and Licaminlimab, 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 Privosegtor, Licaminlimab or other important intellectual property or technology. Any of the foregoing could prevent us from commercializing Privosegtor or Licaminlimab 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 current 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 other 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 licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial 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 of our Annual Report on Form 20-F for the year ended December 31, 2025 (the "*2025 Annual Report*") 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 legal measures, such as 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, for example, limited in time, scope and/or geography, 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 related to our product candidates in the United States and other countries.

We have sought and will continue to seek to protect our intellectual property by filing patent applications related to our development programs and product candidates in the United States and abroad. However, the patent prosecution process is expensive, time-consuming and unpredictable (in part due to variations in law and examination procedures), 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 priority patent applications, for example, United States provisional patent applications. Corresponding patent applications, such as PCT applications or non-provisional applications, must be filed not later than 12 months after the priority application filing date. While we intend to timely file patent applications relating to

our priority 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.

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, 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 challenge 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 prosecution 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 (*"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. 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, we may be unable to prevent competitors from making, using and selling competing products falling within the scope of such patents. 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. 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. 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.

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 infringing technologies and products.

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.

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 activities of would-be infringing 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/biosimilar 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 agencies, 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 administrative/procedural

requirements imposed by domestic and international 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, expiration, enforceability or validity 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, enforceability or validity 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 (before a court or government agency/body), 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.

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, and apart from equitable relief, 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/processes, 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. In addition, we or our licensors may be subject to claims that we are infringing, misappropriating or otherwise violating the intellectual property rights of others, 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.

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.

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 our 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.

We may become involved in lawsuits to protect or enforce our intellectual property or the intellectual property of our licensors, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

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 a patent office, 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.

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 in some jurisdictions (such as the United States and the United Kingdom), there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ordinary shares.

Changes in U.S. or foreign patent laws or their interpretations could impair our ability to protect our products.

The legal and regulatory frameworks governing pharmaceutical patents, drug approvals, and market exclusivity are subject to continuous change and reinterpretation by legislatures, regulatory agencies, and courts. Any shifting legal landscape could make it easier for generic or biosimilar competitors to enter the market, shorten our periods of exclusivity, or impair our ability to successfully enforce our patent rights.

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 negatively impacting the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our future patent rights, 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 own or 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 own or 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 us could therefore be awarded a patent covering an invention even if we had made the invention before it was made by such third-party. This will require us 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, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our 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 our 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 our 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 our business, financial condition, and results of operations.

In the United States, several evolving legal frameworks present significant uncertainties for pharmaceutical companies:

- **U.S. Patent Law and Administrative Challenges**: Changes in how the U.S. Patent and Trademark Office examines patents, or how the Patent Trial and Appeal Board conducts *Inter Partes* Review and Post-Grant Review proceedings, may affect our ability to protect our product candidates. Competitors frequently use these administrative mechanisms to challenge and invalidate brand pharmaceutical patents outside of traditional court litigation, often under lower costs and burdens of proof.
- **Judicial Interpretations**: Decisions by the U.S. Supreme Court and the Court of Appeals for the Federal Circuit continually reshape the legal standards for patent eligibility, enablement, and written description, obviousness, and patent term adjustment. For example, stringent judicial interpretations of what constitutes patent-eligible subject matter or what satisfies enablement standards could render our existing patents vulnerable to invalidation or restrict the scope of pending applications we file, or prevent us from obtaining patents in the future.

- **The Hatch-Waxman Act and BPCIA Reforms**: Legislative proposals frequently aim to amend the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act (BPCIA). Any updates to these laws that reduce the statutory regulatory exclusivity periods for brand-name drugs or reference biologics, alter the litigation frameworks, or restrict a brand company's ability to settle patent litigation with generic or biosimilar developers could accelerate the entry of lower-cost competitive products.
- **Evolving Drug Pricing Legislation**: The federal government and various state legislatures continue to implement and propose sweeping measures designed to reduce healthcare costs. Legislative actions, such as the drug price negotiation provisions of the Inflation Reduction Act, place price caps on certain high-expenditure drugs and establish penalties for price increases that outpace inflation. Even as a pre-commercial company, the long-term commercial viability and valuation of our product candidates depend heavily on our projected launch pricing and reimbursement structures. If future laws expand these pricing controls to broader classes of drugs or shorten the time a drug is exempt from negotiation after launch, our expected return on investment will be materially reduced.

