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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2026

OR

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

For the transition period from _________ to _________

Commission File Number: 001-36687

XENON PHARMACEUTICALS INC.
(Exact name of Registrant as Specified in its Charter)

Canada (State or other jurisdiction of incorporation or organization)	**98-0661854** (I.R.S. Employer Identification No.)
3650 Gilmore Way **Burnaby, British Columbia, Canada** (Address of principal executive offices)	**V5G 4W8** (Zip Code)

Registrant's telephone number, including area code: (604) 484-3300

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, without par value	XENE	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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

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

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

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

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

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

As of May 4, 2026, the registrant had 96,665,550 common shares, without par value, outstanding.

XENON PHARMACEUTICALS INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2026

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In this Quarterly Report on Form 10-Q, “we,” “our,” “us,” “Xenon,” and “the Company” refer to Xenon Pharmaceuticals Inc. and its subsidiary. “Xenon” and the Xenon logo are the property of Xenon Pharmaceuticals Inc. and are registered in the United States and used or registered in various other jurisdictions. This report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this report captioned “Risk Factors.” The following is a summary of the principal risks we face:

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We will need to raise additional funding, which may not be available on acceptable terms, if at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product discovery and development programs or commercialization efforts or other operations.
- Our business substantially depends upon the successful development of azetukalner. If we are unable to obtain regulatory approval for, and successfully commercialize, azetukalner, our business may be materially harmed.
- Clinical studies may fail to demonstrate adequately the safety and efficacy of our, or our collaborators’, product candidates at any stage of clinical development. Terminating the development of any of our, or our collaborators’, product candidates could materially harm our business and the market price of our common shares.
- We, or our collaborators, may find it difficult to enroll patients in our clinical studies which could delay or prevent the successful completion of clinical studies of our product candidates.
- We, or our collaborators, may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our, or our collaborators’, product candidates.
- The regulatory approval processes of the FDA, EMA and regulators in other foreign jurisdictions are lengthy, time-consuming and inherently unpredictable. If we, or our collaborators, are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, our business may be substantially harmed.
- If we are unable to establish our own sales, marketing and distribution capabilities or enter into agreements for these purposes, we may not be successful in independently commercializing any future products.
- Our prospects for successful development and commercialization of our partnered products and product candidates are dependent upon the research, development and marketing efforts of our collaborators.
- Our reliance on third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, APIs or drug products when needed or at an acceptable cost.
- We rely on third parties to conduct our pre-clinical studies and clinical studies. If these third parties do not successfully carry out their contractual duties, including to comply with applicable laws and regulations or meet expected deadlines, our business could be substantially harmed.
- We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products, product candidates or future products.
- We may not be able to protect our intellectual property rights throughout the world.
- Our business and operations could suffer in the event of an actual or perceived information security incident such as a cybersecurity breach, system failure or other compromise of our systems and/or information, including information held by a third-party contractor or vendor.
- The market price of our common shares may be volatile, and purchasers of our common shares could incur substantial losses.
- Future sales and issuances of our common shares or securities convertible into or exchangeable for common shares would cause our shareholders to incur dilution and could cause the market price of our common shares to fall.

Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(Expressed in thousands of U.S. dollars except share amounts)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 545,867	$ 199,163
Marketable securities (note 4)	548,880	349,723
Other receivables	1,165	1,371
Prepaid expenses and other current assets	10,720	10,392
Total current assets	1,106,632	560,649
Marketable securities, long-term (note 4)	244,874	37,152
Operating lease right-of-use asset, net (note 5)	6,288	6,626
Property, plant and equipment, net	8,294	8,721
Deferred tax assets	12,417	12,864
Prepaid expenses, long-term	8,305	7,151
Total assets	$ 1,386,810	$ 633,163
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (note 6)	$ 38,254	$ 40,260
Operating lease liability (note 5)	1,561	1,532
Total current liabilities	39,815	41,792
Operating lease liability, long-term (note 5)	5,930	6,412
Other liabilities, long-term	3,246	3,199
Total liabilities	$ 48,991	$ 51,403
Shareholders' equity:		
Common shares, without par value; unlimited shares authorized; issued and outstanding: 96,624,123 (December 31, 2025 - 80,010,790) (note 7)	$ 2,421,833	$ 1,598,571
Additional paid-in capital	264,879	228,234
Accumulated deficit	(1,347,682)	(1,245,380)
Accumulated other comprehensive income (loss)	(1,211)	335
Total shareholders' equity	$ 1,337,819	$ 581,760
Total liabilities and shareholders' equity	$ 1,386,810	$ 633,163

Commitments and contingencies (note 10)

See accompanying notes to the condensed consolidated financial statements.

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(Expressed in thousands of U.S. dollars except share and per share amounts)

	Three Months Ended March 31,	
	2026	**2025**
Collaboration revenue (note 8)	$ —	$ 7,500
Operating expenses:		
Research and development	88,508	61,200
General and administrative	23,820	19,038
Total operating expenses	112,328	80,238
Loss from operations	(112,328)	(72,738)
Other income:		
Interest income	6,907	8,083
Foreign exchange gain	548	35
Total other income	7,455	8,118
Loss before income taxes	(104,873)	(64,620)
Income tax recovery (expense)	2,571	(427)
Net loss	$ (102,302)	$ (65,047)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities (note 4)	(1,546)	776
Comprehensive loss	$ (103,848)	$ (64,271)
Net loss per common share (note 9):		
Basic and diluted	$ (1.17)	$ (0.83)
Weighted-average common shares outstanding (note 9):		
Basic and diluted	87,345,717	78,687,503

See accompanying notes to the condensed consolidated financial statements.

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Shareholders' Equity
(Unaudited)
(Expressed in thousands of U.S. dollars except share amounts)

	Common shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total shareholders' equity
	Shares	*Amount*				
Balance as of December 31, 2024	76,416,086	$ 1,456,836	$ 199,149	$ (899,470)	$ (1,612)	$ 754,903
Net loss for the period	—	—	—	(65,047)	—	(65,047)
Stock-based compensation expense	—	—	12,174	—	—	12,174
Issuance of common shares pursuant to equity incentive plans	170,273	4,014	(2,863)	—	—	1,151
Other comprehensive income	—	—	—	—	776	776
Balance as of March 31, 2025	76,586,359	$ 1,460,850	$ 208,460	$ (964,517)	$ (836)	$ 703,957
Balance as of December 31, 2025	80,010,790	$ 1,598,571	$ 228,234	$ (1,245,380)	$ 335	$ 581,760
Net loss for the period	—	—	—	(102,302)	—	(102,302)
Issuance of common shares and pre-funded warrants, net	15,370,962	790,198	47,328	—	—	837,526
Exercise of pre-funded warrants	118,980	3,296	(3,296)	—	—	—
Stock-based compensation expense	—	—	16,894	—	—	16,894
Issuance of common shares pursuant to equity incentive plans	1,123,391	29,768	(24,281)	—	—	5,487
Other comprehensive loss	—	—	—	—	(1,546)	(1,546)
Balance as of March 31, 2026	96,624,123	$ 2,421,833	$ 264,879	$ (1,347,682)	$ (1,211)	$ 1,337,819

See accompanying notes to the condensed consolidated financial statements.

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(Expressed in thousands of U.S. dollars)

	Three Months Ended March 31,	
	2026	2025
Operating activities:		
Net loss	$ (102,302)	$ (65,047)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest receivable and accretion of discounts on marketable securities	(877)	2,947
Depreciation of property plant and equipment	587	659
Non-cash operating lease expense	338	322
Deferred income tax expense (recovery)	447	(1,213)
Stock-based compensation expense	16,894	12,174
Unrealized foreign exchange (gain) loss	(204)	182
Realized (gain) loss on marketable securities	(400)	518
Changes in operating assets and liabilities:		
Other receivables	205	(7,178)
Prepaid expenses and other current assets	(1,482)	(926)
Accounts payable and accrued liabilities	(1,801)	(3,783)
Operating lease liability	(349)	(307)
Other liabilities	47	—
Net cash used in operating activities	(88,897)	(61,652)
Investing activities:		
Purchases of property, plant and equipment	(133)	(43)
Purchases of marketable securities	(505,652)	(131,239)
Proceeds from marketable securities	98,503	165,792
Net cash provided by (used in) investing activities	(407,282)	34,510
Financing activities:		
Proceeds from offerings, net	837,526	—
Proceeds from exercise of stock options	5,487	1,151
Net cash provided by financing activities	843,013	1,151
Effect of exchange rate changes on cash and cash equivalents	(130)	(64)
Increase (decrease) in cash and cash equivalents	346,704	(26,055)
Cash and cash equivalents, beginning of period	199,163	142,712
Cash and cash equivalents, end of period	$ 545,867	$ 116,657
Supplemental disclosure of cash paid:		
Operating lease	$ 439	$ 420
Supplemental disclosures of non-cash transactions:		
Fair value of stock options and pre-funded warrants exercised on a cashless basis	$ 17,644	$ 2,085

See accompanying notes to the condensed consolidated financial statements.

1. Nature of the business:

Xenon Pharmaceuticals Inc. (the "Company"), incorporated in 1996 under the predecessor to the Business Corporations Act (British Columbia) and continued federally in 2000 under the Canada Business Corporations Act, is a neuroscience-focused biopharmaceutical company dedicated to drug discovery, clinical development, and commercialization of life-changing therapeutics for patients in need.

The Company has incurred significant operating losses since inception. As of March 31, 2026, the Company had an accumulated deficit of $1,347,682 and a net loss of $102,302 for the three months ended March 31, 2026. Management expects to continue to incur significant expenses in excess of revenue and to incur operating losses for the foreseeable future. To date, the Company has financed its operations primarily through the sale of equity securities, funding received from collaboration and license agreements, and debt financings.

Until such time as the Company can generate substantial product revenue, if ever, management expects to finance the Company's cash needs through a combination of collaboration agreements, equity and debt financings. The continuation of research and development activities and the future commercialization of its products are dependent on the Company's ability to successfully raise additional funds when needed. It is not possible to predict either the outcome of future research and development programs or the Company's ability to continue to fund these programs in the future.

As of March 31, 2026, the Company had cash, cash equivalents and marketable securities of $1,339,621. Although the Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future, the Company expects the cash, cash equivalents and marketable securities to be sufficient to fund current operations for at least the next 12 months from the issuance of the financial statements.

2. Basis of presentation:

These unaudited interim condensed consolidated financial statements are presented in U.S. dollars and include the accounts of the Company and its wholly-owned subsidiary, Xenon Pharmaceuticals USA Inc., a Delaware corporation. All intercompany transactions and balances have been eliminated on consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Certain information has been reclassified to conform with the financial presentation adopted for the current year. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes required for complete consolidated financial statements and should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2025 included in the Company's 2025 Annual Report on Form 10-K filed with the SEC and with the securities commissions in British Columbia, Alberta and Ontario on February 26, 2026.

These unaudited interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods presented. The results of operations for the three months ended March 31, 2026 and 2025 are not necessarily indicative of results that can be expected for a full year. These unaudited interim condensed consolidated financial statements follow the same significant accounting policies as those described in the notes to the audited consolidated financial statements of the Company included in the Company's 2025 Annual Report on Form 10-K for the year ended December 31, 2025.

3. Fair value of financial instruments:

The fair value hierarchy consists of the following three levels:

- *Level 1* - Unadjusted quoted prices in active markets for identical instruments.
- *Level 2* - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

- *Level 3* - Inputs are unobservable and reflect the Company's assumptions as to what market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

The carrying amounts of cash and cash equivalents, other receivables, and accounts payable and accrued liabilities approximate their fair value due to the nature and short-term maturity of these instruments.

The following table summarizes the fair value hierarchy levels used to determine the fair values of the Company's cash and cash equivalents and marketable securities:

	March 31, 2026				December 31, 2025			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:								
Cash and money market fund, mutual funds, commercial paper and U.S. treasuries	$ 522,449	$ 23,418	$ —	$ 545,867	$ 154,659	$ 44,504	$ —	$ 199,163
Total cash and cash equivalents	522,449	23,418	—	545,867	154,659	44,504	—	199,163
Marketable securities:								
Guaranteed investment certificates	7,222	—	—	7,222	14,737	—	—	14,737
U.S. treasuries	273,065	—	—	273,065	142,593	—	—	142,593
Commercial paper	—	80,047	—	80,047	—	39,559	—	39,559
Corporate debt securities	—	433,420	—	433,420	—	189,986	—	189,986
Total marketable securities	280,287	513,467	—	793,754	157,330	229,545	—	386,875
Total	$ 802,736	$ 536,885	$ —	$ 1,339,621	$ 311,989	$ 274,049	$ —	$ 586,038

The fair values of the Company's commercial paper and corporate debt securities are based on prices obtained from independent pricing sources. Securities with validated quotes from pricing services are reflected within Level 2, as they are primarily based on observable pricing for similar assets or other market observable inputs. Typical inputs used by these pricing services include, but are not limited to, reported trades, benchmark yields, issuer spreads, bids, offers or estimates of cash flow, prepayment spreads and default rates.

As of March 31, 2026 and December 31, 2025, the Company did not hold any securities classified as Level 3 and there were no securities transferred between Level 1 and Level 2.

4. Marketable securities:

Amortized cost, unrealized gain (loss) recognized in accumulated other comprehensive income (loss) and fair value of available-for-sale securities consisted of the following:

	March 31, 2026			December 31, 2025		
	Amortized Cost	Unrealized Gain (Loss)	Fair Value	Amortized Cost	Unrealized Gain	Fair Value
Current:						
Guaranteed investment certificates	$ 7,272	$ (50)	$ 7,222	$ 14,348	$ 389	$ 14,737
U.S. treasuries	213,521	52	213,573	111,901	197	112,098
Commercial paper	80,080	(33)	80,047	39,555	4	39,559
Corporate debt securities	248,127	(89)	248,038	182,864	465	183,329
Total current	549,000	(120)	548,880	348,668	1,055	349,723
Non-current:						
U.S. treasuries	59,476	16	59,492	30,292	203	30,495
Corporate debt securities	185,499	(117)	185,382	6,590	67	6,657
Total non-current	244,975	(101)	244,874	36,882	270	37,152
Total	$ 793,975	$ (221)	$ 793,754	$ 385,550	$ 1,325	$ 386,875

Allowance for credit losses or impairment on these marketable securities has not been recognized as these securities are high credit quality, investment grade securities that the Company does not intend to sell and will not be required to sell prior to their anticipated recovery. The change in fair value is primarily due to changes in interest and foreign exchange rates.

5. Leases:

The Company has an operating lease for research laboratories and office space in Burnaby, British Columbia which expires on June 30, 2032, and two renewal options for 5-years each which were not considered in the determination of the right-of-use asset and lease liability. The Company has an additional 65-month operating lease for office space in Needham, Massachusetts, which commenced in October 2022. There is an option to terminate one year prior to the expiry date, which was not considered in the determination of the right-of-use asset and lease liability.

The following table presents supplemental operating leases information:

	Three Months Ended March 31, 2026	2025
Lease cost:		
Operating lease expense	$ 411	$ 408
Variable lease expense[(1)]	219	200
Lease term and discount rate:		
Weighted average remaining lease term (years)	5.5	6.2
Weighted average discount rate	3.7%	3.8%

(1) Variable lease costs are payments that vary because of changes in facts or circumstances and include common area maintenance and property taxes related to the premises. Variable lease costs are excluded from the calculation of minimum lease payments.

Future minimum lease payments as of March 31, 2026 were as follows:

Year ending December 31:	
2026	$ 1,351
2027	1,773
2028	1,072
2029	1,122
2030	1,160
2031 and thereafter	1,797
Total future minimum lease payments	$ 8,275
Less: imputed interest	(784)
Present value of lease liabilities	$ 7,491

6. Accounts payable and accrued liabilities:

Accounts payable and accrued liabilities consisted of the following:

	March 31, 2026	December 31, 2025
Accounts payable	$ 5,748	$ 3,885
Accrued liabilities:		
Employee compensation, benefits, and related accruals	7,631	14,460
Research and development	19,087	18,647
Income and other taxes	269	313
Professional fees	4,179	1,989
Other	1,340	966
Total accrued liabilities	32,506	36,375
Total	$ 38,254	$ 40,260

7. Share capital:

(a) Financing:

In August 2020, the Company entered into an "at-the-market" equity offering sales agreement, amended as of March 2022, with Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, pursuant to which the Company may sell common shares from time to time (the "ATM Program"). Pursuant to a prior prospectus, the Company sold an aggregate of 3,134,119 common shares for proceeds of $129,975, net of commissions and transaction expenses, during the period from January 1, 2026 to February 26, 2026. On February 27, 2026, a new prospectus supplement was filed replacing the prior prospectus, pursuant to which the Company refreshed the ATM Program and may sell common shares having gross proceeds of up to $400,000, from time to time.

In March 2026, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies LLC, TD Securities (USA) LLC, Stifel, Nicolaus & Company, Incorporated, RBC Capital Markets, LLC, and William Blair & Company, L.L.C., relating to an underwritten public offering of 12,236,843 common shares, including 1,710,526 shares sold upon the full exercise of the underwriters' over-allotment option, at a public offering price of $57.00 per common share and pre-funded warrants to purchase 877,194 common shares at $56.9999 per pre-funded warrant (note 7b), with each pre-funded warrant having an exercise price of $0.0001. The public offering was completed in March 2026, and the Company received proceeds of $707,551, net of underwriting discounts, commissions, and offering expenses.

(b) Pre-funded warrants:

The following table presents pre-funded warrants activity:

	Three Months Ended March 31, 2026	2025
Outstanding, beginning of period	2,173,081	2,173,081
Issued	877,194	—
Exercised[(1)]	(118,982)	—
Outstanding, end of period	2,931,293	2,173,081

(1) During the three months ended March 31, 2026, the Company issued 118,980 common shares upon the exercise of 118,982 pre-funded warrants pursuant to a net exercise mechanism under the warrants.

Each pre-funded warrant is exercisable for the purchase of a common share at the holder's discretion at an exercise price of $0.0001, subject to certain post-exercise beneficial ownership limitations as provided under the terms of the pre-funded warrant.

Since the pre-funded warrants meet the condition for equity classification, net proceeds from issuances of the pre-funded warrants are recorded in additional paid-in capital. Upon exercise of the pre-funded warrants, the historical costs recorded in additional paid-in capital along with the exercise price collected from holder will be recorded in common shares. Pre-funded warrants to purchase 2,931,293 (2025 – 2,173,081) common shares are not included in the number of issued and outstanding common shares as of March 31, 2026.

(c) Amended and Restated 2025 Inducement Equity Incentive Plan:

In November 2025, the board of directors of the Company adopted Amended and Restated 2025 Inducement Equity Incentive Plan. Pursuant to the terms of the Amended and Restated 2025 Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted share units, restricted stock, and performance share units as an inducement material to individuals being hired, or rehired following a bona fide period of interruption of employment, as an employee of the Company or any of its subsidiaries, and its terms are substantially similar to the Company's Amended and Restated 2014 Equity Incentive Plan, including with respect to treatment of equity awards in the event of a "merger" or "change of control" as defined under the 2025 Inducement Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award exception or to comply with the Nasdaq acquisition and merger exception. The Company has reserved 900,000 common shares for issuance under the Amended and Restated 2025 Inducement Plan. In accordance with Nasdaq Listing Rule 5635(c)(4), the Company did not seek approval of the Amended and Restated 2025 Inducement Plan by its shareholders. On April 7, 2026, the Company amended and restated the Amended and Restated 2025 Inducement Equity Incentive Plan to increase the aggregate number of common shares reserved for issuance from 900,000 shares to 1,175,000 shares.