As a company trading on the Nasdaq Global Market, our primary market focus includes the United States, but our long-term growth strategy relies on securing international proprietary rights. Foreign patent laws, regulatory pathways, and enforcement mechanisms vary significantly from those in the United States and are subject to independent political and economic pressures. Changes in patent and regulatory laws in international jurisdictions could weaken our global intellectual property protection and prevent us from successfully commercializing our products abroad.

- **Compulsory Licensing and Exclusivity Waivers**: Many foreign governments retain the legal authority to grant compulsory licenses to domestic generic manufacturers if they deem a brand drug unaffordable or necessary for public health crises. Additionally, international trade frameworks or individual countries may enact intellectual property waivers that undermine our foreign patent protections.
- **Varying Standards of Patentability**: Many jurisdictions, including the European Union, India, and China, enforce differing and often stricter legal standards for patenting incremental innovations, such as specific crystalline forms, formulations, or alternative methods of use. We cannot guarantee that the patent strategies we deploy successfully in the United States will be valid or enforceable under foreign legal regimes.
- **Unitary Patent System:** In Europe in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a European patent with unitary effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents under the jurisdiction of the UPC could be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with any certainty the long-term effects of the new unitary patent system.

If we fail to adapt to shifting domestic or international legal frameworks, or if new laws weaken our patent protections and market exclusivity, we may face premature generic or biosimilar competition and depressed pricing power, which would severely harm our business prospects and financial condition.

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.

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.

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.

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 (and other proprietary information) 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, and typically expressly acknowledge irreparable harm for violations. 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 (and other proprietary information), a competitor's discovery 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 (and other proprietary information), our competitors may discover, either through breach of agreements with third parties, independent development or publication of information by any of the third-party collaborators. A competitor's unauthorized discovery of our trade secrets (and other proprietary information) could impair our competitive position and have an adverse impact on our business.

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 and policies 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.

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;
- we may not develop additional proprietary technologies that are patentable; and
- 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.

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, wordmarks, trade names and the like 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, wordmarks, trade names or the like 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 trade names 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 regulations

The regulatory approval processes of the FDA and non-U.S. regulatory agencies 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 agencies 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 agencies 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 regulatory agencies 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, 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 (*"BLAs"*).

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

- the regulatory agencies may disagree with the design, implementation, or results of our clinical trials;
- the regulatory agencies 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 regulatory agencies 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 regulatory agencies that a product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the regulatory agencies 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 regulatory agencies 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 (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. 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. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "*OBBBA*") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Additional health reform measures may continue and affect our business in unknown ways. The current administration is pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services ("*HHS"*), the FDA, the Centers for Medicare & Medicaid Services (*"CMS"*), and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform ("*TrumpRx*"), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (i) directing agencies to reduce agency workforce and cut programs; (ii) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (iii) imposing tariffs on imported pharmaceutical products; and (iv) as part of the Make America Healthy Again ("*MAHA*") Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager ("*PBM*") payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their

operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We expect that 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. 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. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state, leading to a single decision for each EU member state. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU member states in which the trial is to be conducted, and a separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or at the EU member state level may result in significant additional requirements or obstacles that may increase our operating costs. In many EU member states, healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. 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 (*"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 agencies of individual EU member states. On December 15, 2021, the Health Technology Regulation (*"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. The HTA Regulation, which began to apply on January 12, 2025, through a phased implementation, is intended to harmonize the clinical benefit assessment of HTA across the European Union.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the *"Pharma Package"*). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package - comprised of a new directive and regulation to replace existing legislation – aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions; reshape the incentives regime for orphan medicinal products; and expand the Bolar exemption. A decrease in data and market exclusivity opportunities for our product candidates in the EU could make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. 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.

We may not be able to obtain orphan drug designation or exclusivity for our current or future product candidates, and even if we do, that designation may not provide an expedited development or regulatory review or approval process and any orphan drug exclusivity we may receive for approved products may not prevent the FDA or the European Commission from approving other competing products.