(d) Stock-based compensation:

The following table presents the components of stock-based compensation expense:

	Three Months Ended March 31, 2026	2025
Stock-based compensation expense by award type:		
Stock options	$ 14,722	$ 11,666
Restricted share units (RSUs)	1,811	147
Performance share units (PSUs)	361	361
Total	$ 16,894	$ 12,174

Stock Options

The following table presents stock option activity:

	Three Months Ended March 31, 2026	Weighted Average Exercise Price ($)	2025	Weighted Average Exercise Price ($)
Outstanding, beginning of period	11,074,720	32.40	10,709,289	29.90
Granted	2,370,020	42.12	1,873,045	35.57
Exercised[1]	(1,376,361)	21.87	(259,815)	17.31
Forfeited, cancelled or expired	(57,107)	39.33	(226,034)	38.97
Outstanding, end of period	12,011,272	35.49	12,096,485	30.88
Exercisable, end of period	5,684,840	31.02	6,547,609	24.92

(1) During the three months ended March 31, 2026, 510,000 (2025 – 80,086) stock options were exercised for the same number of common shares in exchange for cash. In the same period, the Company issued 459,263 (2025 – 90,187) common shares for the cashless exercise of 866,361 (2025 – 179,729) stock options.

The fair value of each stock option granted is estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended March 31, 2026	2025
Average risk-free interest rate	3.79%	4.09%
Expected volatility	58%	61%
Average expected term (in years)	5.74	5.69
Expected dividend yield	0%	0%
Weighted average fair value of stock options granted	$ 23.67	$ 20.81

As of March 31, 2026, the unrecognized stock-based compensation expense related to unvested stock options was $137,568, which is expected to be recognized over 2.93 years.

RSUs

The following table presents RSU activity:

	Three Months Ended March 31, 2026	Weighted Average Grant Date Fair Value ($)	2025	Weighted Average Grant Date Fair Value ($)
Outstanding, beginning of period	348,994	35.91	—	—
Granted	399,330	42.15	303,417	35.48
Vested	(73,128)	35.48	—	—
Forfeited	(4,049)	37.79	—	—
Outstanding, end of period	671,147	39.66	303,417	35.48

RSUs generally vest annually over a one-year period for directors and a four-year period for employees and officers, subject to continued service on each vesting date. As of March 31, 2026, the unrecognized stock-based compensation expense related to unvested RSUs was $24,882, which is expected to be recognized over 3.50 years.

PSUs

The following table presents PSU activity:

	Three Months Ended March 31,			
	2026	Weighted Average Grant Date Fair Value ($)	2025	Weighted Average Grant Date Fair Value ($)
Outstanding, beginning of period	257,450	40.61	210,000	43.90
Granted	—	—	88,550	35.48
Vested	(81,000)	43.76	—	—
Forfeited	(1,000)	44.37	(16,000)	44.37
Outstanding, end of period	175,450	39.14	282,550	41.23

PSUs vest upon the achievement of certain predefined company-specific performance-based criteria, subject to continued employment to each performance objective achievement date.

As of March 31, 2026, there was no unrecognized stock-based compensation expense related to unvested PSUs that is probable to be achieved. There is $6,867 of unrecognized stock-compensation expense related to PSUs that is not considered probable to be achieved. The recognition of these expenses is subject to the achievement of the performance-based criteria, which are reassessed at each reporting date.

8. Collaboration revenue:

In December 2019, the Company entered into a license and collaboration agreement with Neurocrine Biosciences, Inc. to develop treatments for epilepsy, as described in the Company's 2025 Annual Report on Form 10-K. The agreement also included a multi-year research collaboration to discover, identify and develop additional novel Nav1.6 and dual Nav1.2/1.6 inhibitors, which was completed in June 2022. As part of this ongoing collaboration, in February 2025, NBI-921355 progressed into a Phase 1 first-in-human study as a potential treatment for certain types of epilepsy and a $7,500 milestone was recognized in the three months ended March 31, 2025. Consideration associated with performance milestones is recognized as revenue using the most likely amount method when it is probable that a significant reversal of the cumulative revenue recognized will not occur.

9. Net loss per common share:

The following table presents the calculation of basic and diluted net loss per common share:

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025
Numerator:		
Net loss	$ (102,302)	$ (65,047)
Denominator:		
Common shares (weighted average)	84,998,027	76,514,422
Pre-funded warrants (weighted average)	2,347,690	2,173,081
Weighted average common shares outstanding – basic and diluted	87,345,717	78,687,503
Net loss per common share – basic and diluted	$ (1.17)	$ (0.83)

The weighted average number of common shares used in the basic and diluted net loss per common share calculations includes the weighted average pre-funded warrants outstanding during the period, as they are exercisable at any time for nominal cash consideration (note 7b).

The Company reported net losses for the three months ended March 31, 2026 and 2025, and therefore excluded the potentially dilutive outstanding securities from the computation of diluted net loss per common share as their inclusion would have had an anti-dilutive effect.

The following table summarizes potentially dilutive securities:

	Three Months Ended March 31,	
	2026	2025
Stock options	12,011,272	12,096,485
PSUs	175,450	282,550
RSUs	671,147	303,417
Warrants	—	40,000
Total	12,857,869	12,722,452

10. Commitments and contingencies:

(a) Asset purchase agreement with 1st Order Pharmaceuticals, Inc. (“1st Order”):

In April 2017, the Company acquired azetukalner from 1st Order pursuant to an asset purchase agreement. In August 2020, the Company and 1st Order amended the asset purchase agreement to amend certain definitions in the agreement and to modify the payment schedule for certain milestones. Through March 31, 2026, the Company has paid $2,000 based on progress against these milestones. Future potential payments to 1st Order include up to $6,000 in regulatory milestones. There are no royalty obligations to 1st Order.

(b) Legal contingencies:

From time to time, the Company is subject to claims and legal proceedings arising in the ordinary course of business, and such claims, individually or in the aggregate, are not likely to have a material adverse effect on the Company’s condensed consolidated financial statements.

(c) Guarantees and indemnifications:

The Company has entered into license and research agreements with third parties that include indemnification provisions that are customary in the industry. These indemnification provisions generally require the Company to compensate the other party for certain damages and costs incurred as a result of third-party claims or damages arising from these transactions.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds commercial and product liability insurance. This insurance limits the Company’s exposure and may enable it to recover a portion of any future amounts paid. Historically, the Company has not made any indemnification payments under such agreements and the Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

11. Segment disclosure:

The Company operates as a single reportable segment dedicated to drug discovery, clinical development, and commercialization of life-changing therapeutics for patients in need. The Company has no products approved for sale and has not generated any revenue from product sales. The Company’s Chief Executive Officer acts as the chief operating decision maker and manages the Company’s operations on a consolidated basis, using net loss to assess performance and allocate resources. The accounting policies for the operating segment are the same as those disclosed in the Company’s 2025 Annual Report on Form 10-K. The measure of segment assets is reported on the condensed consolidated balance sheet as total consolidated assets, with a majority of these assets located in the United States.

The following table presents information about reported segment revenues, significant segment expenses, and segment loss:

	Three Months Ended March 31,	
	2026	2025
Collaboration revenue	$ —	$ 7,500
Less:		
Direct external research and development costs:		
Azetukalner	47,073	31,501
Pain programs (XEN1701, XEN1120)	4,391	1,052
Pre-clinical, discovery and other programs	2,958	3,915
Personnel-related expenses	29,010	22,640
Stock-based compensation expense	16,894	12,174
Other research and development costs	4,201	3,425
Other general and administrative costs	7,801	5,531
Interest income	(6,907)	(8,083)
Other segment items[(1)]	(3,119)	392
Net loss	$ (102,302)	$ (65,047)

(1) Other segment items include foreign exchange gain and income tax (recovery) expense.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This section should be read in conjunction with our unaudited interim condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2025 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on February 26, 2026 and with the securities commissions in British Columbia, Alberta and Ontario on February 26, 2026.

Forward-Looking Statements

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and Canadian securities laws. The words or phrases "would be," "will allow," "intends to," "may," "believe," "plan," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, are intended to identify "forward-looking statements." You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- our ability to identify additional products or product candidates either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies;
- the initiation, timing, cost, progress and success of our research and development programs, pre-clinical studies and clinical studies;
- our ability to advance product candidates into, and successfully complete, clinical studies;
- our ability to recruit sufficient numbers of patients for our current and future clinical studies;
- our ability to obtain funding for our operations in sufficient amounts or on terms acceptable to us, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;
- our ability to independently develop and commercialize product candidates;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available;
- our pre-commercial, commercialization, marketing and manufacturing capabilities and strategy;
- our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the timing of, and our and our collaborators' ability to obtain and maintain, regulatory approvals for our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance and clinical utility of any future products;
- the pricing and reimbursement of our product candidates, if approved;
- our expectations regarding federal, state and foreign regulatory requirements;
- the impact of current and future healthcare reforms, including those affecting the delivery of or payment for healthcare products and services;
- our ability to establish and maintain collaborations;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to engage and retain the employees required to grow our business;
- our future financial performance; and

- the direct and indirect impact of pandemics, epidemics and other public health emergencies on our business and operations, including supply chain, manufacturing, research and development costs, clinical study conduct, clinical study data and employees.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments, except as required by law. In this report, "we," "our," "us," "Xenon," and "the Company" refer to Xenon Pharmaceuticals Inc. and its subsidiary. Unless otherwise noted, all dollar amounts in this report are expressed in United States dollars.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Overview

We are a neuroscience-focused biopharmaceutical company dedicated to discovering, developing, and delivering life-changing therapeutics. We are advancing an ion channel product portfolio to address areas of high unmet medical need, including epilepsy and depression.

Azetukalner Clinical Development

Azetukalner is a novel, potent Kv7 potassium channel opener in Phase 3 clinical development for multiple indications, including two in epilepsy – focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS) – as well as neuropsychiatric disorders, including major depressive disorder (MDD) and bipolar depression (BPD).

Epilepsy Programs

- We announced positive topline data from the Phase 3 X-TOLE2 study in March 2026. The study met its primary endpoint of median percent change (MPC) in monthly FOS frequency from baseline to week 12 in both the 25 mg and 15 mg azetukalner dose groups compared to placebo (MPC of -53.2%, -34.5% and -10.4%, respectively; $p<0.0001$ for both 25 and 15 mg vs. placebo). The placebo-adjusted MPC in the 25 mg group was -42.7%, outperforming the previously completed Phase 2b X-TOLE study and demonstrating the highest placebo-adjusted efficacy ever observed in a pivotal FOS study, to our knowledge. The safety and tolerability profile of azetukalner was consistent with the previously disclosed data from the Phase 2b X-TOLE study. Based on the positive results from X-TOLE2 and X-TOLE, we anticipate submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2026.
- X-TOLE2 topline efficacy and safety results were featured as a Late Breaking Science oral and poster presentation at the American Academy of Neurology (AAN) Annual Meeting in Chicago, Illinois, April 18-22. Also at AAN, we presented 48-month data from the ongoing X-TOLE open-label extension study, which demonstrated continued reductions in monthly FOS frequency with longer azetukalner treatment, greater seizure reductions in less refractory patients, and sustained periods of seizure freedom. We also presented real-world data regarding unmet needs in epilepsy, including the need for no-titration options.
- The Phase 3 X-TOLE3 study of azetukalner in FOS continues to enroll and is intended to support regulatory submissions outside the United States. X-TOLE3 enrollment outside of Japan is expected to complete in 2026.
- The Phase 3 X-ACKT study of azetukalner in PGTCS continues to enroll and is intended to support regulatory submissions for an additional epilepsy indication.

Depression Programs

- Enrollment is ongoing for the Phase 3 X-NOVA2 and X-NOVA3 studies evaluating azetukalner in patients with MDD, with topline data from X-NOVA2 expected in H1 2027.
- Enrollment is ongoing in the Phase 3 X-CEED study evaluating azetukalner in patients with BPD I or II.

Early-Stage R&D

We continue to expand our portfolio of potent, selective ion channel modulators using our strong heritage in human genetics, deep understanding of ion channel biology, and expertise in novel chemistries. This includes clinical-stage candidates targeting Nav1.7 and Kv7, which are important targets for pain.

Nav1.7 and Kv7 in Pain

- The Phase 1 Single Ascending Dose (SAD)/Multiple Ascending Dose (MAD) study in healthy adult participants is ongoing for XEN1701 targeting Nav1.7. Study completion is expected in H2 2026 to support initiating a Phase 2 proof-of-concept study in acute pain.
- The Phase 1 SAD/MAD study in healthy adult participants is ongoing for XEN1120 targeting Kv7. Study completion is expected in H2 2026 to support initiating a Phase 2 proof-of-concept study in acute pain.

Nav1.1 in Epilepsy

- IND-enabling studies are ongoing for our Nav1.1 program. Pre-clinical data suggest that targeting Nav1.1 could potentially address the underlying cause and symptoms of Dravet syndrome.
- We presented pre-clinical data for our Nav1.1 program in an oral session at the AAN meeting, demonstrating that selective potentiation of Nav1.1 channels in Dravet mice improves motor performance, suppresses spontaneous seizures, prevents Sudden Unexpected Death in Epilepsy (SUDEP), increases long-term potentiation (a potential cellular correlate of learning and memory), and produces more mature dendritic spine morphology.

Partnered Program

- In collaboration with Neurocrine Biosciences, a Phase 1b study is ongoing for NBI-921355, an investigational, selective inhibitor of voltage-gated sodium channels Nav1.2 and Nav1.6 in development for the potential treatment of certain types of epilepsy. Data from the Phase 1b study are expected in 2027.

We have funded our operations primarily through the sale of equity securities, funding received from our licensees and collaborators, and debt financing. For the three months ended March 31, 2026 and 2025, we recognized revenue of nil and $7.5 million, respectively, in connection with our agreement with Neurocrine Biosciences. To date, we have not had any products approved for sale and have not generated any revenue from product sales. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate, which we expect will take a number of years, if ever, and the outcome of which is subject to significant uncertainty.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred net losses in each year since inception and expect to continue to incur net losses for the foreseeable future. We had a net loss of $102.3 million and $65.0 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $1,347.7 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We anticipate that our operating expenses will increase substantially, particularly as we:

- prepare for the potential commercial launch of azetukalner;
- invest significantly to further develop azetukalner for our current and future indications;
- advance additional product candidates into pre-clinical and clinical development;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- hire additional commercial, clinical, scientific, management and administrative personnel;
- acquire or in-license other assets and technologies;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations and any future commercialization efforts.

Financial Operations Overview

Revenue

To date, our revenue has been primarily derived from collaboration and licensing agreements and we have not generated any revenue from product sales. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

We may also generate revenue in the future from payments as a result of license or collaboration agreements for any of our product candidates or intellectual property, such as our license and collaboration agreement with Neurocrine Biosciences, or the Neurocrine Collaboration. We cannot provide assurance as to the timing of future milestone or royalty payments under the Neurocrine Collaboration, or that we will receive any of these payments at all.

In February 2025, NBI-921355, a Nav1.2 and Nav1.6 sodium channel inhibitor in development for the potential treatment for certain types of epilepsy, progressed into a Phase 1 clinical study in healthy adult participants, triggering a $7.5 million milestone which was recognized as revenue.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct development of our proprietary product candidates and our drug discovery efforts, including any acquired or in-licensed product candidates or technology, and costs to support any partnered product candidates.

Research and development expenses consist of costs incurred in performing research and development activities, including:

- personnel-related expenses, consisting of salaries, benefits and stock-based compensation for employees engaged in scientific research and development;
- third-party expenses incurred in connection with the pre-clinical and clinical development of our product candidates, including under agreements with clinical research organizations;
- third-party expenses relating to formulation, process development and manufacture of drug substance and drug product for use in our pre-clinical testing, clinical studies and potential commercial supply;
- third-party acquisition, license and collaboration fees;
- laboratory consumables; and
- certain indirect costs incurred in support of overall research and development activities, including facilities, depreciation and information technology costs.

Project-specific expenses reflect costs directly attributable to our clinical development candidates for which we have incurred significant expenses. All remaining research and development expenses are reflected in pre-clinical, discovery and other program expenses. At any given time, we have several active early-stage research and drug discovery programs. Our personnel and infrastructure are typically deployed over multiple projects and are not directly linked to any individual internal early-stage research or drug discovery program. Therefore, we do not maintain financial information for our internal early-stage research and internal drug discovery programs on a project-specific basis.

We expense all research and development costs as incurred. Payments we make for research and development services prior to the services being rendered are recorded as prepaid assets in our consolidated balance sheets and are expensed as the services are provided. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect that our research and development expenses will increase substantially in the future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development and we continue to conduct clinical studies, advance our internal drug discovery programs into pre-clinical development and continue our early-stage research. 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, scope and duration of later-stage clinical studies.

Clinical development timelines, likelihood of regulatory approval, and commercialization and associated costs are uncertain, difficult to estimate, and can vary significantly. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we cannot accurately estimate or know the nature, timing and costs that will be necessary to complete the pre-clinical and clinical development for any of our product candidates or when and to what extent we may generate revenue from the commercialization and sale of any of our product candidates or achieve profitability.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, consisting of salaries, benefits and stock-based compensation for our employees engaged in executive, finance, legal, business development, commercial and administrative functions, insurance costs, professional fees for auditing, tax and legal services, costs related to maintenance and filing of intellectual property, costs incurred as we prepare for commercialization, and allocated facility-related and information technology costs not otherwise included in research and development expenses.

We expect that general and administrative expenses will increase in the future as we expand our operating activities to support our continued research activities and development of our product candidates, and as we prepare for commercialization. We will also continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income

Interest income. Interest income consists of income earned on our cash and investment balances. We anticipate that our interest income will continue to fluctuate depending on our cash and investment balances and interest rates.

Foreign exchange gain. Foreign exchange gain consists of gains from the impact of foreign exchange fluctuations on our monetary assets and liabilities that are denominated in currencies other than the U.S. dollar (principally the Canadian dollar). We will continue to incur substantial expenses in Canadian dollars and will remain subject to risks associated with foreign currency fluctuations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the revenue and expenses incurred during the reported periods. We base estimates on our historical experience, known trends and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies and significant judgments and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and significant estimates include those related to research and development costs and stock-based compensation.

There have been no material changes in our critical accounting policies and significant judgments and estimates during the three months ended March 31, 2026, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Significant Judgments and Estimates" included in our 2025 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC, and with the securities commissions in British Columbia, Alberta and Ontario, or the Canadian Securities Commissions, on February 26, 2026. We believe that the accounting policies discussed in the Annual Report are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Results of Operations

Comparison of three months ended March 31, 2026 and 2025

The following table summarizes the results of our operations together with changes in those items (in thousands):

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025	Change 2026 vs. 2025 Increase/(Decrease)
Collaboration revenue	$ —	$ 7,500	$ (7,500)
Research and development expenses	88,508	61,200	27,308
General and administrative expenses	23,820	19,038	4,782
Other:			
Interest income	6,907	8,083	(1,176)
Foreign exchange gain	548	35	513
Loss before income taxes	$ (104,873)	$ (64,620)	$ (40,253)

Collaboration Revenue

We did not recognize any revenue during the three months ended March 31, 2026. Collaboration revenue of $7.5 million recognized during the three months ended March 31, 2025 was related to a milestone payment in connection with the Neurocrine Collaboration.