We received orphan drug designation from the FDA and the European Commission for Privosegtor for the treatment of optic neuritis. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan product candidates by the European Commission in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission (as applicable) from approving another marketing authorizations application for another similar product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union (which can be extended to 12 years if the sponsor complies with an agreed upon pediatric investigation plan). The exclusivity period in the European Union can be reduced to six years if at the end of the fifth year it is determined that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our current or future product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that

affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. In addition, the European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current 10-year marketing exclusivity period in the EU for certain orphan medicines. Depending on what changes the FDA and the European Commission may make to its orphan drug regulations and policies, our business could be adversely impacted.

Breakthrough Therapy designation from the FDA may not lead to a faster development or regulatory review and does not assure ultimate approval.

We have received Breakthrough Therapy designation from the FDA for Privosegtor for the treatment of ON. FDA may grant Breakthrough Therapy designation to a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, prioritized interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. The receipt of Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later revoke Breakthrough Therapy designation.

The U.S. Government and non-U.S. regulatory agencies actively enforce laws and regulations regarding the promotion of pharmaceutical products, and if we are found to have violated any such laws or regulations, we may be subject to significant liability.

The FDA and other U.S. Government agencies and non-U.S. regulatory agencies strictly regulate the manner in which medicinal products may be marketed. In particular, a medicinal 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 legislation, 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 (*"SmPC"*), as approved by the competent agencies 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 agencies of the EU member states 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, as well as reputational harm, 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 regulations of foreign agencies, requirements to provide accurate information to the FDA or equivalent foreign agencies, 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 agencies 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 agencies 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 agencies 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, commercial partners, customers, CROs and third-party payors in connection with our current and future business activities may be subject to federal, state and foreign 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 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;
- 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;
- HIPAA, as amended by HITECH 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; and
- Foreign equivalents to the above-mentioned rules.

Certain state and local jurisdictions require certain regulatory licenses to manufacture or distribute pharmaceutical products commercially and/or the registration of pharmaceutical sales representatives. State and foreign laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the 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 and foreign laws require biotechnology companies to report information on the pricing of certain drug products. 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 agencies 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. For example, our Phase 2 ACUITY trial of Privosegtor was conducted entirely in France, and our Phase 3 DIAMOND trials in OCS-01 included trial sites outside the United States. Our business activities are subject to the U.S. Foreign Corrupt Practices Act (*"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.

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 agencies 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 agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, their 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 regulatory agencies to perform routine functions. Average review times at regulatory agencies 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 agencies, including government budget and funding levels, statutory, regulatory, and policy changes, layoffs, their ability to hire and retain key personnel as well as impacts resulting from broader market conditions may affect the such agency’s ability to perform routine functions thereby extending the time necessary for new product candidates or

modifications to be cleared, or approved products to be reviewed and approved by necessary government agencies. Over the last several years, the U.S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA or other regulatory authorities is reduced, priorities change, a prolonged government shutdown occurs, or current or future global health concerns prevent the FDA or other regulatory authorities from conducting regulator inspections, reviews or other activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. The current administration is pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of HHS, FDA, Center for Medicare and Medicaid Services and related agencies. These actions may propose policy changes that create additional uncertainty for our business and could affect the FDA's relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs, 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 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.

Our 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 our ordinary shares are listed exclusively on the United States Nasdaq Global Market and the Nasdaq Iceland Main 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 our ordinary shares are listed exclusively on the United States Nasdaq Global Market and the Nasdaq Iceland Main 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 committee members 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 committee members 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 of our 2025 Annual Report entitled "*Enforcement of Civil Liabilities*."

Our status as a Swiss stock corporation means that our shareholders enjoy certain rights that may limit our 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 our shareholders may introduce a capital band pursuant to which share capital that can be issued by our 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 our 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 our 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 31,020,888 ordinary shares (capital band) and to place rights to acquire such number of new shares corresponding to up to an additional 6,750,000 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 15.0% 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 of our 2025 Annual Report 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 U.S. 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 U.S. Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to U.S. 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.

We may also choose to take advantage of other exemptions including but not limited to the exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans using conditional share capital approved by the shareholders.

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 U.S. 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 U.S. 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 of our 2025 Annual Report 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 50.0% of its assets cannot be located in the United States, and (c) its business must be administered principally outside the United States. If we lost this status, we 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 Accounting Standards, which would involve significant time and cost and could result in variations, which could be material, between historical financial results reported under IFRS Accounting Standards and as reported under U.S. GAAP. We may also be required to make changes in our 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 we 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 we lose our foreign private issuer status and are unable to devote adequate funding and the resources needed to maintain compliance with U.S. securities laws, while continuing our operations, we could be forced to deregister with the SEC. A deregistration would substantially reduce or effectively terminate the trading of our 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 us to obtain director and officer liability insurance, and we 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.