Research and Development Expenses

The following table summarizes research and development expenses together with changes in those items (in thousands):

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025	Change 2026 vs. 2025 Increase/(Decrease)
Direct external costs:			
Azetukalner	$ 47,073	$ 31,501	$ 15,572
Pain programs (XEN1701, XEN1120)	4,391	1,052	3,339
Pre-clinical, discovery and other programs	2,958	3,915	(957)
Indirect costs:			
Personnel-related (including stock-based compensation)	29,885	21,307	8,578
Other unallocated expenses	4,201	3,425	776
Research and development expenses	$ 88,508	$ 61,200	$ 27,308

Direct external costs related to azetukalner increased by $15.6 million for the three months ended March 31, 2026, primarily due to our ongoing Phase 3 clinical studies in the MDD and BPD programs. Pain programs costs increased by $3.3 million due to our ongoing Phase 1 clinical studies of XEN1701 and XEN1120. Personnel-related costs increased by $8.6 million due to higher headcount to support late-stage development.

General and Administrative Expenses

The following table summarizes general and administrative expenses together with changes in those items (in thousands):

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025	Change 2026 vs. 2025 Increase/(Decrease)
Personnel-related (including stock-based compensation)	$ 16,019	$ 13,507	$ 2,512
Professional and consulting fees	5,146	3,347	1,799
Other	2,655	2,184	471
General and administrative expenses	$ 23,820	$ 19,038	$ 4,782

Personnel-related costs increased by $2.5 million for the three months ended March 31, 2026, primarily due to higher headcount to support our expanding research and development activities and future potential commercialization. Professional and consulting fees increased by $1.8 million due to an increase in pre-commercial expenses and higher expenses related to maintenance and filing of intellectual property.

Other Income

The following table summarizes our other income together with changes in those items (in thousands):

	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025	Change 2026 vs. 2025 Increase/(Decrease)
Interest income	$ 6,907	$ 8,083	$ (1,176)
Foreign exchange gain	548	35	513
Other income	$ 7,455	$ 8,118	$ (663)

Interest income decreased by $1.2 million for the three months ended March 31, 2026, driven by lower average market yields on investments, partially offset by a higher average balance of cash and cash equivalents and marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through the sale of equity securities, funding received from collaboration and license agreements, and debt financing. Since our initial public offering through March 31, 2026, we have raised aggregate net cash proceeds of approximately $2.3 billion primarily from the issuance of equity securities. As of March 31, 2026, we had cash and cash equivalents and marketable securities of $1,339.6 million.

Except for any obligations of our collaborators to make milestone payments under our agreements with them, we do not have any committed external sources of capital. Until such time as we can generate substantial product revenue, if ever, we expect to finance our cash needs through a combination of collaboration agreements and equity or debt financings.

We entered into an “at-the-market” equity offering sales agreement, amended as of March 2022, with Jefferies LLC and Stifel, Nicolaus & Company, Incorporated, pursuant to which we may sell common shares from time to time (the “ATM Program”). Pursuant to a prior prospectus, we sold an aggregate of 3,134,119 common shares for proceeds of $130.0 million, net of commissions and transaction expenses, during the period from January 1, 2026 to February 26, 2026. On February 27, 2026, a new prospectus supplement was filed replacing the prior prospectus, pursuant to which we refreshed the ATM Program and may sell common shares having gross proceeds of up to $400.0 million, from time to time.

On March 10, 2026, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies LLC, TD Securities (USA) LLC, Stifel, Nicolaus & Company, Incorporated, RBC Capital Markets, LLC, and William Blair & Company, L.L.C., relating to an underwritten public offering of 12,236,843 common shares, including 1,710,526 shares sold upon the full exercise of the underwriters' over-allotment option, at a public offering price of $57.00 per common share and pre-funded warrants to purchase 877,194 common shares at $56.9999 per pre-funded warrant, with each pre-funded warrant having an exercise price of $0.0001. The public offering was completed in March 2026, and we received proceeds of $707.6 million, net of underwriting discounts, commissions, and offering expenses.

Funding Requirements

We have incurred significant operating losses since inception. As of March 31, 2026, we had an accumulated deficit of $1,347.7 million. We expect to continue to incur significant expenses in excess of our revenue and expect to incur operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we prepare for the potential commercial launch of azetukalner; invest significantly to further develop azetukalner for our current and future indications; advance additional product candidates into pre-clinical and clinical development; seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies; manufacture larger quantities of our product candidates of clinical development and potential commercialization; hire additional commercial, clinical, scientific, management and administrative personnel; acquire or in-license other product candidates and technologies; make milestone or other payments under our in-license or other agreements, including, without limitation, payments to 1st Order Pharmaceuticals, Inc and other third parties; maintain, protect and expand our intellectual property portfolio; establish a sales, marketing, distribution and other commercial infrastructure to commercialize any products for which we may obtain marketing approval; create additional infrastructure and incur additional costs to support our operations and our product development and planned future commercialization efforts; and experience any delays or encounter issues with any of the above.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- if approved, the costs of commercialization activities for any product candidate that receives regulatory approval to the extent such costs are not the responsibility of an existing or future collaborator, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to the receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates and any other additional product candidates we may develop and pursue in the future;
- whether our existing collaborations generate substantial milestone payments and, ultimately, royalties on future approved products for us;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- our headcount growth and associated costs as we expand our research and development and initiate pre-commercial and commercial activities;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the ongoing costs of operating as a public company.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of the date of this report will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, our estimates and assumptions may prove to be wrong, and we cannot guarantee that our existing capital resources will be sufficient to conduct and complete all of our anticipated research and development efforts and future commercialization efforts. Additionally, the process of testing drug candidates in clinical studies is costly, and the timing of progress in these studies remains uncertain. Further, inflation may affect our use of capital resources by increasing our cost of labor and research and development expenses. Our long-term funding requirements will consist of operational, capital, and manufacturing expenditures, including those contractual commitments described below. Because of the inherent risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of capital outflows and operating expenditures associated with our long-term anticipated pre-clinical studies and clinical studies.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
Net cash used in operating activities	$ (88,897)	$ (61,652)
Net cash provided by (used in) investing activities	(407,282)	34,510
Net cash provided by financing activities	843,013	1,151

Operating Activities

For the three months ended March 31, 2026, net cash used in operating activities totaled $88.9 million, compared to $61.7 million for the same period in 2025. The increase in cash used in operating activities was primarily driven by higher research and development and general and administrative expenses and no revenue recognized in the period ended March 31, 2026, lower interest income, partially offset by changes in operating assets and liabilities.

Investing Activities

For the three months ended March 31, 2026, net cash used in investing activities totaled $407.3 million, compared to net cash provided of $34.5 million for the same period in 2025. The change was driven primarily by an increase in the purchase of marketable securities, net of redemptions.

Financing Activities

For the three months ended March 31, 2026, net cash provided by financing activities was $843.0 million, compared to $1.2 million for the same period in 2025. The increase was primarily related to $837.5 million net proceeds from offerings, as well as an increase in proceeds from stock option exercises.

Contractual Obligations and Commitments

Our future significant contractual obligations as of December 31, 2025 were reported in our Annual Report on Form 10-K, filed with the SEC and the Canadian Securities Commissions on February 26, 2026.

As of March 31, 2026, there have been no material changes from the contractual commitments previously disclosed in the Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks, including changes in currency exchange rates and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices.

Foreign currency risk

As of March 31, 2026, we had U.S. dollar denominated cash and cash equivalents and marketable securities of $1,306.7 million and Canadian dollar denominated cash and cash equivalents and marketable securities of CAD$46.0 million.

We are subject to foreign currency exchange rate risk in part, as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly those denominated in Canadian dollars. We also hold Canadian dollar denominated cash and cash equivalents, other receivables, and accounts payable.

Changes in foreign currency exchange rates can create significant foreign exchange gains or losses to us. We do not currently hedge our exposure and thus assume the risk of future gains or losses on the amounts of Canadian dollars held. We do not believe that an immediate 10% increase or decrease in the relative value of the U.S. dollar to the Canadian dollar would have a material effect on our operating results.

Interest rate sensitivity

As of March 31, 2026, we had cash and cash equivalents and marketable securities of $1,339.6 million. Interest rate risk relates to potential changes in interest income and the fair value of our investment portfolio. Cash and cash equivalents are short-term in nature and would not have a material impact from changes in interest rates. Marketable securities are primarily fixed-income securities and are subject to fair value changes as interest rates fluctuate. A 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $5.9 million decrease in the fair value of our marketable securities as of March 31, 2026. We do not enter into investments for speculative purposes and have not used any derivative financial instruments to manage interest rate exposure.

Item 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective, in design and operation, at the reasonable assurance level.

(b) Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the period ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. Our risk factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

Risks Related to Our Financial Condition and Capital Requirements

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial capital expenditures and significant risk that a product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including pre-clinical studies, manufacturing of investigational drug and our clinical studies. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. We do not expect to have sustained profitability for the foreseeable future. We had net losses of $102.3 million and $65.0 million for the three months ended March 31, 2026 and 2025, respectively, and an accumulated deficit of $1,347.7 million as of March 31, 2026, which were driven by expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for our product candidates.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we:

- seek marketing authorization for and prepare for the potential commercial launch of azetukalner;
- invest to further develop azetukalner for our current and future indications;
- advance additional product candidates into pre-clinical and clinical development;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- hire additional commercial, clinical, scientific, management and administrative personnel;
- acquire or in-license other assets and technologies;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations and any future commercialization efforts.

Our expenses could increase beyond expectations for a variety of reasons, including if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform clinical and other studies including post-approval commitments in addition to those that we currently anticipate, or if there are any delays in establishing appropriate manufacturing arrangements to support our clinical studies, the development of any of our product candidates or commercialization. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

We do not generate any revenue from product sales and may never become profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical studies, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our existing or future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We and our existing or future collaborators may never succeed in these activities and, even if we do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the FDA, EMA or other regulatory authorities to perform clinical studies in addition to those currently expected, or if there are any delays in completing our clinical studies or the development of any of our product candidates.

If any of our product candidates fail in clinical studies or do not gain regulatory approval, or if any of our future products, if any, once approved, fail to achieve market acceptance or adequate market share, we may never become profitable. If we are unable to generate sufficient revenue to become profitable and remain so, our financial condition and operating results will be negatively impacted, and the market price of our common shares might be adversely impacted.

We will need to raise additional funding, which may not be available on acceptable terms, if at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product discovery and development programs or commercialization efforts or other operations.

Since our inception, we have dedicated most of our resources to the discovery and development of our pre-clinical and clinical product candidates. We expect to continue to spend substantial amounts of resources to continue the pre-clinical and clinical development of our current and future programs. If we are able to gain marketing approval for product candidates that we develop, we will require significant additional amounts of capital in order to launch and commercialize such product candidates to the extent that such launch and commercialization are not the responsibility of a collaborator. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including but not limited to:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- if approved, the costs of commercialization activities for any product candidate that receives regulatory approval to the extent such costs are not the responsibility of an existing or future collaborator, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to the receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates and any additional product candidates we may develop and pursue in the future;
- whether our existing collaborations generate substantial milestone payments and, ultimately, royalties on future approved products for us;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such arrangements;

- the costs associated with any transactions to acquire or in-license other product candidates and technologies;
- our headcount growth and associated costs as we expand our research and development efforts and initiate pre-commercial and commercial activities;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the ongoing costs of operating as a public company.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of the date of this report, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Raising funds in the future may present additional challenges and future financing may not be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization.

We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on other 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 management resources, we focus on a limited number of research programs and product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for our current product candidates in other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spend on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. 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 arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from any approved product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, royalty-based financing, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

The terms of any financing arrangements we enter into may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares to decline. The sale of additional equity or convertible securities also would dilute all of our shareholders.

Historically, we have also financed our operations through the incurrence of debt. Any future incurrence of indebtedness would result in increased fixed payment obligations and, potentially, the imposition of restrictive covenants. Such covenants could include limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

We could also be required to seek funds through collaborations or marketing, distribution or licensing arrangements, or royalty-based financings with third parties, and we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, reduce or terminate our product discovery and development programs, commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We are subject to risks associated with currency fluctuations which could impact our results of operations.

A portion of our cash and cash equivalents and marketable securities are denominated in Canadian dollars, and we incur significant expenses in Canadian dollars in connection with our operations in Canada. We do not currently engage in foreign currency hedging arrangements for our Canadian dollar expenditures, and, consequently, foreign currency fluctuations, including as a result of trade relations between Canada and the United States, may adversely affect our earnings; however, in the future, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. Any hedging technique we implement may fail to be effective. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on the market price of our common shares.

Risks Related to Our Business and Industry

We and our collaborators face substantial competition in the markets for our product candidates, which may result in others discovering, developing or commercializing products before us or doing so more successfully than we, or our collaborators, do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition in drug discovery and product development from many different approaches and sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, as well as public and private research institutions. Any product candidates that we, or our collaborators, successfully develop and commercialize will compete with existing products and any new products that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety and/or tolerability, convenience and ease of administration, price, the potential advantages of alternative products, the level of generic competition, and the availability of coverage and adequate reimbursement from government and other third-party payers.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we, or our collaborators, do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large and established companies.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products or therapies that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected by decisions made by insurers or other third-party payers or public health systems to secure favorable coverage and reimbursement as well as the commercial success of our product candidates.

If one or more of our proprietary or partnered products were approved for the treatment of epilepsy, we anticipate that they could potentially compete with other anti-seizure medications, or ASMs, or one another. If one or more of our proprietary products were approved for the treatment of major depressive disorder, or MDD, we anticipate that they could potentially compete with other anti-depressant medications, or ADs. In addition, we plan to develop one or more proprietary products for the treatment of bipolar disorder, or BPD, and if any such products were approved for treatment of BPD, we anticipate that they could potentially compete with other anticonvulsant and antipsychotic medications.

We have no marketed proprietary products and are advancing clinical development through Phase 3 clinical studies for our azetukalner program in epilepsy, major depressive disorder, and bipolar depression. These studies may not result in regulatory approval or successful commercialization of our product candidates.

As a company, we have no previous experience in completing a Phase 3 clinical study and related regulatory requirements including a New Drug Application, or NDA, or equivalent submission, or the commercialization of products. We have not yet demonstrated our ability to independently and repeatedly conduct clinical development after Phase 2, obtain regulatory approval, manufacture drug substance or drug product on a registrational and commercial scale or arrange for a third-party to do so on our behalf, and commercialize therapeutic products. We will need to develop such abilities if we are to execute on our business strategy to develop and independently commercialize product candidates.

While we are advancing our Phase 3 clinical studies in azetukalner, significant risks remain. There can be no assurance that these or any future clinical studies will be successful, that we will be able to obtain regulatory approval, or that we will be able to manufacture or independently commercialize any product candidates. We may encounter delays or difficulties in advancing our product candidates through late-stage development, obtaining regulatory approval, or achieving commercial success, which could adversely affect our business prospects.

To execute on our business plan for the development of independent programs, we will need to successfully:

- reach agreement with multiple regulatory agencies on clinical and pre-clinical studies required for registration;
- execute our clinical development and manufacturing plans for later-stage product candidates;
- obtain required regulatory approvals in each jurisdiction in which we will seek to commercialize products;
- build and maintain appropriate pre-commercialization capabilities as well as commercial sales, distribution and marketing capabilities;
- build and implement effective market access strategy and gain market acceptance for our future products, if any; and
- manage our spending as costs and expenses increase due to clinical studies, regulatory approvals and commercialization activities.

If we are unsuccessful in accomplishing these objectives, we will not be able to develop and commercialize any future product candidates independently and could fail to realize the potential advantages of doing so.

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

We have built a product development pipeline by identifying product candidates either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies. Both our internal discovery efforts and our assessment of potential acquisition or in-licensing opportunities require substantial technical, financial and human resources, regardless of whether we identify any viable product candidates.

If we are unable to identify additional product candidates suitable for clinical development and commercialization either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies, we may not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact the market price of our common shares.

If we fail to attract and retain our executive officers and key personnel, we may be unable to successfully develop our product candidates, perform our obligations under our collaboration agreements, conduct our clinical studies and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other 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 develop, gain regulatory approval of and commercialize products successfully.

We are highly dependent upon our executive officers, including Mr. Ian Mortimer, our President and Chief Executive Officer. The loss of services of one or more of our executive officers could materially delay or even prevent the successful development of our product candidates.

In addition, we will need to hire additional personnel as we expand our clinical development activities and develop commercial capabilities, including a sales infrastructure to support our independent commercialization efforts. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee may impede the progress of our research, development and commercialization objectives.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including non-compliance with legal and regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, investigational site staff, consultants, commercial partners and other personnel. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- the regulations of the FDA, EMA and other foreign regulators, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- insider trading laws;
- data privacy, data protection and security;
- federal and state healthcare fraud and abuse laws and regulations in the U.S. and abroad; and
- laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Additionally, we are subject to applicable foreign, federal and state data privacy and security laws. For additional information, see “Risk Factors — We are subject to evolving global laws and regulations relating to privacy, data protection and information security, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.”

Various 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. Any misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical studies or creating fraudulent data in our pre-clinical studies or clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, officers, directors, agents and representatives, including consultants, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or claims, demands, or lawsuits stemming from an actual or alleged failure to comply with these laws and 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 ourselves, achieving a favorable settlement or otherwise asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Additionally, 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 us, our business may be impaired.

We may encounter difficulties in managing our growth, including headcount, and expanding our operations successfully.

Our business strategy involves continued development and, where development is successful, commercialization of select product candidates. In order to execute on this strategy, we will need to build out a regulatory, sales, manufacturing, supply chain and marketing infrastructure and expand our development capabilities or contract with third parties to provide these capabilities and infrastructure for us. To achieve this, we will need to identify, hire and integrate personnel, compensate our employees on adequate terms in an increasingly competitive, inflationary market and continue to implement and improve our managerial, operational and financial systems. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties.

Future growth will impose significant added responsibilities on members of management including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its 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 business, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We are subject to evolving global laws and regulations relating to privacy, data protection and information security, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

In the ordinary course of business, we process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data about study participants collected in connection with clinical studies, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the U.S., federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information that apply to most U.S. healthcare providers with which we interact, such as our U.S. clinical study sites. At the state level, many jurisdictions in which we are operating also have laws and regulations relating to data privacy, cybersecurity and protection of personal information, including the California Consumer Privacy Act, or CCPA. CCPA and similar state comprehensive consumer privacy laws create consumer rights protection and impose obligations on businesses on which they apply, including requirements to conduct data processing risk assessments, to enter data processing agreements with vendors and other third-parties with whom a business shares personal information, and to make detailed disclosures to residents of those states about the business' data collection, use and sharing practices. Many of these state laws also allow for statutory fines for noncompliance. In addition, several states have enacted health-focused consumer privacy laws, such as Washington state's My Health, My Data Act, which impose obligations related to the collection and sharing of certain health-related information that is not subject to HIPAA and that does not fall within certain other exceptions in the law. Although these state consumer data and consumer health data privacy laws generally exempt some data processed in the context of clinical studies, to the extent they are applicable in our business and operations, these laws may increase compliance costs and potential liability with respect to other personal information we maintain about residents of these states.

Additional data privacy and security laws have been proposed and enacted at the federal, state, and local levels in recent years, which could further complicate compliance efforts. For example, in June 2024, the Protecting Americans’ Data from Foreign Adversaries Act of 2024 took effect. This law prohibits data brokers from making available certain personally identifiable sensitive data of U.S. individuals to “foreign adversary” countries, such as the People’s Republic of China, or the PRC, and entities controlled by such countries. Additionally, in January 2025, the U.S. Department of Justice published a final rule implementing President Biden’s Executive Order 14117, “Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern,” which became effective in April 2025. This final rule prohibits certain data brokerage transactions involving certain bulk sensitive personal information, including human genomic data and biospecimens from which such data can be derived, with restricted persons and jurisdictions, such as the PRC. The final rule also places restrictions on certain vendor, employment and investment agreements with such jurisdictions. These restrictions may affect our ability to engage in collaborations or license agreements with entities in restricted countries or with a nexus to such countries going forward.