Changes to the SEC's foreign private issuer rules could adversely affect our ability to maintain foreign private issuer status and the exemptions and accommodations available to us.

The SEC is currently reviewing the regulatory framework applicable to foreign private issuers, including the eligibility criteria for foreign private issuer status and certain accommodations, exemptions and reporting requirements available to foreign private issuers. As a result of this review, the SEC may in the future adopt changes to the foreign private issuer rules that could significantly alter the requirements applicable to us, limit or eliminate certain exemptions and accommodations currently available to us, or affect our ability to maintain foreign private issuer status. The timing, scope and ultimate outcome of any such regulatory changes, as well as their impact on our business, reporting obligations, governance practices, compliance costs and capital markets activities, are uncertain and cannot be predicted. Any such changes could require us to modify our practices, incur significant additional legal, accounting and other compliance expenses, and could reduce or eliminate some of the benefits we currently enjoy as a foreign private issuer.

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 and Swiss francs. Our functional currency is the Swiss franc and the majority of our operating expenses are paid in 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 dual-listed public company

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

We have and will continue to incur significant legal, accounting, insurance and other expenses as a result of being a public company with shares listed both on the Nasdaq Global Market in the United States and the Nasdaq Main Market in Iceland. As a U.S. 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. As a company listed on the Nasdaq Iceland Main Market, we are subject to reporting requirements under various Icelandic laws, including those implementing EU legislation. This includes, but is not limited to, Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014, on market abuse ("*MAR*") and the Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market (the "*Transparency Directive*"). We are also subject to corporate governance requirements in the United States, Switzerland and Iceland. Our management and other personnel have and will need to devote a substantial amount of time to these reporting compliance initiatives. Moreover, we expect that compliance with these rules and regulations will continue to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. As we were no longer an "emerging growth company" as of December 31, 2025, as defined in Section 2(a) of the Securities Act, these expenses have increased and may continue to increase even more as we implement the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. For example, we expect these rules and regulations will continue 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 or executive committee.

The market price and trading volume of our ordinary shares and warrants may be volatile and could decline significantly, and may make it more difficult for you to sell your ordinary shares.

The United States Nasdaq Global Market, on which our ordinary shares and warrants are listed under the symbols "OCS" and "OCSAW," respectively, and the Nasdaq Iceland Main Market on which our ordinary shares trade under the symbol "OCS," have from time to time experienced significant price and volume

fluctuations. The market price of our ordinary shares and warrants may be volatile and could decline significantly. Generally, securities of biopharmaceutical companies tend to be volatile and experience significant price and volume fluctuations. For example, our share price experienced a significant decline after we announced results of our DIAMOND clinical trials in May 2026.

In addition, the trading volume in our ordinary shares and warrants may fluctuate and cause significant price variations to occur. The average trading volume of our ordinary shares traded per day from January 1, 2025 to December 31, 2025 on the Nasdaq Global Market was approximately 58,114 shares per day. The average trading volume of our ordinary shares can be very sporadic and may impair the ability of holders of our ordinary shares to sell their shares at the time they wish to sell them or at a price that they consider reasonable. A low trading volume may also reduce the fair market value of our ordinary shares. Also, due to the low volume of shares traded on any trading day, persons buying or selling in relatively small quantities may easily influence prices of our ordinary shares. Accordingly, there can be no assurance that the price of our ordinary shares will reflect our actual value. There can be no assurance that the daily trading volume of our ordinary shares will increase or improve.

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 herein;
- 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 the United States Nasdaq Global Market or Nasdaq Iceland Main Market;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations in the United States, Switzerland and Iceland;
- future issuances, sales or resales, or anticipated issuances, sales or resales, of our 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;
- 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.

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

The trading market for ordinary shares is influenced by the research and reports that industry or securities analysts may publish about us, our business, our market, or our competitors. If any of the analysts who may cover our company change their recommendation regarding ordinary shares adversely, cease to provide coverage or provide more favorable relative recommendations about our competitors, the price of our ordinary shares would likely decline.