Outside the U.S., the European Union’s General Data Protection Regulation, or EU GDPR, and the United Kingdom’s GDPR, or UK GDPR, impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Certain foreign jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions, such as transferring or receiving personal data that originates in the European Union, or EU. Additional jurisdictions have enacted and continue to enact and modify their data privacy laws, which increases the complexity of the data privacy landscape.

Although we endeavor to comply with all applicable data privacy and security obligations, these obligations are quickly changing in an increasingly stringent fashion, creating some uncertainty as to how to comply, and potentially requiring us to modify our policies and practices, which may be costly and may divert the attention of management and technical personnel. Further, we may at times fail, or be perceived to have failed, to have complied and could face significant consequences. These consequences may include, but are not limited to, government enforcement actions, investigations and other proceedings; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations, including our clinical studies; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Our business and operations could suffer in the event of an actual or perceived information security incident such as a cybersecurity breach, system failure, or other compromise of our systems and/or information, including information held by a third-party contractor or vendor.

We rely on both internal information technology systems and networks, and those of third-party vendors and contractors, to acquire, transmit, store and otherwise process information in connection with our business activities. Our ability to effectively manage our business depends on the security, reliability and adequacy of our and our third-party contractors' and vendors' technology systems. Any incident, whether hostile or inadvertent, that adversely impacts the confidentiality, integrity or availability of our systems and/or data, including phishing, business email compromise, social engineering, ransomware or other malware, or any security breach, security incident or other destruction, loss, or unauthorized use or other processing of data maintained or otherwise processed by us or on our behalf could result in a loss of intellectual property or misappropriation of trade secrets, disruptions to our business and operations, subject us to increased costs and require us to expend time and resources to address the matter, may subject us to claims, demands, and proceedings by private parties, regulatory investigations and other proceedings, and fines, penalties, and other liability and have a material adverse effect on our business. In addition, the loss, alteration or other damage to or other unavailability of pre-clinical data or clinical study data from completed or ongoing clinical studies for our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any cyberattack, security breach or incident, or other destruction, loss or unauthorized processing of data maintained or otherwise processed by us or on our behalf, or the perception any such matter has occurred, could result in actual or alleged violations of applicable U.S. and international privacy, data protection, information security and other laws and regulations, harm our reputation and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal proceedings and liability. In addition, we may incur significant additional expense to implement further measures relating to privacy, data protection and information security, whether in response to an actual or perceived security breach or incident or otherwise.

To date, we have not experienced any material impact to our business, financial position or operations resulting from cyberattacks or other information security incidents; however, because of frequently changing attack techniques, along with the increased volume and sophistication of such attacks, our business, financial position or operations could be adversely impacted in the future. Moreover, the increasingly distributed nature of computing, including prevalent use of mobile devices to access confidential information and widespread use of cloud-based applications hosted in remote data centers, increases the risk of security breaches and incidents. These risks may be heightened due to the increasing number of our and our third-party vendors' and contractors' personnel working remotely. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate information security vulnerabilities, threats and incidents. While we have implemented layered security measures, our computer systems and the external systems and services used by our third-party contract manufacturers, or CMOs, and contract research organizations, or CROs, and their vendors and contractors remain potentially vulnerable to these events and there can be no assurance that we will be successful in preventing cyberattacks or successfully mitigating their effects. Our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

A variety of risks associated with international operations could materially harm our business.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we operate and plan to operate outside the U.S., including those countries outside the U.S. in which we are conducting clinical studies. As we engage in significant cross-border and international activities, we will be subject to risks related to international operations, including:

- different regulatory requirements for conducting clinical studies, registering and maintaining approval of, manufacturing and advertising drugs in foreign countries;
- reduced protection for intellectual property rights in certain countries;
- changes in tariffs, trade barriers and regulatory requirements, including tariffs that have been imposed on certain goods by the current presidential administration and reciprocal tariffs imposed by Canada and other countries in which we do business, as well as potential tariffs on pharmaceutical products and components manufactured outside the United States that the current presidential administration has contemplated;
- economic weakness, including inflation, political instability or open conflict in particular foreign economies and markets;
- differing and multiple payer reimbursement regimes, government payers or patient self-pay systems;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations of doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;

- potential or actual violations of domestic and international anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, or of U.S. and international import, export and re-export control and sanctions laws and regulations, the likelihood of which may increase with an increase of operations in foreign jurisdictions, directly or indirectly through third parties (whose corrupt or other illegal conduct may subject us to liability), which may involve interactions with government agencies or government-affiliated hospitals, universities and other organizations, such as conducting clinical studies, selling our products, and obtaining necessary permits, licenses, patent registrations, and other regulatory approvals;
- tighter restrictions on privacy and data protection, and more burdensome obligations associated with the collection, use and retention of data, including clinical data and genetic material, may apply in jurisdictions outside of North America;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war, civil and political unrest and terrorism, or natural disasters including earthquakes, typhoons, floods and fires;
- supply and other disruptions resulting from the impact of public health pandemics or epidemics on our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely; and
- business interruptions resulting from increased government scrutiny on the use of certain foreign biotechnology service providers due to national security concerns, including the potential for legislation that restricts or prohibits the use of such third-party service providers.

If we are unable to successfully manage these risks associated with cross-border and international activities, our business could be materially harmed.

U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

U.S. investors should be aware that based on our gross income and gross assets, we were a passive foreign investment company, or PFIC, for the taxable year ended December 31, 2025 and we may be a PFIC in 2026.

Generally, for any taxable year in which 75% or more of our gross income is passive income, or at least 50% of the quarterly average percentage of our assets (as determined under applicable Treasury Regulations) are held for the production of, or produce, passive income, we would be characterized as a PFIC, for U.S. federal income tax purposes. For PFIC testing purposes, a range of factors can affect the determination including the market price of our common shares and how we spend or otherwise hold our cash. Thus, our status as a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In addition, a company’s PFIC status can be made only after the end of each taxable year. Accordingly, we cannot provide any assurance regarding our PFIC status for the current taxable year or future taxable years.

If we are a PFIC for any year in which a U.S. investor hold our shares, such U.S. holders of our common shares may suffer adverse tax consequences including in years after we cease to be classified as a PFIC. Gains realized by such U.S. holders on the sale of our common shares would be taxed as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would be lost. Interest charges would also be added to taxes on gains and dividends realized by all U.S. holders. U.S. holders should consult their own tax advisors with respect to their particular circumstances.

A U.S. holder may avoid these adverse tax consequences by timely making a qualified electing fund election. For each year that we would meet the PFIC gross income or asset test, an electing U.S. holder would be required to include in gross income its pro rata share of our net ordinary income and net capital gains, if any. A U.S. holder may make a qualified electing fund election only if we commit to provide U.S. holders with their pro rata share of our net ordinary income and net capital gains. We will provide, upon request, our U.S. holders with the information that is necessary in order for them to make a qualified electing fund election and to report their pro rata shares of ordinary earnings and net capital gains for each year we believe we were a PFIC. U.S. holders should consult their own tax advisors with respect to making this election and the related reporting requirements.

A U.S. holder may also mitigate the adverse tax consequences by timely making a mark-to-market election. Generally, for each year that we meet the PFIC gross income or asset test, an electing U.S. holder would include in gross income the increase in the value of its common shares during each of its taxable years and deduct from gross income the decrease in the value of such shares during each of its taxable years. A mark-to-market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including the Nasdaq Global Market, or Nasdaq. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U.S. holder might not be eligible to make a mark-to-market election to mitigate the adverse tax consequences if we are characterized as a PFIC. U.S. holders should consult their own tax advisors with respect to the possibility of making this election.

In addition, if we are or become a PFIC (or our PFIC status is uncertain), it may deter certain U.S. investors from purchasing our common shares, which could have an adverse impact on the market price of our common shares.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have significant Canadian federal net operating loss carryforwards which are limited in life, Canadian federal investment tax credit carryforwards and provincial investment tax credit carryforwards which could expire unused and be unavailable to offset future income tax liabilities. The rules dealing with Canadian and U.S. federal, provincial, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Canada Revenue Agency, Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws, or changes in interpretations of existing laws (which changes may have retroactive application), including with respect to net operating losses and tax credits, could adversely affect us or holders of our common shares. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We may become subject to income tax in jurisdictions in which we are organized or operate, which would reduce our future earnings.

There is a risk that we may become subject to income tax in jurisdictions outside of Canada and the U.S., if under the laws of any such jurisdiction, we are considered to be carrying on a trade or business there or earn income that is considered to be sourced there and we do not qualify for an exemption. In jurisdictions where we do not believe we are subject to tax, we can provide no certainty that tax authorities in those jurisdictions will not subject one or more tax years to examination. Tax examinations are often complex as tax authorities may disagree with the treatment of items reported by us, the result of which could have a material adverse effect on our operating results and financial condition.

Acquisitions or other strategic transactions could disrupt our business, cause dilution to our shareholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis, including the acquisition of other businesses, products or technologies as well as pursuing strategic alliances, licensing transactions or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to pursuing strategic transactions and managing any such strategic alliances, joint ventures or acquisition integration challenges;
- dilution to our shareholders if we issue equity in connection with such transactions;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance or acquisition may not materialize. 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 cannot predict the number, timing or size of future acquisitions, or the effect that any such transactions might have on our operating results.

Our current and future operations in the U.S. and elsewhere will be subject, directly or indirectly, to applicable federal and state fraud and abuse, government pricing and transparency, health information privacy and security, and other healthcare laws and regulations, non-compliance with which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers and third-party payers in the U.S. and national health systems in other jurisdictions play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with healthcare providers, third-party payers, patients and other parties within the healthcare delivery system may expose us 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 any products for which we obtain marketing approval. Restrictions under applicable healthcare and data privacy laws and regulations include the following, some of which will apply only if and when we have a marketed product:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower, or qui tam actions, as well as civil monetary penalty laws can impose criminal and civil penalties, assessment, and exclusion from participation for various forms of fraud and abuse involving the federal healthcare programs, such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also establishes requirements related to the privacy, security, and transmission of individually identifiable health information which apply to many healthcare providers, physicians, and third-party payers with whom we interact;
- the FDCA, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under governmental healthcare programs;
- the so-called federal "sunshine law" or Open Payments which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to teaching hospitals, physicians, and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- 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 payers, including private insurers; state and foreign laws that limit financial interactions between manufacturers and healthcare providers; require manufacturers to adopt certain compliance standards; require disclosure to the government and public of financial interactions; require disclosure of marketing expenditures or pricing information, regulate drug pricing and/or require the registration of pharmaceutical sales representatives; and state and foreign laws governing the collection, export, privacy, use, protection and security of biological materials and health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Efforts to ensure that our activities comply with applicable healthcare laws and regulations will involve substantial costs and, if and when one of our product candidates is approved, our compliance efforts will need to expand and evolve to address newly applicable laws. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with such laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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 the success of our business.

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in molecular and cellular biology. For example, we routinely use cells in culture and we employ small amounts of radioisotopes. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials through our maintenance of up-to-date licensing and training programs. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering certain claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to Canadian federal, provincial, and local laws and regulations and may be subject to U.S. and/or foreign, laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Complying with regulations regarding the use of these materials could be costly, and if we fail to comply with these regulations, it could have a material adverse effect on our operations and profitability.

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

Our headquarters are located in Burnaby, British Columbia, Canada. We are vulnerable to natural disasters such as earthquakes that could disrupt our operations. If a natural disaster, power outage, fire or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our CMOs upon whom we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Such events may result in damage or loss of our products and product candidates during their manufacture and shipment, cause delays in clinical development due to study site disasters or result in losses of critical data, any of which may adversely impact our operations. Although we carry insurance for earthquakes and other natural disasters, we may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans that we have in place may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or earthquake, which could have a material adverse effect on our business. In addition, we may lose samples or other valuable data. The occurrence of any of the foregoing could have a material adverse effect on our business.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our business substantially depends upon the successful development of azetukalner. If we are unable to obtain regulatory approval for, and successfully commercialize, azetukalner, our business may be materially harmed.

We currently have no products approved for commercial sale and are investing significant efforts and financial resources in the development of our clinical-stage product candidate, azetukalner for the treatment of epilepsy, MDD, BPD and potentially other neurological disorders. While we are advancing our Phase 3 clinical studies in azetukalner, there can be no assurance that these or any future clinical studies will be successful, that we will be able to obtain regulatory approval, or that we will be able to manufacture or independently commercialize any product candidates. Our future business success depends on the continued development and ultimate regulatory approval of azetukalner. The future regulatory and commercial success of azetukalner is subject to a number of risks, including:

- successful patient enrollment in clinical studies and ultimate completion of clinical studies;
- safety and efficacy data from our clinical programs that support acceptable risk-benefit profiles of azetukalner in the intended patient populations;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for azetukalner;
- making arrangements with third-party manufacturers for both clinical and commercial supplies of azetukalner;
- establishing sales, marketing and distribution capabilities and commercial launch of azetukalner, if and when approved, whether alone or in collaboration with others;
- successful commercial launch of azetukalner, if and when approved;
- acceptance of azetukalner, if and when approved, by patients, the medical community, third-party payers, national health systems, and health technology authorities where applicable to ensure effective market access and adoption by healthcare providers and patients;

- obtaining and maintaining acceptable pricing, third-party insurance coverage and adequate reimbursement;
- maintaining a continued acceptable safety and durable efficacy profile of azetukalner following approval;
- effectively competing with other therapies;
- enforcing and defending intellectual property rights and claims; and
- raising sufficient funds to support regulatory approval and commercialization activities.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission and approval process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we or any collaborator are unable to develop, receive regulatory approval for, or successfully commercialize azetukalner for our initial or potential additional indications, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

In addition, of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA or the equivalent foreign regulatory authorities and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval for azetukalner for any indication, any such approval may be subject to limitations on the indications or uses or patient populations for which we may market azetukalner. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot ensure that we will successfully develop or commercialize azetukalner for any indication.

Our approach to drug discovery is unproven, and we do not know whether we will be able to develop any products of commercial value.

Our approach to drug discovery may not reproducibly or cost-effectively result in the discovery of product candidates and development of commercially viable products that safely and effectively treat human disease.

Our drug discovery efforts may initially show promise in identifying additional product candidates yet fail to yield viable product candidates for clinical development or commercialization. Such failure may occur for many reasons, including that any product candidate may, on further study, be shown to have serious or unexpected side effects or other characteristics that indicate it is unlikely to be safe or otherwise does not meet applicable regulatory criteria and/or not be capable of being produced in commercial quantities at an acceptable cost, or at all.

If our discovery activities fail to identify novel targets for drug discovery, or such targets prove to be unsuitable for treating human disease, or if we are unable to develop product candidates with specificity and selectivity for such targets, we will fail to develop viable products. If we fail to develop and commercialize viable products, we will not achieve commercial success.

Results of pre-clinical studies and/or earlier clinical studies may not be predictive of the results of later-stage clinical studies and the results of our clinical studies may not satisfy regulatory requirements and we may experience delays or unexpected difficulties in obtaining regulatory approval.

The results of pre-clinical studies, either generated by us, by our CROs or by other third parties from which we have in-licensed or acquired a product candidate, may not be predictive of results in clinical testing. Moreover, pre-clinical results can often be difficult to compare across different studies for a variety of reasons, including differences in experimental protocols and techniques, personnel, equipment and other factors, which may make the pre-clinical results less reliable and predictive of clinical study results. In addition, published clinical data or case reports from third parties or early clinical study data of our product candidates may not be predictive of the results of later-stage clinical studies. Interpretation of results from early, usually smaller, studies that suggest a clinically meaningful response in some patients, requires caution. Results from later stages of clinical studies enrolling more patients may fail to show acceptable safety and efficacy results according to applicable regulatory requirements or otherwise fail to be consistent with the results of earlier studies of the same product candidate. Later clinical study results may not replicate earlier clinical studies for a variety of reasons, including differences in study design, different study endpoints (or lack of study endpoints in exploratory studies), patient population, number of patients, patient selection criteria, study duration, drug dosage and formulation and lack of statistical power in the earlier studies. These uncertainties are enhanced where the diseases or disorders under study lack established clinical endpoints, validated measures of efficacy, as is often the case with disorders for which no drugs have been developed previously and where the product candidates target novel mechanisms. The absence of well-defined regulatory pathways and recognized efficacy benchmarks can make clinical development, regulatory approval, and commercialization more challenging and unpredictable.

Further, our product candidates may not be approved even if they achieve their primary endpoints in our Phase 3 clinical studies. The FDA, EMA or other foreign regulatory authorities may disagree with our study design and our interpretation of data from pre-clinical studies and clinical studies or require additional data. In addition, any of these regulatory authorities may change its requirements or recommendations for the approval of a product candidate at any time in the future, even after reviewing and providing comments or advice on a protocol for a pivotal clinical study that, if successful, would potentially form the basis for an application for approval by the FDA, EMA or another foreign regulatory authority. For example, the FDA may refuse to accept our planned NDA for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval. If the FDA does not approve our planned NDA, it may require that we conduct additional clinical, nonclinical or manufacturing studies before it will reconsider our application. Depending on the extent of these or any other studies required by the FDA or another regulatory authority, approval of an NDA or equivalent filing may be significantly delayed or we may be unable to obtain approval of an NDA or equivalent filing because such studies may require us to expend more resources than we have available. Furthermore, applicable regulatory authorities may also approve our product candidates for a narrower indication or population than we request or may grant approval contingent on the performance of costly post-marketing commitments.

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

From time to time, we may publicly disclose preliminary or topline data from our pre-clinical studies and clinical studies, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the complete data set for the relevant pre-clinical or clinical study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or have access to all data, and we may not have had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify the initial findings, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published or disclosed. As a result, topline data should be interpreted with caution until the final, comprehensive data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the perceived value of the particular program, the approvability or commercial potential of the particular product candidate or product and could have a material adverse effect on our business prospects. In addition, the information we choose to publicly disclose regarding a particular study is based on what is typically extensive complex body of information, and others may not agree with our determination of what constitutes material or otherwise appropriate information for disclosure. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be adversely affected, which could negatively impact our business, results of operations, prospects or financial condition. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common shares.

Clinical studies may fail to demonstrate adequately the safety and efficacy of our, or our collaborators', product candidates at any stage of clinical development. Terminating the development of any of our, or our collaborators', product candidates could materially harm our business and the market price of our common shares.

Our and our collaborators' clinical product candidates, which include azetukalner and NBI-921355 (being developed by our collaborator Neurocrine Biosciences), along with product candidates we expect to enter clinical development, which include our pre-clinical compounds, are in varying stages of development and will require substantial clinical development, testing and regulatory approval prior to commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we, or our collaborators, must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical studies that each product candidate is both safe and effective for use in each target indication. Failure can occur at any time during the clinical study process. Clinical studies often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Most product candidates that commence clinical studies are never approved as products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. In addition to the safety and efficacy studies of any product candidate, clinical study failures may result from a multitude of factors including flaws in study design, dose selection, statistical analysis plan, placebo effect, patient enrollment criteria, patient compliance and study execution. Data obtained from studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Failure of a clinical study due to any of these reasons could materially harm our business and the market price of our common shares.