The dual listing of our ordinary shares may adversely affect the liquidity and value of those ordinary shares.

Our ordinary shares are listed on the United States Nasdaq Global Market and on the Nasdaq Iceland Main Market. The trading of our ordinary shares in these markets takes place in different currencies (U.S. dollars on Nasdaq Global Market and Icelandic Krona on Nasdaq Iceland Main Market), at different times (resulting from different time zones, different trading days and different public holidays in the United States and Iceland) and with different settlement mechanics. The trading prices of ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of ordinary shares on Nasdaq Iceland Main Market could cause a decrease in the trading price of ordinary shares on Nasdaq Global Market and vice versa. Investors could seek to sell or buy ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the trading prices on one exchange and ordinary shares available for trading on the other exchange. Further, the dual listing of ordinary shares may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for ordinary shares in the United States.

The listing of ordinary shares on Nasdaq Iceland Main Market may result in increased additional compliance risk, which could have a material effect on our business, results of operations and financial condition, or may delay or discourage a takeover attempt.

The Nasdaq Iceland Main Market is a regulated market in Iceland operated by Nasdaq Iceland hf., the Icelandic stock exchange. Issuers on Nasdaq Iceland Main Market are subject to the rules of Nasdaq Iceland Main Market and the relevant rules and regulations given the fact that the securities of the issuer are admitted to trading on a regulated market.

As a dual-listed Swiss company listed on Nasdaq Iceland Main Market and Nasdaq Global Market, we are subject to reporting requirements discussed above as well as certain other applicable requirements under Swiss law, U.S. law and Icelandic law, including, but not limited to:

Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014, on market abuse, as amended, as implemented into Icelandic law with Act No. 60/2021 ("MAR"). MAR imposes specific requirements on Oculis, members of the Board and management, as well as persons closely associated with members of the Board and management, including (i) public disclosure of inside information, (ii) procedural requirements on both the disclosing participant and the receiving participant related to market soundings, (iii) requirements to draw up and maintain insider lists, and (iv) requirements that persons within Oculis that discharge managerial responsibilities and persons closely associated with them notify Oculis and the Financial Supervisory Authority of the Central Bank of Iceland of any transactions relating to shares or any debt instruments of Oculis or to derivatives or other financial instruments linked thereto, and Oculis shall in turn disclose the information to the public.

Further, MAR imposes restrictions on all insiders and persons performing or conducting transactions in financial instruments issued by Oculis. It is prohibited for any person to make use of inside information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, financial instruments to which that information relates, as well as an attempt thereto (insider dealing). In addition, it is prohibited for any person to disclose inside information to anyone else except where the disclosure is made in the normal exercise of an employment, profession or duties, or, whilst in possession of inside information, to recommend or induce anyone to acquire or dispose of financial instruments to which the information relates. Furthermore, it is prohibited for any person to engage in or attempt to engage in market manipulation, for instance by conducting transactions which give, or are likely to give, false or misleading signals as to the supply of, the demand for or the price of a financial instrument.

Non-compliance with the above obligations under MAR is an economic offense and could lead to the imposition of criminal prosecution, administrative fines, imprisonment or other sanctions. Nasdaq Iceland hf. may impose administrative penalties or a cease-and-desist order under penalty for non-compliance.

Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, as amended, as implemented into Icelandic law with Act No. 20/2021 (the "Disclosure Act"). The Disclosure Act imposes requirements including (i) periodic disclosure of financial reports (annual and half-yearly reports), prepared in accordance with the Icelandic Act, no. 3/2006, on Annual Accounts (the Annual Accounts Act) or in accordance with the applicable Switzerland legislation if deemed to be equivalent to that of the Annual Accounts Act, (ii) disclosure by shareholders that acquire or dispose of ordinary shares if it results in the holding exceeding or falling below the thresholds of 5, 10, 15, 20, 25, 30, 35, 40, 50, 66 2/3 and 90% and (iii) equal treatment and shareholders rights, including but not limited to ensuring that all information necessary to enable shareholders to exercise their rights are available. Shareholders are advised to consult with their own legal advisors to determine whether the notification obligations apply to them.

Icelandic procedural rules that may become applicable to any takeover bid as set out in the Icelandic legal Act no. 108/2007 (the Takeover Act) which *inter alia* regulates the process relating to the submission of a voluntary takeover offer.

Corporate Sustainability Reporting Directive (EU) 2022/2464 ("CSRD"). In addition, we expect that we may need to comply with the CSRD, once implemented into Icelandic law, which requires EU and non-EU companies with activities in the EU to file annual sustainability reports alongside their financial statements.

Failure to comply with these new compliance requirements, when applicable to Oculis, could have a material effect on our business, results of operations and financial condition, or may delay or discourage a takeover attempt.

We have issued and expect to continue to issue additional ordinary shares, including under our equity incentive plan. Any such issuances would dilute the interest of our shareholders and likely present other risks.

We have issued and expect to continue to issue a substantial number of ordinary shares, including under our Stock Option and Incentive Plan Regulation 2023 (the *"2023 Plan"*).

Ordinary shares reserved for future issuance under the 2023 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 reserved for issuance under the 2023 Plan is 12,677,700 ordinary shares. As of December 31, 2025, we had awards issued and outstanding covering 6,171,582 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 our ordinary shares if securities are issued with rights senior to those afforded to our ordinary shares; and
- may adversely affect prevailing market prices for our ordinary shares.

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ordinary shares. In addition, Swiss law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your shares for the foreseeable future and the success of an investment in the shares will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of the shares after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the shares will appreciate in value or even maintain the price at which our shareholders have purchased them. Investors seeking cash dividends should not purchase the shares.

In addition, exchange rate fluctuations may affect the amount of euro that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in Swiss Francs, if any. These factors could harm the value of the shares, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the shares.

Our BCA Public Warrants, BCA Private Warrants and Amended BlackRock Warrant are exercisable for our 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 BCA Public Warrants and BCA Private Warrants to purchase an aggregate of 4,403,294 ordinary shares became exercisable on April 2, 2023. The exercise price of these Warrants is $11.50 per ordinary share, or approximately $50.6 million, assuming none of the Warrants are exercised through “cashless” exercise. As of December 31, 2025, 2,045,596 BCA Public Warrants and BCA Private Warrants remained outstanding. On July 31, 2025, as additional consideration for our existing loan facility with Kreos, we entered into an amended warrant with Kreos Capital VII Aggregator SCSp, an affiliate of Kreos (the *“Amended BlackRock Warrant*”). The Amended BlackRock Warrant may be exercised to purchase up to 494,259 ordinary shares, subject to vesting, at a price per ordinary share equal to $12.17 with respect to 361,011 ordinary shares from the prior warrant agreement, and $18.64 with respect to the remaining 133,248 ordinary shares. As of December 31, 2025, the Amended BlackRock Warrant is exercisable for 59,310 ordinary shares. To the extent such warrants are exercised, additional ordinary shares will be issued, which will result in dilution to the holders of our 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. On December 31, 2025, the last reported closing price of our ordinary shares on Nasdaq Global Market was $19.97 per share and the last reported closing price of our BCA Public Warrants was $8.56 per warrant. Because the recent trading price for our ordinary shares is greater than the exercise price of our outstanding warrants, we believe the holders of our warrants are likely to exercise their warrants to purchase our ordinary shares. 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, if the warrants are not exercised prior to their expiration, they may expire worthless.

The BCA Public Warrants and BCA Private Warrants may expire worthless and the terms of the BCA Public Warrants may be amended in a manner adverse to a holder if holders of at least 50.0% of the then outstanding BCA Public Warrants approve of such amendment.

The exercise price for our BCA Public Warrants and BCA Private Warrants is $11.50 per ordinary share. We believe the likelihood that warrant holders will exercise their BCA Public Warrants and BCA Private 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 ordinary share, we believe

warrant holders will be unlikely to exercise their Warrants. Because the recent trading price for our ordinary shares is greater than $11.50 per ordinary share, we believe holders of our BCA Public Warrants and BCA Private Warrants are likely to exercise their warrants. However, if the BCA Public Warrants and BCA Private Warrants remain unexercised prior to their expiration, they may expire worthless.