In the case of some of our and our collaborators' product candidates, we and our collaborators are seeking to develop treatments for certain diseases or disorders for which there is relatively limited clinical experience, and clinical studies may use novel endpoints and measurement methodologies or subjective patient feedback, which adds a layer of complexity to these clinical studies and may delay regulatory approval. Negative or inconclusive results from our, or our collaborators', clinical studies could lead to a decision or requirement to conduct additional pre-clinical testing or clinical studies or result in a decision to terminate the continued development of a product candidate. For example, on March 9, 2026, we released topline data from our Phase 3 X-TOLE2 clinical study of epilepsy in adult patients with FOS. In addition, our Phase 3 X-NOVA2 and X-NOVA3 studies in MDD and our Phase 3 X-CEED study in BPD are ongoing and continue to recruit patients. There can be no assurance that our ongoing azetukalner Phase 3 clinical studies or any other future Phase 3 clinical studies will demonstrate adequate efficacy and safety results and that we will be able to obtain regulatory approval of azetukalner. Any of the foregoing outcomes would materially and adversely impact our business, product candidate pipeline and future prospects.

If our, or our collaborators', product candidates are not shown to be both safe and effective in clinical studies, such product candidates will be unable to obtain regulatory approval or be successfully commercialized. In addition, our, or our collaborators', failure to demonstrate positive results in clinical studies in any indication for which we, or our collaborators, are developing clinical product candidates could adversely affect development efforts in other indications. In such case, we would need to develop other compounds and conduct associated pre-clinical testing and clinical studies, as well as potentially seek additional financing, all of which would have a material adverse effect on our business, growth prospects, operating results, financial condition and results of operations.

We, or our collaborators, may find it difficult to enroll patients in our clinical studies which could delay or prevent the successful completion of clinical studies of our product candidates.

We, or our collaborators, may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete clinical studies in a timely manner, or at all. Patient enrollment for clinical studies is affected by factors including:

- severity of the disease or disorder under investigation;
- design of the study protocol;
- size of the patient population and geographic dispersion;
- identification of patients;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical study investigators with the appropriate competencies, staff and experience;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies; and
- patient referral practices of physicians.

Our and our collaborators' clinical studies will compete with other clinical studies for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our studies may instead opt to enroll in a study being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical studies at the same clinical study sites that some of our competitors use, which will reduce the number of patients who are available for our clinical studies at such clinical study sites.

Our and our collaborators' inability to enroll a sufficient number of patients for our clinical studies would result in significant delays or might require us to abandon one or more clinical studies altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical studies, affect product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, any of which could cause the value of our company to decline and limit our ability to obtain additional financing if needed.

Our success also depends on the collective performance, contributions, and expertise of the personnel who manage our clinical study sites. There is significant competition for qualified personnel, particularly those with higher educational degrees, in the biopharmaceutical and related services industries. Increased personnel turnover and labor shortages facing the biopharmaceutical services industry could have a negative impact on the third parties we rely on to execute our clinical studies. While we seek to choose study sites with adequate staffing support, we cannot be certain that personnel turnover or the broader labor market dynamics in this industry will not negatively impact our study sites. If our clinical study sites are negatively impacted by these factors, our ability to enroll our clinical studies in a timely fashion may be hindered and might negatively affect our business, development timelines, and financial condition.

We, or our collaborators, may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our, or our collaborators', product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we, or our collaborators, must demonstrate through extensive pre-clinical and clinical studies that our, or our collaborators', product candidates are safe and effective in humans. We, or our collaborators, may experience delays in completing our, or our collaborators', pre-clinical or clinical studies, and initiating or completing additional pre-clinical or clinical studies, including as a result of regulators not allowing or delay in allowing clinical studies to proceed under an IND, or not approving or delaying approval for any clinical study application or similar approval we need to initiate a clinical study. We, or our collaborators, may also experience numerous unforeseen events during our clinical studies that could delay or prevent our, or our collaborators', ability to complete development for a product candidate, or receive marketing approval or commercialize the product candidates we, or our collaborators, develop, including:

- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical study at a prospective study site, or their suspension or termination of a clinical study once commenced;
- inability to reach agreement with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites, or the breach of such agreements;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical studies;
- side effects or adverse events in study participants presenting an unacceptable safety risk;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements, including good clinical practices, or GCPs;
- difficulty in having patients complete a study, adhere to the study protocol, or return for post-treatment follow-up;
- the number of subjects or patients required for clinical studies of our product candidates may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- clinical sites deviating from study protocol or dropping out of a study;
- we may have to amend clinical study protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which it may be required to resubmit to an IRB and regulatory authorities for re-examination;
- challenges or delays with accessing certain species of animals to complete our pre-clinical studies;
- problems with investigational medicinal product storage, stability and distribution;
- our inability to manufacture, or obtain from third parties, adequate supply of drug substance or drug product sufficient to complete our pre-clinical and clinical studies, including supply chain issues resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- a requirement to undertake and complete additional pre-clinical studies to generate data required to initiate clinical development or to support the continued clinical development of a product candidate or submission of an NDA or equivalent;
- unforeseen disruptions, caused by man-made or natural disasters, public health pandemics or epidemics, civil unrest or military conflict, or other business interruptions;
- governmental or regulatory delays; and

- changes to the policies, regulations and guidelines of the FDA, EMA or other foreign regulators regarding development, approval, and marketing of biopharmaceutical products, including but not limited to, in the U.S., as a result of policies implemented by the current presidential administration that may, for example, render our clinical data insufficient for approval or restrict us from marketing our product candidates in the manner in which we anticipate.

These risks and uncertainties could impact any of our, or our collaborators', clinical programs and any of the clinical, regulatory or operational events described above could change our, or our collaborators', planned clinical and regulatory activities. Challenges in enrolling and retaining patients in our clinical studies, including in our azetukalner Phase 3 clinical studies, whether as a result of pandemics, geopolitical events, or for any other reasons, may further delay the studies or cause them to be discontinued.

The results of any Phase 3 or other pivotal clinical studies may not be adequate to support marketing approval. These clinical studies are lengthy and usually involve many hundreds to thousands of patients, which can be complicated by the difficulty of identifying eligible patients. Even if patients are successfully identified, they may fail to meet screening criteria, including baseline seizure burden for epilepsy clinical studies, and, as a result, may not be enrolled. Difficulties in identifying, screening and/or enrolling patients in our studies may extend the time needed to complete our clinical studies or require the initiation of additional sites to achieve target enrollment numbers to complete our clinical studies. These may increase the cost of our operations and/or delay the timing of our regulatory approval. In addition, if the FDA, EMA or another foreign regulator disagrees with our, or our collaborators', choice of the key testing criterion, or primary endpoint, or if the results for the primary endpoint are not sufficiently robust or statistically significant or clinically meaningful relative to the control group of patients not receiving the experimental therapy, or our statistical analysis is inconclusive, such regulator may refuse to approve our product candidate in the region in which it has jurisdiction. The FDA, EMA or other foreign regulators also may require additional clinical studies as a condition for approving any of these product candidates.

We, or our collaborators, could also encounter delays if a clinical study is suspended or terminated by us, by our collaborators, by the IRBs of the institutions in which such study is being conducted, by any Data Safety Monitoring Board for such study, or by the FDA, EMA or other foreign regulatory authorities. Such suspensions or terminations may arise from a variety of factors, including failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols, regulatory inspections, imposition of a clinical hold, manufacturing problems, unforeseen safety issues or adverse side effects, lack of demonstrated benefit, changes in governmental regulations or administrative actions or insufficient funding to continue the clinical study. In addition, delays can occur due to safety concerns arising from studies or other clinical data regarding another company's product candidate in the same compound class as one of ours.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes or to include additional objectives that could yield important scientific information critical to our overall development strategy. The protocol amendment process often requires review and approval by several review bodies, including regulatory agencies and scientific, regulatory and ethics boards and IRBs which may affect timely completion of a clinical study. Further, there is no guarantee that these protocol amendments will be accepted by the review bodies in the form submitted, or at all, which may impact costs, timing or successful completion of a clinical study.

If we, or our collaborators, experience delays in the completion of, or termination of, any clinical study of one of our product candidates, the commercial prospects of the product candidate may be harmed, the period during which we may have the exclusive right to commercialize our products under patent protection could be shortened, and our, or our collaborators', ability to commence product sales and generate product revenue from the product will be delayed. In addition, any delays in completing our clinical studies will increase our costs and slow down our product candidate development and approval process and may ultimately lead to the termination of a clinical study and development of a product candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our, or our collaborators', product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities.

Results of our clinical studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, while adverse events in our X-TOLE and X-NOVA clinical studies were generally mild or moderate in severity, there can be no guarantee that we will observe a similar tolerability profile of azetukalner in our ongoing Phase 3 clinical studies or in other future clinical studies. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, EMA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our studies are conducted, could suspend, limit or terminate our clinical studies, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our studies, or the FDA, EMA or comparable foreign regulatory authorities could order us to cease clinical studies or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical study subjects or cause subjects that enroll in our clinical studies to discontinue participation in our clinical studies. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical studies and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical studies of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical studies. Consequently, it is possible that our clinical studies may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

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

As product candidates are developed through pre-clinical to late-stage clinical studies towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulations, are altered along the way in an effort to optimize products, processes and results, and/or to target different populations. Such changes may also result in inventions that result in additional patent protection. Any of these changes could cause our product candidates to perform differently and not provide the same drug exposure profile in children and/or cause side effects different to those observed with the same formulation in adults or with other formulations. Unexpected changes in the performance of a new formulation may affect the results of planned clinical studies or other future clinical studies conducted with the altered materials. This could delay completion of clinical studies, require the conduct of additional bridging clinical studies or the repetition of one or more clinical studies, increase clinical study costs and/or delay or jeopardize approval of our product candidates and/or jeopardize our, or our collaborators', ability to commence product sales and generate revenue.

The regulatory approval processes of the FDA, EMA and regulators in other foreign jurisdictions are lengthy, time-consuming and inherently unpredictable. If we, or our collaborators, are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, our business may be substantially harmed.

The regulatory approval process is expensive and the time required to obtain approval from the FDA, EMA or other foreign regulatory authorities in other jurisdictions to sell any product is uncertain and may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of pre-clinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and even if the pre-clinical studies show promising results and clinical studies are successfully completed, we cannot guarantee that the FDA, EMA or other foreign regulatory authorities in other jurisdictions will interpret the results as we do, and more clinical studies, manufacturing-related studies or non-clinical studies could be required before we submit our product candidates for approval. Many companies that have believed their product candidates performed satisfactorily in pre-clinical and clinical studies have nonetheless failed to obtain marketing approval of their products. To the extent that the results of our studies are not satisfactory to the FDA, EMA or other foreign regulatory authorities in other jurisdictions for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. It is also possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

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

- the FDA, EMA or other foreign regulatory authorities may disagree with the design or implementation of our, or our collaborators', clinical studies;
- we, or our collaborators, may be unable to demonstrate to the satisfaction of the FDA, EMA or other foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical studies may not meet the level of statistical significance required by the FDA, EMA or other foreign regulatory authorities for approval;
- we, or our collaborators, may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA, EMA or other foreign regulatory authorities may disagree with our, or our collaborators’, interpretation of data from pre-clinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA, EMA or other foreign regulatory authorities may fail to approve the manufacturing processes, controls or facilities of third-party manufacturers with which we, or our collaborators, contract for clinical and commercial supplies;
- the pre-approval inspections of Xenon, manufacturing, clinical sites, pre-clinical or clinical service providers, conducted by regulatory authorities may identify errors or omissions that may result in the product candidate not being approved; and
- the approval policies or regulations of the FDA, EMA or other foreign regulatory authorities may significantly change in a manner rendering our, or our collaborators’, clinical data insufficient for approval.

Even if we, or our collaborators, obtain approval for a particular product, regulatory authorities may grant approval contingent on the performance of costly post-approval commitments including clinical studies, or may approve a product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product.

In addition, the FDA's, EMA's or other foreign regulatory authorities’ policies with respect to clinical studies may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical studies in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022. The implementation of the CTR also includes the implementation of the Clinical Trials Information System, or CTIS, a new clinical study portal and database that will be maintained by the EMA in collaboration with the European Commission and the EU Member States. The objectives of the CTR include consistent rules for conducting studies throughout the EU, consistent data standards and adverse events listing, and consistent information on the authorization status. Information on the conduct and results of each clinical study carried out in the EU will be made publicly available. The CTR authorizes EU Member States to regulate certain aspects of clinical studies at the national level. To the extent an EU Member State where we plan to conduct any of our clinical studies is slow to adopt CTIS or implements other regulatory changes at the national level, or technical issues are encountered with the CTIS system and/or process, our clinical study may be delayed in such EU Member State, and our costs may be increased. The main legislation that applies to clinical studies in the United Kingdom, or UK, is the UK Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the EU Clinical Trials Directive into domestic law. The UK has implemented the Integrated Research Application System, which allows a single application to be reviewed by both the Medicines and Healthcare products Regulatory Agency and a research ethics committee at the same time. Requirements and obligations that relate to the conduct of clinical studies in the UK remain largely aligned with the EU position. A statutory instrument to amend the Medicines for Human Use (Clinical Trials) Regulations 2004 was laid before parliament on December 12, 2024. The new regulations will take full effect on April 10, 2026 after a 12-month implementation period to address the research sector’s need for a more efficient, streamlined and adaptable regulatory framework for clinical studies. Complying with changes in regulatory requirements in different jurisdictions can result in additional costs, delay our clinical development plans, or expose us to greater liability if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical studies, our development plans, including our azetukalner Phase 3 clinical studies, may be impacted.

Additionally, because there may be approved treatments for some of the diseases or disorders for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate in clinical studies that the product candidates we develop to treat those diseases or disorders are not only safe and effective, but may need to be compared to existing methods of treatment within healthcare systems, which may make it more difficult for our product candidates to receive regulatory approval or adequate reimbursement. Demonstrating superiority or added value over existing therapies is often a critical factor for both regulators and payers, and failure to do so may limit market access and adoption within healthcare systems.

Even if we obtain and maintain approval for our product candidates from one jurisdiction, we may never obtain approval for our product candidates in other jurisdictions, which would limit our market opportunities and adversely affect our business.

Sales of our approved products, if any, will be subject to the regulatory requirements governing marketing approval in the countries in which we obtain regulatory approval, and we plan to seek, ourselves or with collaborators, regulatory approval to commercialize our product candidates in North America, the EU and in additional foreign countries. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. For example, approval in the U.S. by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by the FDA, EMA or regulatory authorities in other countries. Approval procedures vary among jurisdictions and can be lengthy and expensive, and involve requirements and administrative review periods different from, and potentially greater than, those in the U.S., including additional pre-clinical studies or clinical studies. Even if our product candidates are approved, regulatory approval for any product may be withdrawn by the regulatory authorities in a particular jurisdiction. We do not have experience in obtaining regulatory approval in international markets. If we, or our collaborators, fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

If product liability lawsuits are brought against us, we may incur substantial liabilities in excess of our limited product liability insurance coverage and may be required to limit commercialization of our current and any future products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, and we will face an even greater risk if we commercialize any product candidates. For example, we may be sued if any of our product candidates, including any that are developed in combination with other therapies, allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state or provincial consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical study participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to study participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in the market price of our common shares.

We currently carry product liability insurance with amounts of coverage that we believe are appropriate relative to our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may then be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the market price of our common shares to decline and, if judgments exceed our insurance coverage, could adversely affect our future results of operations and business.

Patients with certain of the diseases, or disorders, targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening conditions. During the course of treatment, patients have in the past and may in the future suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market those product candidates, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Even if regulatory agencies grant marketing approvals to azetukalner or any other of our product candidates, we may not be successful in commercializing any of our future products.

Successful commercialization of any our current or future product candidates, if approved, could be materially adversely impacted by a number of foreseen and unforeseen factors, including:

- any delays in our ability to produce sufficient quantities of or our current or future product candidates, at an acceptable cost or quality, including such delays arising out of quality assurance concerns or changes in regulatory guidance, or those caused by our reliance on our third-party manufacturers;
- our inability to recruit, train and retain adequate numbers of effective sales, marketing, access, and payer and patient support personnel;
- the inability of sales personnel to obtain access to prescribers and accounts;
- an inadequate number of prescribers or accounts prescribing any of our future products;
- our inability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of side effects associated with any of our future products;
- our inability to compete with current or future competitor products;
- the convenience and ease of administration of our future products relative to alternative therapies, if any;
- our inability or delay in gaining or maintaining reimbursement and broad patient access at a price that reflects the value of our future products;
- our inability to address product labeling or product insert requirements, including any changes mandated by regulatory authorities after initial approval;
- limitations on the content or form of the consumer and/or prescriber-facing marketing materials that we may use;
- our inability to equip customer-facing personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare professionals regarding applicable diseases relevant to our future products;
- publications of scientific literature, consensus papers and treatment guidelines unfavorable to the administration of our products and product candidates and/or the positioning of the class of drugs to which each of our products and product candidates belongs; and
- our inability to develop or obtain and sustain sufficient operational functions and infrastructure to support our commercial activities.

The incidence and prevalence for target populations of azetukalner and our other product candidates has not been established with precision. If the market opportunities for our product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of our targeted patient population, our revenue may be materially adversely affected.

The precise incidence and prevalence for all the conditions we aim to address with our programs are not known with specificity. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, if approved, are based largely on our extrapolation from available population studies and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, pharmacy claims analyses, large national surveillance databases or market research, and may prove to be incorrect. Further, new trials and therapeutic options may lead to changes in the estimated incidence or prevalence of these diseases, or relevant subpopulations thereof. As a result, the number of patients who may benefit from our product candidates, if approved, may be lower than expected.

If we are unable to establish our own sales, marketing and distribution capabilities or enter into agreements for these purposes, we may not be successful in independently commercializing any future products.

We do not have a sales or marketing infrastructure and, as a company, have no sales, marketing or distribution experience. Our strategy involves building our own commercial infrastructure to selectively commercialize future products in certain commercial markets which will be expensive and time consuming. For certain products, including azetukalner, and/or specific commercial markets, we evaluate commercial partners from time to time. In some cases, we may seek to retain the right to participate in the future development and commercialization of such products if we believe such involvement would advance our business. We cannot be certain that we will be successful in consummating any such commercial partnerships or, if consummated, whether such partnerships will be successful.

To develop internal sales, distribution and marketing capabilities in the U.S., we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that any of our product candidates will be approved. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a commercial organization. For any future products for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- the maintenance of existing or the establishment of new supply arrangements with third-party logistics providers and secondary packagers;
- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- a continued acceptable safety profile following any marketing approval;
- our ability to recruit and retain adequate numbers of qualified sales and marketing personnel or develop alternative sales channels;
- the ability of our products to secure acceptance from physicians, healthcare providers, patients, third-party payers and the medical community including identifying an adequate number of physicians and patients;
- 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;
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization; and
- our ability to compete with other therapies.

Where and when appropriate, we may elect to utilize contract sales forces, distribution partners or collaborators that have sales, marketing and distribution capabilities to assist in the commercialization of or to independently commercialize our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for a product, the resulting revenue or the profitability from this revenue to us is likely to be lower than if we had sold, marketed and distributed that product ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market, and distribute our current or any future products effectively.

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and delays.

Any of our product candidates for which we, or any existing or future collaborators, obtain regulatory approval, as well as the manufacturing processes, post-approval studies, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to user fees and periodic inspection by the FDA and other regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. In addition, our product candidates may receive schedule classifications under the Controlled Substances Act of 1970 (or scheduling classifications under similar legislation outside of the U.S.) which will result in additional complexity and may result in delays and restrictions with respect to manufacturing, supply chain, licensing, import/export and distribution.

Even if a product is approved, the FDA or another applicable regulatory authority, as the case may be, may limit the indications for which the product may be marketed, require extensive precautions and warnings on the product labeling or require expensive and time-consuming post-approval commitments including clinical studies or onerous risk management activities, including Risk Evaluation and Mitigation Strategies, or REMS, in the U.S. as conditions of approval to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug.

For any approved product, we, or our collaborators, will need to ensure continued compliance with extensive regulations and requirements regarding the manufacturing processes, labeling, packaging, serialization, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with current good manufacturing practices, or cGMP, good distribution practices, or GDP, and current good clinical practices, or cGCP, for any clinical studies that we, or our collaborators, are required to conduct post-approval.

Post-approval discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or other problems with our product or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, amongst other things, restrictions on the labeling or marketing, withdrawals, consent decrees, clinical holds, post-approval requirements or restrictions, recalls, fines, warning letters, injunctions, penalties, exclusions from federal healthcare programs, seizures and/or detentions, among other consequences and adverse actions. Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations.

If any of our product candidates are approved, we must comply with requirements concerning the advertising and promotion of our products, which are subject to a variety of legal and regulatory restrictions and may be promoted only for the approved indications in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label use may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA and other foreign regulators do restrict manufacturers' communications on the subject of off-label use of their products. The EU and other foreign jurisdictions also prohibit direct-to-consumer advertising for prescription-only medicines. Even if any of our product candidates receive regulatory approval, our sales and marketing efforts may not be successful or may be limited by future governmental policies or initiatives. For example, the FDA stated in September 2025 that it intends to more aggressively enforce requirements for direct-to-consumer drug advertising and sent warning or untitled letters to a significant number of pharmaceutical companies alleging deceptive prescription drug advertising, which represents a dramatic increase in FDA actions compared to prior years. The current administration’s focus on pharmaceutical advertising heightens the risk that we may, in the future, receive a warning letter or be subject to enforcement action related to our advertising and marketing practices, which could adversely affect our business.

To the extent we develop and commercialize product candidates that contain or are considered controlled substances, any failure by us or our CROs, CMOs and other contractors to comply with controlled substance laws and regulations, may adversely affect the results of our business operations and our financial condition.

We may in the future develop product candidates that are considered controlled substances in multiple jurisdictions, such as the U.S., Canada, and the EU, which will expose us to additional controlled substance regulatory requirements in each applicable jurisdiction where we engage in regulated activities, including storage, manufacture, research, clinical studies, import, and export, among other activities. For example, obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our controlled substance product candidates and may extend our anticipated timelines for clinical studies we run.

Controlled substances or scheduled substances are regulated by the DEA under the CSA. The DEA regulates compounds as Schedule I, II, III, IV or V substances. Pharmaceutical products approved for use in the U.S. may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Authorities outside the U.S. apply the United Nations International Drug Control Conventions to control substances or schedule substances that are liable to abuse or ill effects.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule, which may introduce a delay into the approval and any potential rescheduling process. There can be no assurance that the DEA will make a favorable scheduling decision. Substances that are Schedule II, III, IV or V controlled substances at the federal level may also require scheduling determinations under state laws and regulations, as well as similar foreign controlled substances regulations, if applicable. If approved by the FDA, a number of post-approval activities involving controlled substances will be subject to regulation by the DEA, including DEA regulations relating to registration and inspection of facilities, manufacturing, storage, distribution and physician prescription procedures, among others. Furthermore, failure of our contractors, such as our CROs and CMOs, to maintain compliance with the CSA during development and/or commercialization, as applicable, can result in a material adverse effect on our business, financial condition and results of operations.

Individual U.S. states and countries outside of the U.S. have also established controlled substance laws and regulations. Those laws and regulations, including state-controlled substances laws that often but not necessarily mirror federal law, may separately schedule our product candidates. Complying with different controlled substances requirements across different jurisdictions can increase the cost of our operations and expose us to additional liabilities.

Even if we obtain marketing approval for our product candidates, the presence of a controlled substance in the product candidate may lead to adverse publicity or public perception regarding our current or future product candidates.

If our product candidates that are subject to controlled substances regulation are approved for commercial sale, adverse publicity or public perception of controlled substances in general or other controlled substances could negatively impact market acceptance or consumer perception of our product candidates. We may face limited adoption if clinicians or patients are unwilling to try a novel treatment that contains a controlled substance. Any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our or similar therapies distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events and research in controlled substances that are present in the product candidates could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

Any product candidates for which we obtain approval may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations, which may adversely affect demand for such products as well as our ability to obtain an appropriate return from the sale of the products.

Our, or our collaborators', ability to commercialize any products successfully if and when approved for marketing will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, such as Medicare and Medicaid, and private third-party payers, such as private health insurers, managed care plans, and other organizations. Government authorities and private third-party payers decide which drugs they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we, or our collaborators, commercialize and, if reimbursement is available, the level of reimbursement. In addition, coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or a collaborator obtains marketing approval. If coverage and reimbursement are not available or are limited, we, or our collaborators, may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There is significant uncertainty related to third-party payer coverage and reimbursement of newly approved products. Within the U.S., coverage and reimbursement varies from one third-party payer to another. One third-party payer's determination to provide coverage for a product candidate does not assure that other third-party payers will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors payers consider in determining reimbursement are based on whether the product is: (i) a covered benefit under a payer health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. We may be required to provide scientific and clinical support for the use of our products to each third-party payer separately, with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. Even if a third-party payer provides coverage and adequate reimbursement, the payer may implement controls to manage utilization (e.g., requiring specific approval in advance to cover a product when used by a specific patient).

As federal and state governments implement additional healthcare cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payers, and if covered, that the reimbursement will be adequate or competitive with other marketed products. Actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and healthcare costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development.

Additionally, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or demanded by private payers and by any future change in laws related to imports of drugs from other countries, including where they may be sold at lower prices than in the U.S. In order to obtain and maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we may have to offer discounts or rebates from list prices or to implement other unfavorable pricing modifications. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

Outside the U.S., the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. These jurisdictions consistently encounter market access challenges for innovative therapies, particularly with respect to the breadth, speed, and cost of adoption. Market access decisions are principally guided by rigorous assessments of cost-effectiveness and affordability. As a result, access to new medical technologies or interventions may be denied or restricted to smaller patient populations than those covered by the approved label, based on these assessments. Additionally, concerns regarding the potential impact on healthcare budgets can cause the speed and rate of uptake for new therapies to be slower than anticipated. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control, reimbursement restrictions or mandatory rebate mechanisms. These requirements are often imposed as conditions for new products to be adopted and reimbursed for use in national health systems. Such mechanisms can further limit the commercial potential of new therapies by reducing pricing flexibility and potentially delaying or restricting market access. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical study that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we, or our collaborators, are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Some of our or our collaborators' target patient populations may be in orphan or niche indications, such as SCN8A-DEE. In order for therapies that are designed to treat smaller patient populations to be commercially viable, the pricing, coverage and reimbursement for such therapies needs to be higher, on a relative basis, to account for the lack of volume. Accordingly, we or our collaborators may need to implement pricing, coverage and reimbursement strategies for any approved product that accounts for the smaller potential market size. If we or our collaborators are unable to establish or sustain coverage and adequate reimbursement for our or our collaborators' current and any future products from third-party payers or the government, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those products.

Healthcare and other reforms may increase the difficulty and cost for us to commercialize any products that we, or our collaborators, develop and affect the prices we may obtain.

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system generally and drug pricing and payment specifically, in ways that could affect our ability to sell any of our products profitably, once such products are approved for sale. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the PPACA, was enacted and includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers.

In the U.S. in recent years, including under the current presidential administration, the pharmaceutical industry has been a particular focus of such reform efforts and has been significantly affected by major legislative, administrative and executive initiatives. For example, the Inflation Reduction Act (IRA) of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the PPACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. More recently, an Executive Order was issued in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA, accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs, and increasing drug importation. In May 2025, another Executive Order was issued that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients), prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States, and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored nation price. In the wake of the Executive Orders and related executive initiatives, some pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices or reached agreements with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A future website sponsored by the federal government that is anticipated to offer pharmaceutical direct-to-consumer channels has also been announced. Federal agencies are developing new drug pricing pilot programs, such as a Medicaid model which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to change.

Other healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured patients.

At the state level, legislatures have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing costs disclosure and transparency measures, and in some cases designed to encourage importation from other countries and bulk purchasing. Additionally, a number of states have enacted state drug price transparency and reporting laws that increase compliance burdens and exposure for non-compliance.

Further, a number of states have enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws if and when we have marketed products. These and other health reform measures that are implemented may have a material adverse effect on our operations.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA 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 the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty. Other government actions could have an adverse effect upon, and could prevent, our products' commercial success. For example, the current presidential administration's announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Additionally, 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. 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.

The nature and extent of future healthcare reforms cannot be predicted. There is uncertainty regarding the nature or impact of any drug pricing or broader healthcare reform implemented at the federal or state level and the extent to which such action may be subject to litigation or other challenges. Ongoing efforts to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if approved, and our ability to achieve or maintain profitability.

In the EU, similar political, economic and regulatory developments may affect our, or our collaborators', ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The EU is undergoing a revision of its general pharmaceutical legislation to consolidate various legal instruments and achieve key policy objectives such as improving patient access to medicines, enhancing supply chain security, promoting innovation, ensuring environmental sustainability, and addressing antimicrobial resistance. The legislative proposal was considered by the European Parliament in April 2024 for a position to be adopted. The legislative process will take considerable time to complete as the proposal will require agreement by the European Parliament and the European Council. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payers. An adequate level of reimbursement might not be available for such products and third-party payers' reimbursement policies might adversely affect our, or our collaborators' ability to sell any future products profitably.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or in other jurisdictions. If we, or our collaborators, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we, or our collaborators, are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Disruptions at the FDA and other government agencies caused by staffing or funding shortages could prevent our product candidates from being developed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review or approve new product candidates can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. For example, over the last several years, the U.S. federal government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, preventing the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory 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.

Additionally, the current presidential administration has taken several actions that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities. Further, the current presidential administration has substantially reduced the FDA's workforce and may make further reductions, which may lead to disruptions and delays in the FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development programs. Although it has been reported that there have not been reductions in workforce in the review or inspection divisions, any such reductions could extend review timelines, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications. It is difficult to predict how these executive actions and executive actions that may be taken under the current presidential administration may affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Risks Related to Our Dependence on Third Parties

Our prospects for successful development and commercialization of our partnered products and product candidates are dependent upon the research, development and marketing efforts of our collaborators.

We have no control over the resources, time and effort that our collaborators may devote to our programs and limited access to information regarding or resulting from such programs. We are dependent on our collaborators, including Neurocrine Biosciences, to fund and conduct the research and any clinical development of product candidates under our agreements with each of them, and for the successful regulatory approval, marketing and commercialization of one or more of such products or product candidates. Such success will be subject to significant uncertainty.

Our ability to recognize revenue from successful collaborations may be impaired by multiple factors including:

- a collaborator may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaborator may cease development in therapeutic areas which are the subject of our strategic alliances;
- a collaborator may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaborator may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaborator concerning the research or development of a product candidate, commercialization of a product or payment of royalties or milestone payments, any of which could result in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- a collaborator may not adequately protect the intellectual property rights associated with a product or product candidate;
- a collaborator may use our proprietary information or intellectual property in such a way as to invite litigation from a third-party; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions.

If our collaborators do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts could be delayed, terminated or be commercially unsuccessful. Conflicts between us and our collaborators may arise. In the event of termination of one or more of our collaboration agreements, it may become necessary for us to assume the responsibility of any terminated product or product candidates at our own expense or seek new collaborators. In that event, we could be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business could be materially and adversely affected.

We may not be successful in establishing new collaborations or maintaining our existing alliances, which could adversely affect our ability to develop product candidates and commercialize products.

In the ordinary course, we engage with other biotechnology and pharmaceutical companies to discuss potential in-licensing, out-licensing, alliances and other strategic transactions. The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. Additionally, there are certain jurisdictions where a collaborator may be able to realize the market potential of our product candidates better than us. For these or other reasons, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization.

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish other collaborations or other alternative arrangements for any current or future product candidates because our research and development pipeline may be insufficient, our current or future product candidates may be deemed to be at too early of a stage of development for collaboration effort and/or third parties may view our product candidates as lacking the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If any of our existing collaboration agreements are terminated, or if we determine that entering into other product collaborations is in our best interest but we either fail to enter into, delay in entering into or fail to maintain such collaborations:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development or commercialization of any such product candidates would increase significantly and we may need to seek additional financing sooner than expected;
- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, some of which we do not currently have;
- we may delay commercialization or reduce the scope of any sales or marketing activities;
- we will bear all of the risk related to the development or commercialization of any such product candidates; and
- the competitiveness of any product that is commercialized could be reduced.

Our reliance on third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our raw materials, APIs or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing or testing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for the manufacture and supply of the active pharmaceutical ingredients, or APIs, in our product candidates and the final drug product formulation for all of our product candidates that are being used in our clinical studies and pre-clinical studies as well as packaging, labelling and distribution of clinical study supplies. Our current strategy is to outsource all manufacturing of our product candidates to third parties.

In addition, we rely on our collaborators, either directly or through CMOs, to manufacture product candidates licensed to them or to work with CMOs to produce sufficient quantities of materials required for the manufacture of our product candidates for pre-clinical testing and clinical studies and intend to do so for the commercial manufacture of our products. If we, or our collaborators, are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we, or our collaborators, may not be able to successfully produce sufficient supply of a product candidate or we, or our collaborators, may be delayed in doing so. Such failure or substantial delay could delay our clinical studies and materially harm our business. The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the third-party manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on these third parties for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third-party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), the impact of industry consolidation, including business combinations involving such third parties, and the possibility of termination or nonrenewal of the agreement by the third-party at a time that is costly or damaging to us. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

In addition, we typically order raw materials, APIs and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Further, the FDA, EMA and other foreign regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA, EMA and other foreign regulatory agencies. They are also subject to pre-approval inspections and periodic unannounced inspections by the FDA, EMA and other foreign regulatory agencies. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including product recall, suspension of manufacturing, importation bans, product seizure or a voluntary withdrawal of the drug from the market. Any failure by our, or our collaborators', third-party manufacturers to comply with cGMP or any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

In addition to third-party manufacturers, we rely on other third parties to store, test, monitor, label, package and transport bulk drug substance and drug product. If we are unable to arrange for such third-party sources, or fail to do so on commercially reasonable terms, we may not be able to successfully supply sufficient product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs and time to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical studies and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the requirements for registration and validation and the demands of clinical studies or market demands, which could delay regulatory approvals and decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

We rely on third parties to conduct our pre-clinical and clinical studies. If these third parties do not successfully carry out their contractual duties, including to comply with applicable laws and regulations or meet expected deadlines, our business could be substantially harmed.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party collaborators, to monitor, support, conduct and/or oversee pre-clinical and clinical studies of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit study subjects than if we conducted these studies with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our studies in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical study information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements to ensure the quality and integrity of the data generated by them or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical studies of our future product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other foreign regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We, our CROs and CMOs are required to comply with current good laboratory practices, or cGLP, cGCP and cGMP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Economic Area and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these regulations through periodic inspections of clinical study sponsors, principal investigators, clinical study sites, manufacturing facilities, nonclinical testing facilities and other contractors. If we or any of our CROs or CMOs fail to comply with these applicable regulations, the clinical data generated in our non-clinical and clinical studies may be deemed unreliable and our submission of marketing applications may be delayed or the FDA, EMA or another foreign regulatory authority may require us to perform additional clinical studies before approving our marketing applications. Upon inspection, the FDA, EMA or another foreign regulatory authority could determine that any of our clinical studies fail or have failed to comply with applicable cGCP regulations. In addition, our clinical studies must be conducted with product produced under the cGMP regulations enforced by the FDA, EMA and other foreign regulatory authorities, and our clinical studies may require a large number of test subjects. Our failure to comply with cGLP, cGCP and cGMP regulations may require us to repeat clinical studies or manufacture additional batches of drug, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs or CMOs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or if this is asserted or reported to have occurred.

If any of our clinical study sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical studies unless we are able to transfer the care of those patients to another qualified clinical study site. Further, if our relationship with any of our CROs or CMOs is terminated, we may be unable to enter into arrangements with alternative CROs or CMOs on commercially reasonable terms, or at all.

Our use of foreign CROs and CMOs in some jurisdictions, such as China, may be or may become subject to U.S. legislation, sanctions, trade restrictions and other regulatory requirements which may increase the cost of and cause delays for our pre-clinical product candidates.

Switching or adding CROs, CMOs or other suppliers can involve substantial cost and require extensive management time and focus. The process of transitioning to new partners often necessitates significant planning, coordination, and oversight to ensure that ongoing projects are not disrupted and that quality and regulatory standards are maintained. Any delays or issues during this transition period could adversely affect timelines, increase operational risks, and potentially impact the overall success of our development and commercialization efforts. In addition, there is a natural transition period when a new CRO, CMO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

Risks Related to Intellectual Property

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates or future products.

Our commercial success will depend, in part, on our ability to obtain and maintain patent, trademark and trade secret protection of our product candidates and future products, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending against possible third-party challenges. We evaluate our global patent portfolio in the ordinary course of business to enhance patent protection in areas of our strategic focus and in key markets for our product candidates and future products and may abandon existing patents or patent applications related to terminated development programs, areas, or markets of low strategic importance. Patents might not issue with respect to our patent applications that are currently pending, and issued patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our product candidates or any future products, or fail to otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain because it involves complex legal and factual considerations that may be impacted by changes in the law. In addition, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices in issuing patents are not always applied uniformly or predictably, and also may be subject to changing law. Consequently, patents may not issue from our pending patent applications, or we may end up with patent claims of different scope in different jurisdictions. As such, we do not know the degree of future protection that we will have on our future products and proprietary technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and future products, as well as other proprietary technology could have a material adverse impact on our business and ability to achieve profitability.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and various governmental patent offices outside of the U.S. in several stages over the lifetime of the patents and/or patent applications. The USPTO and foreign governmental patent offices require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application and maintenance process. We employ reputable law firms and other professionals to help us comply with respect to the patents and patent applications that we own or co-own, and we rely upon collaborators to effect compliance with such requirements with respect to some patents and patent applications that we out-license and/or in-license.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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 may not permit us to maintain our competitive advantage. The following non-exhaustive examples are by way of illustration only:

- others may be able to make compounds that are similar to our product candidates or future products but that are not covered by the claims of the patents that we own, co-own or may in-license;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- patents that we own, co-own or may in-license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, the term(s) may expire prior to or soon after the commercial sale of the related product, thereby limiting the commercial value of our patents;
- we might not have been the first to make or file upon the inventions covered by the patents or pending patent applications;
- it is possible that our pending patent applications will not issue as patents;
- we cannot predict the scope of protection of any patent issuing from our patent applications, including whether the patent applications that we own will result in patents with claims directed to our product candidates or future products or uses thereof in the United States or in foreign countries;
- our competitors might conduct research and development activities 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 fail to develop additional proprietary technologies that are patentable and/or may fail to adequately protect such technologies;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and

- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing our future products.

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

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from offering to sell, selling, using, making or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our inventions in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting, enforcing and defending intellectual property rights in certain foreign countries. The legal systems of some countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

We may be involved in lawsuits to enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful, and those patents could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we or our licensors take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology.