The BCA Public Warrants and BCA Private Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and EBAC, and were assumed by us at the time of the Closing, 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 50.0% of the then-outstanding BCA Public Warrants to make any change that adversely affects the interests of the registered holders of BCA Public Warrants. Accordingly, we may amend the terms of the BCA Public Warrants in a manner adverse to a holder if holders of at least 50.0% of the then-outstanding BCA Public Warrants approve of such amendment and, solely with respect to any amendment to the terms of the BCA Private Warrants or any provision of the warrant agreement with respect to the BCA Private Warrants, 50.0% of the number of the then outstanding BCA Private Warrants. Although our ability to amend the terms of the BCA Public Warrants with the consent of at least 50.0% of the then-outstanding BCA 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 BCA Public Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless.

We may redeem the BCA 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 BCA 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 our ordinary shares equals or exceeds $18.00 per ordinary 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 our 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 BCA Public Warrants become redeemable by us, we may exercise the redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding BCA Public Warrants could force holders (i) to exercise the BCA Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous to do so, (ii) to sell the BCA Public Warrants at the then-current market price when holders might otherwise wish to hold the BCA Public Warrants, or (iii) to accept the nominal redemption price which, at the time the outstanding BCA Public Warrants are called for redemption, is likely to be substantially less than the market value of the BCA Public Warrants.

In addition, we will have the ability to redeem the outstanding BCA 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 our ordinary shares equals or exceeds $10.00 per ordinary share (as adjusted for share

sub-divisions, 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 our ordinary shares have exceeded the $10.00 per ordinary share threshold at which the BCA Public Warrants would become redeemable. In such a case, the holders will be able to exercise their BCA Public Warrants prior to redemption for a number of ordinary shares determined based on the redemption date and the fair market value of our ordinary shares.

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

Risks related to taxation

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.

All Swiss cantons, including the Canton of Zug and 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 Zug, Canton of Zug and 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 2025 in Zug, Canton of Zug will be approximately 11.7% and in Lausanne, Vaud will be approximately 14.7%.

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

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 75.0% 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 25.0% of the shares by value, is passive income, or (ii) at least 50.0% 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 25.0% 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.

Based on our analysis of our income, assets, activities, and market capitalization, we believe that we were not a PFIC for our taxable year ended December 31, 2025. The determination of whether a non-U.S. corporation is a PFIC is a fact-intensive determination made on an annual basis 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. The amount of passive income and passive assets we take into account for PFIC testing purposes depends, in part, on the size of our cash balance (taking into account the timing and manner in which such cash is used) and the interest rates applicable thereto. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to our market capitalization from time to time, which may fluctuate considerably. As a result, there can be no assurance with respect to our PFIC status for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for any 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 Co-operation and Development, 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. The OBBBA, the IRA, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020 (the *"CARES Act"*), and the Tax Cuts and Jobs Act enacted in 2017 (the *"TCJA"*) made many significant changes to the U.S. Internal Revenue Code of 1986, as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years.

Changes in or interpretations under the OBBBA, the TCJA, the IRA, or other tax legislation, or the enactment of new tax legislation, could increase our future tax liability, which could in turn adversely impact our business and future profitability.

Our tax treatment may also be impacted by tax policy initiatives and reforms such as the Base Erosion and Profit Shifting (*"BEPS"*) Project (including *"BEPS 2.0"*) of the Organisation for Economic Co-operation and Development (*"OECD"*), 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 includes the reallocation of global profits above a fixed profit margin of large multinational companies to market jurisdictions based, broadly, on customer location (referred to as the Pillar One rules) as well as the introduction of a global minimum tax (referred to as the Pillar Two rules). Core elements of the OECD minimum tax rate rules (referred to as the Pillar Two rules) have been implemented in Switzerland by means of an ordinance. The people and cantons approved the necessary constitutional amendment in a popular vote on June 18, 2023. During its meeting on December 22, 2023, the Federal Council decided to implement the minimum tax rate with the introduction of a supplementary tax, Qualified Domestic Minimum Top-up Tax in Switzerland as from January 1, 2024. On September 4, 2024, the Federal Council decided to bring the international supplementary tax under the income inclusion rule into force with effect from 1 January 2025. The introduction of the Under-Taxed Payment Rule has been postponed to a later date. Within six years, the Federal Council must additionally submit to the Swiss Parliament a federal act that replaces the ordinance. Many countries have enacted, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds, we currently expect to be outside the scope of both the Pillar One and Pillar Two rules, but could fall within their scope in the future, which could increase our tax obligations and compliance costs.

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.