Competitors may infringe our patents or the patents of our licensors. To stop infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent in suit is not valid or is not enforceable. In such cases, third parties may be able to use our technology without paying licensing fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party’s activities are not covered by our patents or that the legal requirements for imposing injunctive relief are not met. In addition, third parties may affirmatively challenge our rights to, or the scope or validity of, our patents. An adverse result in any litigation or post-grant proceeding could put additional patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. Any efforts to enforce our intellectual property rights are likely to be costly and may divert the efforts of our scientific and management personnel.

For example, if we were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates or future products, the defendant could defend or counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some foreign countries, defendant defenses and counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, patent ineligibility, loss of priority claims, lack of written description, or lack of enablement. Grounds for an assertion of unenforceability could be an allegation that someone connected with prosecution of the patent knowingly withheld material information from the USPTO or an applicable foreign counterpart where such a duty to disclose exists, or made a misleading statement, during prosecution. Patents may be subject to challenge in multiple different ways. For example, administrative proceedings such as derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes review, post-grant review, or opposition proceedings, provoked by third parties or initiated by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patents or a patent of our licensor. An unfavorable outcome in any of these proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation and/or other administrative proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Certain foreign countries may provide for compulsory licensing of our patent rights that would preclude us from enforcing our patents against a third party.

With respect to challenges to the validity of our patents or the patents of our licensors, for example, there might be prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate or future product. As another example, a litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such challenges is unpredictable. Even if a challenger does not prevail, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the challenger and others. The cost of defending such a challenge, particularly in a foreign country, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Patent protection and patent prosecution for some of our product candidates and future products is dependent on, and the ability to assert patents and defend them against claims of invalidity is maintained by, third parties.

There have been and may be times in the future when certain patents that relate to our product candidates or any future products are controlled by our collaborators, including licensees, sublicensees or licensors. Although we may, under such arrangements, have rights to consult with our collaborators on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. For example, currently the rights relating to the patent portfolio for certain selective Nav1.6 inhibitors and dual Nav1.2/1.6 inhibitors are exclusively licensed to Neurocrine Biosciences, and Neurocrine Biosciences has the first right to bring and control any action in connection with product infringement.

If any current or future collaborator with rights to file, prosecute, enforce and/or defend patents related to our product candidates or future products fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates or future products are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidates or future products may be adversely affected and we may not be able to prevent competitors from making, using, importing, offering for sale, and/or selling competing products.

Claims that our product candidates or the sale, offer for sale, importation, manufacture, or use of our future products infringe the patent or other intellectual property rights of third parties could result in costly litigation, could require substantial time and money to resolve, even if litigation is avoided, and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, upon our ability to develop product candidates and commercialize our future products, without infringing the intellectual property rights or other proprietary rights of others. Third parties might allege that we, or our collaborators, are infringing, misappropriating, or otherwise violating their intellectual property rights. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is possible that relevant patents or patent applications held by third parties will cover our product candidates at the time of launch and we may also fail to identify relevant patents or patent applications held by third parties that might be asserted to cover our product candidates. For example, U.S. applications filed before November 29, 2000, and certain applications filed after that date that were not filed outside the U.S. remain confidential until patents issue. Other patent applications in the U.S. and several other jurisdictions are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we, or our collaborators, were the first to invent, or the first to file patent applications on our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that will be issued in the future. Additionally, pending patent applications and patents which have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future products, if any, or their use.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, our future products, or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. Furthermore, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims of a third party's patent by requesting an administrative proceeding, for example, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes review, post-grant review, or opposition proceedings, before the USPTO or proceedings before any foreign patent authority. The costs of these administrative proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result in the USPTO or any foreign patent office, we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or future products.

Defending against claims of patent infringement or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation or threatened litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that the selling, using, making, offering to sell, or importing, of our product candidates or future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

Third parties may be able to sustain the costs of complex intellectual property litigation or proceedings more effectively than we can. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical studies, continue our internal research programs, in-license needed technology, or enter into strategic collaborations that would help us bring our product candidates to market.

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

Any future intellectual property litigation and/or other administrative proceedings will result in additional expense and distraction of our personnel. There is inevitable uncertainty in intellectual property litigation, and we could lose, even if the case against us is weak or flawed. An unfavorable outcome in such litigation or proceedings may expose us or any future strategic collaborators to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or future product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or future product.

For example, if third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology or barred from developing and commercializing certain future products. Alternatively, we may be required to pay substantial damage awards to the plaintiff, including up to treble damages and attorneys' fees if we are found to have willfully infringed a patent. As another alternative, we may be required to obtain a license from the intellectual property owner to continue our research and development programs or to market any resulting product. It is also possible that we may be required to modify or redesign our product candidates or future products, if any, in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render those products less competitive, or may delay or prevent the entry of those products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more product candidates, or both.

If we choose or are required to seek a license from a third-party, we may be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or any future collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations as a result of actual or threatened litigation. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement. In the future, we may receive offers to license and demands to license from third parties claiming that we are infringing their intellectual property or owe license fees and, even if such claims are without merit, we could fail to successfully avoid or settle such claims.

If Neurocrine Biosciences or other collaborators license or otherwise acquire rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be developed or commercialized in a country without the third-party intellectual property rights or, where it is decided that it would be useful to acquire such third-party rights to develop or commercialize the product, they are eligible under our collaboration agreements to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

If we breach any agreement under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business.

Under existing or future license and other agreements, we are or may become subject to various obligations, including diligence obligations such as development and commercialization obligations, as well as potential milestone payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the applicable license in whole or in part or convert an exclusive license to a non-exclusive license. Generally, the loss of any such license, or any license exclusivity thereunder, could materially harm our business, prospects, financial condition and results of operations.

If we are unable to prevent unauthorized disclosure of trade secrets and other proprietary information, our competitive position could be harmed.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our discovery platform, business strategy and product candidates, which can be difficult to protect, in order to maintain our competitive position. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory, manufacturing, pre-clinical development or clinical development goods or services or potential strategic collaborators. In addition, each of our employees and consultants is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. Our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information in breach of these confidentiality agreements or our trade secrets may otherwise be misappropriated. Our collaborators might also have rights to publish data and we might fail to apply for patent protection prior to such publication. It is possible that a competitor will make use of such information, and that our competitive position will be compromised. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, then our ability to protect our trade secret information would be jeopardized, which would adversely affect our competitive position.

In addition, we, or our licensors, may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we, or our licensors, may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our, or our licensors', ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we, or our licensors, fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents, thereby impairing our ability to protect our product candidates and future products.

Our success is heavily dependent on intellectual property, particularly patents. The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the U.S. or other countries. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, there have been recent changes regarding how patent laws are interpreted, and both the USPTO and Congress have recently made significant changes to the patent system. There have been U.S. Supreme Court decisions that indicate a distinctly negative view of some patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain, maintain and/or enforce patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents, the costs to prosecute our patent applications and enforce our patents and/or the patents and applications of our collaborators. The patent situation in these fields outside the U.S. also has uncertainties. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. As an example, European patent applications have the option, upon issuance of a patent, of becoming a Unitary Patent, which is subject to the jurisdiction of the Unitary Patent Court, or UPC. The option of a Unitary Patent and the creation of the UPC are significant changes in European patent practice. As the UPC is a new court system, there is little precedent for the court, increasing the uncertainty of any litigation in the UPC.

Intellectual property litigation and/or other administrative proceedings may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

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

If we do not obtain protection under the Hatch-Waxman Act in the U.S. and similar foreign legislation by extending the patent terms for patents covering our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. However, we may not be granted an extension if, for example, we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than five years.

If we are unable to obtain patent term extension or the duration of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

If any of our products are approved by the FDA, listing patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) is mandatory, and the decision to list or not list a given patent in the Orange Book could give rise to allegations of antitrust or unfair competition liability, from the Federal Trade Commission, other government entities or private parties. In addition, we may be required by court order to delist patents from the Orange Book that are found to be improperly listed, which could impact our ability to take advantage of the benefits of the Hatch-Waxman Act, including the 30-month stay of generic approval.

If our trademarks are not adequately protected, we may not be able to build name recognition in our markets of interest, which could adversely affect our business.

Our current and future trademarks, including our corporate name, Xenon, has not been trademarked in each market where we operate and plan to operate. Our trademark applications for our corporate name or the name of our products may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections, which we may be unable to overcome in our responses. Third parties may also attempt to register trademarks utilizing the Xenon name on their products, and we may not be successful in preventing such usage. In addition, in the USPTO and in comparable patent offices in many foreign countries, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Moreover, any name we have proposed to use with our product candidates in the United States, regardless of whether we have registered it or applied to register it as a trademark, must be approved by the FDA. Similar requirements exist in Europe and other foreign countries. If the FDA (or an equivalent administrative body in a foreign country) objects to any of our proposed product names, we may need to identify a suitable substitute name, for example, that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. This may require additional expense.

In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks that incorporate variations of or allegedly cause confusion with our registered or unregistered trademarks. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively, and our business may be adversely affected.

Our expanding use of artificial intelligence exposes us to operational, regulatory, legal, and ethical risks that could adversely affect our business, reputation, financial condition, and results of operations.

We increasingly develop, procure, and deploy artificial intelligence, or AI, and machine learning, or ML, technologies across our operations. While these tools may create efficiencies, they also introduce material risks related to data quality and bias, transparency and explainability, model drift and reliability, cybersecurity, intellectual property, privacy, discrimination, liability, and vendor/supply chain dependencies. Errors or bias in AI outputs, inadequate monitoring, or insufficient documentation could impair clinical development, pharmacovigilance, manufacturing quality, or commercial activities, resulting in delays, higher costs, product or batch actions, or reputational harm.

Additionally, the emergence of AI and other technologies may exacerbate other risks, including those related to regulation, litigation, compliance issues, ethical concerns, confidentiality, and data privacy or security. For example, regulatory uncertainty related to AI or other emerging technologies may require significant resources to adjust business practices to comply with developing laws.

Risks Related to Ownership of Our Common Shares

The market price of our common shares may be volatile, and purchasers of our common shares could incur substantial losses.

Our common shares are listed on Nasdaq under the trading symbol “XENE.” The market price of our common shares has fluctuated in the past and is likely to be volatile in the future. As a result of this volatility, investors may experience losses on their investment in our common shares. The market price for our common shares may be influenced by many factors, including the following:

- announcements by us or our competitors of new products, product candidates or new uses for existing products, significant contracts, commercial relationships or capital commitments and the timing of these introductions or announcements;
- actions by any of our collaborators regarding our product candidates they are developing, including announcements regarding clinical or regulatory decisions or developments of our collaboration;
- unanticipated serious safety concerns related to the use of any of our products and product candidates;
- negative or inconclusive results from clinical studies of our product candidates, leading to a decision or requirement to conduct additional pre-clinical testing or clinical studies or resulting in a decision to terminate the continued development of a product candidate;
- delays of clinical studies of our product candidates;
- failure to obtain or delays in obtaining or maintaining product approvals or clearances from regulatory authorities;
- adverse regulatory or reimbursement announcements;

- announcements by us or our competitors of significant acquisitions, strategic collaborations, licenses, joint ventures or capital commitments;
- the results of our efforts to discover or develop additional product candidates;
- our dependence on third parties, including our collaborators, CROs, clinical study sponsors and clinical investigators;
- regulatory or legal developments in Canada, the U.S. or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated quarterly variations in our financial results or those of our competitors;
- sales of common shares by us, our insiders or our shareholders in the future, as well as the overall trading volume of our common shares;
- changes in the structure of healthcare payment systems;
- commencement of, or our involvement in, litigation;
- the impact of pandemics, epidemics or other public health crises on our business and the macroeconomic environment;
- general economic, industry and market conditions, including changes resulting from governmental actions, such as tariffs;
- market conditions in the pharmaceutical and biotechnology sectors and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market in general, and Nasdaq and the biopharmaceutical industry in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. Fluctuating inflation and interest rates, for example, can result in significant volatility. These broad market and industry fluctuations may adversely affect the market price of our common shares, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Future sales and issuances of our common shares or securities convertible into or exchangeable for common shares would cause our shareholders to incur dilution and could cause the market price of our common shares to fall.

The market price of our common shares could decline as a result of sales of a large number of our common shares or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Pursuant to our equity incentive plans, our compensation committee (or a subset or delegate thereof) is authorized to grant equity-based incentive awards to our employees, directors and consultants. Future stock option grants and issuances of common shares under our share-based compensation plans will result in dilution to all shareholders and may have an adverse effect on the market price of our common shares.

In addition, in the future, we may issue additional common shares, preferred shares, or other equity or debt securities convertible into common shares in connection with a financing, collaboration agreement, acquisition, litigation settlement, employee arrangements or otherwise. We may also issue additional common shares upon the exercise of pre-funded warrants that we have issued from time to time. Any such issuance, including any issuances pursuant to our "at-the-market" equity offering program under our sales agreement with Jefferies and Stifel, could result in substantial dilution to our existing shareholders and could cause the market price of our common shares to decline.

We are governed by the corporate and securities laws of Canada which in some cases have a different effect on shareholders than the corporate laws of Delaware and U.S. securities laws.

We are governed by the Canada Business Corporations Act, or CBCA, and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our articles and by-laws, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the CBCA and Delaware General Corporation Law, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles) the CBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote; and (ii) under the CBCA, holders of 5% or more of our shares that carry the right to vote at a meeting of shareholders can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL. In addition, our board of directors is responsible for appointing the members of our management team and certain provisions of the CBCA and our articles and by-laws may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors. Certain of these provisions include the following:

- shareholders cannot amend our articles unless such amendment is approved by shareholders holding at least two-thirds of the shares entitled to vote on such approval;
- shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholders' meetings; and
- applicable Canadian corporate and securities laws generally require, subject to certain exceptions, a tender offer (also known as a take-over bid) to remain open for a minimum of 105 days and that more than 50% of the outstanding securities not owned by the offeror be tendered before the offeror may take up the securities.

Any provision in our articles, by-laws, under the CBCA or under any applicable Canadian securities law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their common shares, and could also affect the price that some investors are willing to pay for our common shares, thereby depressing the market price of our common shares.

U.S. civil liabilities may not be enforceable against us, our directors, or our officers.

We are governed by the CBCA and our principal place of business is in British Columbia, Canada. Many of our directors and officers reside outside of the U.S., and all or a substantial portion of their assets as well as a substantial portion of our assets are located outside the U.S. As a result, it may be difficult for investors to effect service of process within the U.S. upon us and certain of our directors and officers or to enforce judgments obtained against us or such persons, in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. federal securities laws or any other laws of the U.S. Additionally, rights predicated solely upon civil liability provisions of U.S. federal securities laws or any other laws of the U.S. may not be enforceable in original actions, or actions to enforce judgments obtained in U.S. courts, brought in Canadian courts, including courts in the Province of British Columbia.

We are at risk of securities class action litigation.

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 biotechnology companies have experienced significant share 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. In addition, an increase in litigation against biotechnology companies may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has broad discretion in the application of our cash resources. Shareholders may not agree with our decisions, and our use of our cash resources may not improve our results of operation or enhance the value of our common shares. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the market price of our common shares to decline. In addition, pending their use, they may be placed in investments that do not produce significant income or that may lose value.

We do not anticipate paying any cash dividends on our common shares in the foreseeable future.

We do not currently intend to pay any cash dividends on our common shares in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common shares may be investors' sole source of gain for the foreseeable future.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common shares.

The trading market for our common shares depends in part on the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our common share price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common shares or trading volume to decline.

There is no public market for our outstanding pre-funded warrants.

There is no public trading market for our outstanding pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to list the outstanding pre-funded warrants on Nasdaq or any other national securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the outstanding pre-funded warrants will be limited.

General Risk Factors

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have at times experienced extreme disruptions, characterized by increased market volatility, increased rates of inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. Current and future global conflicts, such as those between Ukraine and Russia and in the Middle East, have created, and may in future create, volatility in the capital markets and may have further global economic consequences. If the equity and credit markets were to deteriorate significantly in the future, including as a result of a pandemic, political unrest or war, or further instability of the global banking sector, it may make any necessary equity or debt financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and the market price of our common shares and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current collaborators, service providers, manufacturers and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have incurred, and expect to continue to incur, significant costs as a result of laws, regulations and investor-driven standards relating to corporate governance and other matters.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Sarbanes-Oxley Act of 2002, the CBCA, applicable Canadian securities laws, and rules adopted or proposed by the SEC, Nasdaq, Corporations Canada and applicable Canadian securities regulators have resulted in, and will continue to result in, significant compliance costs to us as we evaluate the implications of these rules and respond to their requirements.

Compliance with the various reporting and other requirements applicable to public companies also requires considerable time and attention of management. In the future, if we are not able to issue an evaluation of our internal control over financial reporting, as required, or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common shares could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Outside of the United States, Canadian securities regulators regularly pursue various rulemaking efforts with respect to ESG matters, which has resulted in the adoption of new laws and regulations. A variety of organizations also measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. If additional rules regarding ESG matters are formally adopted or if investors continue to increase their focus on ESG matters, we could incur substantially higher costs in our efforts to comply and cannot be certain that our efforts will be viewed as adequate by regulators or by such investors.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” each as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

(a) Exhibits.

Exhibit Number	Description of Document	Incorporated by Reference Form	File No.	Exhibit	Filing Date
3.1	Articles of the Company.	10-Q	001-36687	3.1	December 15, 2014
3.1A	Articles of Amendment to the Articles of the Company, creating the Series 1 Preferred Shares.	8-K	001-36687	3.1	March 28, 2018
3.2	Amended and Restated By-laws of the Company.	10-Q	001-36687	3.2	December 15, 2014
4.1	Form of Pre-Funded Warrant.	8-K	001-36687	4.1	March 12, 2026
10.1#	Employment Agreement by and between the Company and Ian Mortimer, effective as of February 25, 2026.	10-K	001-36687	10.37	February 26, 2026
10.2#	Employment Agreement by and between the Company and Thomas P. Kelly, effective as of February 25, 2026.	10-K	001-36687	10.38	February 26, 2026
10.3#	Employment Agreement by and between the Company and Andrea DiFabio, effective as of February 25, 2026.	10-K	001-36687	10.39	February 26, 2026
10.4#	Employment Agreement by and between the Company and Christopher Kenney, effective as of February 25, 2026.	10-K	001-36687	10.40	February 26, 2026
10.5#	Employment Agreement by and between the Company and Darren Cline, effective as of February 25, 2026.	10-K	001-36687	10.41	February 26, 2026
10.6#	Amended and Restated 2025 Inducement Equity Incentive Plan and related form agreements.	8-K	001-36687	10.1	April 13, 2026
10.7	Form of Restricted Share Unit Award Agreement.				
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).				
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).				
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.				
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document with Embedded Linkbases Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

# Indicates management contract or compensatory plan.

* The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Xenon Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Date: May 7, 2026

XENON PHARMACEUTICALS INC.

By: /s/ Ian Mortimer
Ian Mortimer
President and Chief Executive Officer

Date: May 7, 2026

By: /s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer

Exhibit 10.7

RESTRICTED SHARE UNIT AWARD AGREEMENT

THIS AGREEMENT made on [________] (the "Date of Grant")

AMONG:

Xenon Pharmaceuticals Inc., a company incorporated under the laws of Canada
(the "Company")

AND:

[First Name, Last Name, Title]
(the "Grantee")

WHEREAS:

A. The Grantee is a newly employed employee of the Company or one of its subsidiaries who (i) was not previously an employee of the Company or any of its subsidiaries or a Director, or (ii) is returning to employment with the Company following a bona-fide period of non-employment with the Company or any of its subsidiaries;

B. The Company considers that the grant to the Grantee of a Restricted Share Unit Award to be an inducement material to the Grantee's entering into employment with the Company or any of its subsidiaries in accordance with the Inducement Listing Rule; and

C. This Restricted Share Unit Award is granted pursuant to the exception to shareholder approval provided for inducement grants under the Inducement Listing Rule.

NOW THEREFORE THIS AGREEMENT WITNESSES THAT in consideration of the mutual premises and respective covenants and agreements herein contained, the parties hereto covenant and agree as follows:

ARTICLE I
INTERPRETATION

1.1. Definitions

In this Agreement, unless there is something in the subject matter or context inconsistent therewith, words and terms used herein will have the meanings set forth herein. To the extent a capitalized term is used herein and not otherwise defined, it shall have the meaning prescribed under the Plan:

(1) "Affiliate" has the meaning ascribed thereto under the Canada Business Corporations Act in effect on the date hereof;

(2) "Legal Representative" means a committee or duly appointed attorney of the Grantee or of the estate of the Grantee on the grounds that the Grantee is incapable, by reason of physical or mental infirmity, of managing his or her affairs;

(3) "Plan" means the Amended and Restated 2025 Inducement Equity Incentive Plan of the Company, as the same may from time to time be supplemented or amended and in effect;

(4) "Separate Agreement" has the meaning under Section 2.6(2) of this Agreement.

1.2. Interpretation

For the purposes of this Agreement, except as otherwise provided:

(1) "this Agreement" means this Restricted Share Unit Award Agreement as it may from time to time be supplemented or amended and in effect, and which is deemed to be an Award Agreement in accordance with the Plan;

(2) all references in this Agreement to "Articles", "Sections" and other subdivisions are to the designated Articles, Sections and other subdivisions of this Agreement;

(3) the words "herein", "hereof", "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Article, Section or other subdivision;

(4) the headings are for convenience only and do not form a part of this Agreement and are not intended to interpret, define or limit the scope, extent or intent of this Agreement or any provision hereof;

(5) the singular of any term includes the plural, and vice versa, the use of any term is equally applicable to any gender and, where applicable, a body corporate, the word "or" is not exclusive and the word "including" is not limiting whether or not non-limiting language (such as "without limitation" or "but not limited to" or words of similar import) is used with reference thereto;

(6) where the time for doing an act falls or expires on a day other than a Business Day, the time for doing such act is extended to the next day which is a Business Day;

(7) any reference to a statute is a reference to the applicable statute and to any regulations made pursuant thereto and includes all amendments made thereto and in force from time to time and any statute or regulation that has the effect of supplementing or superseding such statute or regulation; and

(8) any other capitalized terms not defined herein but defined in the Plan shall have the meaning as set out in the Plan.

ARTICLE II
THE RSUS

2.1 Grant

Subject to the provisions of this Agreement and the Plan, on the Date of Grant set forth above, the Company hereby grants to the Grantee a Restricted Share Unit Award consisting of [•] restricted share units (the "RSUs"), giving the Grantee the conditional right to receive, on the terms and conditions provided herein and in the Plan, one Common Share with respect to each RSU forming part of this Award, subject to adjustment pursuant to Section 10.3 of the Plan in respect of transactions occurring after the date hereof. The RSUs will vest, if at all, in accordance with the terms set forth on Exhibit A hereto.

2.2 Nontransferability of RSUs

The Restricted Share Unit Award is not transferable or assignable by the Grantee except as expressly permitted under Section 10.2 of the Plan.

2.3 Issuance of Shares

The Company will have no obligation to issue Common Shares upon the vesting or settlement of the RSUs unless the Board of Directors is satisfied that the issuance of such Common Shares to the Grantee will be exempt from all registration or qualification requirements of applicable securities laws and will be permitted under the applicable rules and regulations of all regulatory authorities to which the Company is subject, including any stock exchange or other organized market on which the Common Shares may from time to time be listed or posted for trading.

2.4 Compliance with Laws

The Board of Directors may from time to time take such steps and require such documentation from the Grantee which in its opinion is necessary or desirable to ensure compliance with all applicable laws. The Board of Directors may also from time to time take such steps which in its opinion are necessary or desirable to restrict the transferability of any Common Shares acquired on the settlement of any RSUs in order to ensure such compliance, including the endorsement of a legend on any certificate representing Common Shares acquired on the settlement of the RSUs to the effect that such Common Shares may not be offered, sold or delivered except in compliance with the applicable securities laws and regulations of Canada or the United States.

2.5 Delivery of Share Certificates

Subject to Sections 2.3 and 2.4, the Company will, as soon as practicable after the issuance of any Common Shares in settlement of the RSUs, issue and deliver a certificate or certificates representing the Common Shares so issued.

2.6 Vesting Conditions; Cessation of Employment; Change of Control

(1) Vesting Conditions. Except as provided in Section 2.6(2) and Section 2.6(3) below, the RSUs shall vest on the applicable "Vesting Date" (as such term is defined in Exhibit A); provided, that no RSUs shall vest pursuant to this Agreement unless the Grantee has continuously remained a Service Provider from the Date of Grant through the applicable Vesting Date.

(2) Cessation of Employment. Except as expressly provided for in this Agreement or in a written employment or service agreement, offer letter, change in control severance agreement, or any other agreement that, prior to the Date of Grant, has been entered into between the Grantee and the Company or any subsidiary of the Company or any Affiliate of the Company (such agreement, a "Separate Agreement"), if the Grantee ceases to be a Service Provider for any reason, including due to termination of employment by the Company or any of its subsidiaries or any of its Affiliates without Cause or alleged constructive dismissal or due to voluntary termination by the Grantee, all outstanding RSUs granted under this Agreement will automatically and immediately be cancelled for no consideration on the effective date of such termination, which shall be deemed to be the last day the Grantee actively works in the business of the Company, any of its subsidiaries or any of its Affiliates (or in the case of an alleged constructive dismissal, the date on which the alleged constructive dismissal is alleged to have occurred), and no statutory, contractual or common law notice entitlement or any entitlement to compensation in lieu of such notice shall operate to extend the vesting of the RSUs past said deemed termination date.

(3) Change of Control. Notwithstanding anything to the contrary in the Plan or this Agreement, in the event of a Change of Control, the treatment of the RSUs in connection with such Change of Control shall be as set forth in Exhibit A.

For greater certainty, for the purpose of this Agreement and the Plan, the date on which the employment of the Grantee is terminated without Cause or pursuant to voluntary resignation shall be deemed to be the last day the Grantee actively works in the business of the Company, any of its subsidiaries or any of its Affiliates (or in the case of an alleged constructive dismissal, the date on which the alleged constructive dismissal is alleged to have occurred), and not during or as of the end of any period following such date during which the Grantee is in receipt of, or entitled to receive, statutory, contractual or common law notice of termination or any compensation in lieu of such notice.

Further, and notwithstanding the above, and for greater certainty for the purposes of this Agreement and the Plan, if the Grantee's employment is terminated by the Company, any of its subsidiaries or any of its Affiliates and prior thereto, concurrently therewith or immediately thereafter the Grantee commences employment with the Company, any of its subsidiaries or any of its Affiliates, as the case may be, the Grantee will not cease to be a Service Provider and the vesting of the RSUs will not change as a result of such event.

Further, and notwithstanding the above, the Board of Directors may at its discretion accelerate the vesting of the RSUs, provided that the Board of Directors determines that such acceleration is appropriate and in the best interest of the Company in the circumstances and it is agreed and acknowledged that there is no obligation on the Board of Directors to exercise such discretion nor shall the Board of Directors be required to provide reasons for exercise or non-exercise of such discretion.

2.7 Settlement of RSUs

The Company shall, as soon as practicable upon the vesting of a RSU hereunder but in no event later than March 15th of the year following the year in which the applicable RSU vests, with respect to each such RSU that so vests, transfer one (1) Common Share to the Grantee (or, in the event of the Grantee's death, to the person to whom this Restricted Share Unit Award has passed by will or the laws of descent and distribution).

2.8 Forfeiture; Recovery of Compensation

The Board of Directors may cancel, rescind, withhold or otherwise limit or restrict this Restricted Share Unit Award at any time if the Grantee is not in compliance with all applicable provisions of this Agreement and the Plan. By accepting this Restricted Share Unit Award, the Grantee expressly acknowledges and agrees that his or her rights under this Restricted Share Unit Award, and those of any permitted transferee of this Restricted Share Unit Award, including the right to any Common Shares acquired under this Restricted Share Unit Award or proceeds from the disposition thereof, are subject to the Xenon Pharmaceuticals Clawback Policy, as such policy may be amended and in effect from time to time (and any successor or similar policy), to the extent applicable, and Section 10.5 of the Plan (including any successor provision). Nothing in the preceding sentence shall be construed as limiting the general application of Section 5.12 of this Agreement.

2.9 Dividends; Other Rights

This Restricted Share Unit Award shall not be interpreted to bestow upon the Grantee any equity interest or ownership in the Company or any Affiliate prior to the date on which the Company delivers Common Shares (if any) to the Grantee. The Grantee is not entitled to vote any Common Shares by reason of the granting of this Restricted Share Unit Award nor is the Grantee entitled to receive or be credited with any dividends declared and payable on any Common Share prior to the date on which any such share is delivered to the Grantee hereunder. The Grantee shall have the rights of a shareholder only as to those Common Shares, if any, that are actually delivered under this Restricted Share Unit Award.

2.10 Taxes

The Grantee expressly acknowledges that the vesting and/or settlement of the RSUs acquired hereunder may give rise to "wages" subject to withholding. So as to ensure that the Company will be able to comply with the applicable obligations under any federal, provincial, state or local law relating to the withholding of tax or other required deductions, the Company shall withhold or cause to be withheld from any amount payable to a Grantee, either under this Restricted Share Unit Award or otherwise, such amount as may be necessary to permit the Company to so comply. Unless otherwise agreed to between the Company and the Grantee, the Grantee authorizes the Company, on behalf of the Grantee, to sell or otherwise dispose of such portion of the Common Shares acquired by the Grantee on the settlement of the RSUs as is necessary to provide sufficient funds to the Company to enable it to satisfy any liability for any such withholding obligations. The Company shall remit the applicable portion of the net proceeds of such sale (after deduction of all fees commissions or costs in respect of such sale) to the appropriate governmental authority and shall remit to the Grantee any unapplied balance of the net proceeds of such sale. Any sale will be made at prevailing market prices and the Company shall not be under any obligation to obtain or indemnify the Grantee in respect of a particular price for the Common Shares so sold.

Notwithstanding anything in this Agreement to the contrary, the Grantee acknowledges and agrees that the Grantee shall remain fully responsible for satisfying his or her tax obligations relating to the Restricted Share Unit Award in all cases and nothing in this Section 2.10 shall be construed as relieving the Grantee of any liability for satisfying his or her tax obligations relating to the Restricted Share Unit Award.

ARTICLE III
ADJUSTMENTS

3.1 Adjustments

This Agreement will be amended by the Company unilaterally (without the need of consent or notice to the Grantee) upon the occurrence of the events referred to in Section 10.3(a) of the Plan so that the rights of the Grantee hereunder, including the number of Common Shares subject to the Restricted Share Unit Award, will be adjusted in accordance with the provisions set forth in the Plan. Successive adjustments will be made in the case of the occurrence of more than one such event as provided for therein, but, in the case of each such event, only from and after the occurrence of such event. Without limiting the other provisions of this Agreement, this Restricted Share Unit Award is subject to the provisions of Section 10.3 of the Plan.

ARTICLE IV
COVENANTS AND REPRESENTATIONS

4.1 Representations and Covenants of the Company

(1) The Company hereby covenants that it will reserve or cause to be reserved for allotment sufficient Common Shares for issue to the Grantee of all Common Shares which may become issuable from time to time under the Restricted Share Unit Award.

(2) The Company represents that the Grantee is a bona fide employee of the Company or of a subsidiary of the Company on the Date of Grant.

4.2 Representations and Covenants of the Grantee

The Grantee hereby represents and covenants that:

(1) the Grantee is an employee of the Company or of a subsidiary of the Company on the Date of Grant;

(2) the Grantee’s participation in the Plan is voluntary;

(3) the Grantee is aware that the grant of the Restricted Share Unit Award and the issuance by the Company of Common Shares thereunder are exempt from the obligation under applicable securities laws to file a prospectus or other registration document (other than a registration statement on Form S-8 with the United States Securities and Exchange Commission) qualifying the distribution of the RSUs or the Common Shares to be distributed thereunder under any applicable securities laws and if such exemption for any reason becomes unavailable, the obligation of the Company to grant any RSUs or issue any Common Shares upon the vesting or settlement of any RSUs will cease;

(4) if the Grantee ceases to be a Service Provider due to termination of employment by the Company, any of its subsidiaries or any of its Affiliates without cause or alleged constructive dismissal or due to voluntary termination by the Grantee, the Grantee will not make any claims for continued vesting of RSUs past the effective date of such termination, which shall be deemed to be the last day the Grantee actively works in the business of the Company, any of its subsidiaries or any of its Affiliates (or in the case of an alleged constructive dismissal, the date on which the alleged constructive dismissal is alleged to have occurred), and will not make any claims for compensation in lieu of statutory, contractual or common law notice or damages relating thereto;

(5) if the Grantee or the Legal Representative of the Grantee receives any Common Shares in respect of the RSUs, the Grantee or the Legal Representative, as the case may be, will prior to and upon any sale or disposition of any Common Shares received in respect of the RSUs, comply with all applicable securities laws and all applicable rules and regulations of all regulatory authorities to

which the Company is subject, including any stock exchange or other organized market on which the Common Shares may be listed or posted for trading, and will not offer, sell or deliver any of such Common Shares, directly or indirectly, in the United States or to any citizen or resident of, or any company, partnership or other entity created or organized in or under the laws of, the United States, or any estate or trust the income of which is subject to United States federal income taxation regardless of its source, except in compliance with the securities laws of the United States; and

(6) the Grantee agrees that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes the Grantee's tax liabilities and the Grantee will not make any claim against the Company, any of its subsidiaries, any of its Affiliates or any of their respective officers, directors or employees related to tax liabilities arising from the RSUs or any of the Grantee's other compensation.

ARTICLE V
MISCELLANEOUS

5.1 Section 409A

This Restricted Share Unit Award is intended to be exempt from Section 409A of the Code as a short-term deferral thereunder and shall be construed and administered in accordance with that intent. Notwithstanding the foregoing, in no event will the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A of the Code.

5.2 Notices

Any notice or other communication required or permitted to be delivered under this Agreement will be considered delivered only if in writing and when it is actually delivered (which delivery may be by telex, telecopy or other telecommunications device) to the attention of the party to whom it is intended at the principal business address of the Company, if addressed to the Company, or to the address specified above, if to the Grantee, or to such other address as such party may designate to the other party by notice in writing delivered in accordance with this Section 5.2.

5.3 Interpretation; Administration

Any question arising as to the interpretation of this Agreement will be determined by the Board of Directors and/or the Compensation Committee and, absent manifest error, such determination will be conclusive and binding on the Company and the Grantee. Either the Board of Directors or the Compensation Committee may administer and make determinations under this Agreement and references to the Board of Directors in this Agreement shall refer to the Board of Directors and/or the Compensation Committee, as applicable.

5.4 Further Assurances

Each of the parties hereto will, on demand by the other party hereto, execute and deliver all such further documents and instruments and do all such further acts and things as the party may either before or after the execution and delivery of this Agreement reasonably request to evidence, carry out and give full effect to the terms, conditions, intent and meaning of this Agreement.

5.5 Severability

If any provision of this Agreement is determined to be void, illegal or unenforceable, such provision will be construed to be separate and severable from this Agreement and will not impair the validity, legality or enforceability of any other provision of this Agreement and the remainder of this Agreement will continue to be binding on the parties hereto as if such provision had been deleted.

5.6 No Assignment

Neither this Agreement nor the Restricted Share Unit Award may be assigned, transferred or charged in whole or in part by the Grantee, and any purported assignment, transfer or charge shall cause this Agreement and the Restricted Share Unit Award to lapse forthwith and be null and void after that time.

5.7 Burden and Benefit

This Agreement will be binding upon and will enure to the benefit of the Company and its successors and assigns and the Grantee and, if applicable, his or her Legal Representative.

5.8 Time

Time will be of the essence in this Agreement.

5.9 Effect on Employment

Neither the grant of this Restricted Share Unit Award, nor the issuance of Common Shares upon the vesting or settlement of any RSUs, will give the Grantee any right to be retained in the employ or service of the Company or any of its Affiliates, affect the right of the Company or any of its Affiliates to discharge or discipline the Grantee at any time, or affect any right of the Grantee to terminate his or her employment at any time.

5.10 Governing Law and Jurisdiction

This Agreement and all matters arising hereunder will be governed by and construed in accordance with the laws of the Province of British Columbia. Subject to any written agreement between the parties, the parties will submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of British Columbia.

5.11 Electronic Delivery and Acceptance

The Company may, in its sole discretion, decide to deliver any documents related to RSUs awarded under the Plan or future awards that may be awarded under the Plan by electronic means or request the Grantee’s consent to participate in the Plan by electronic means, including, without limitation, by posting them on a website maintained by the Company or a third party under contract with the Company or through such methods indicated in this Agreement. The Grantee hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through any on-line or electronic system established and maintained by the Company or a third party designated by the Company.

If the Company posts such documents on a website, it shall notify the Grantee by e-mail or such other reasonable manner as then determined by the Company.

5.12 Incorporation of the Terms of the Plan

This Agreement shall be deemed to have incorporated all the terms of the Plan and the RSUs granted hereunder shall be subject to the terms of the Plan. Except as expressly provided herein, in the event of any conflict between the provisions of this Agreement and the terms of the Plan, the terms of the Plan shall govern.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

XENON PHARMACEUTICALS INC.

By: ______________________________
Title: Corporate Secretary

____
[First Name Last_Name]

Exhibit A

1. General. The RSUs will vest as to [ ] of the RSUs on each of the first [ ] anniversaries of the Date of Grant (each such vesting date, a "Vesting Date"), subject to the Grantee continuously remaining a Service Provider through the applicable Vesting Date.

2. Treatment of RSUs on a Change of Control. Notwithstanding anything in this Exhibit A, if the Grantee ceases to be a Service Provider due to a termination of employment by the Company without Cause or the Grantee terminates his or her employment for Good Reason (but only if the Grantee is party to a Separate Agreement that contains a definition of "Good Reason"), in either case within the twelve (12) month period following a Change of Control, to the extent any RSUs are outstanding and unvested immediately prior to such termination of employment, such outstanding RSUs, if any, will automatically vest in full upon such termination of employment.

Exhibit 31.1

CERTIFICATIONS

I, Ian Mortimer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenon Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2026

By: /s/ Ian Mortimer
Ian Mortimer
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Thomas P. Kelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenon Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2026

By: /s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

XENON PHARMACEUTICALS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Xenon Pharmaceuticals Inc. (the “Company”) on Form 10-Q for the quarter ended March 31, 2026, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Ian Mortimer, President and Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 7, 2026

By: /s/ Ian Mortimer
Ian Mortimer
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Xenon Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

XENON PHARMACEUTICALS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Xenon Pharmaceuticals Inc. (the “Company”) on Form 10-Q for the quarter ended March 31, 2026, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Thomas P. Kelly, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 7, 2026	By: /s/ Thomas P. Kelly
	Thomas P. Kelly
	Chief Financial Officer
	(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Xenon Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.