UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 September 30, 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: 001-43270

Odyssey Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**86-3384382**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
51 Sleeper Street, Suite 800 Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 865-9628

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 Stock, par value $0.0001 per share	ODTX	The Nasdaq Stock Market LLC

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, 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 November 2, 2026, the registrant had 48,067,877 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements about us and our industry within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, plans for and results of preclinical studies and clinical trials, research and development costs, manufacturing plans, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical studies, clinical trials and research programs for our product candidates, including OD-001 and OD-002;
- the beneficial characteristics, safety and efficacy of our product candidates and the potential advantages of our product candidates compared to alternative therapies;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
- the rate and degree of market acceptance and therapeutic benefits of our product candidates, if approved;
- our ability to develop or partner and progress our current and future product candidates;
- the implementation of our strategic plans for our business, product candidates, research programs and technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- anticipated developments related to our competitors and our industry;
- our competitive position and the success of competing therapies that are or may become available;
- our ability to maintain our current license agreements and collaborations and identify and enter into future license agreements and collaborations;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory, manufacturing or commercialization expertise;
- our reliance on third parties to conduct clinical trials of or manufacture our product candidates;
- our plans relating to sales strategy, manufacturing and commercializing our product candidates, if approved;
- anticipated regulatory developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- our ability to attract and retain key scientific and management personnel;
- our financial performance;
- the costs of operating as a public company;

- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act, as amended, or the JOBS Act, or a smaller reporting company; and
- our anticipated use of our existing resources and the proceeds from our initial public offering, or IPO, and the concurrent private placement, capital requirements and need for additional financing.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Quarterly Report.

We have based the forward-looking statements contained in this Quarterly Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section of this Quarterly Report titled "*Risk Factors*" and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report to reflect events or circumstances after the date of this Quarterly Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, other strategic transactions or investments we may make or enter into.

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, and while 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 an exhaustive 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.

SUMMARY OF RISK FACTORS

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in Part II, Item 1A - Risk Factors in this Quarterly Report. These risks include, among others:

- We are a clinical-stage biotechnology company with a limited operating history and a history of incurring substantial net losses, have no products approved for commercial sale, have never generated revenue from product sales and may never be profitable.
- We will require substantial additional capital to finance our operations. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our business depends entirely on the success of our product candidates and research and development programs, including OD-001 and OD-002, and we cannot guarantee that any or all of our current or future product candidates will successfully enter or complete clinical development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our future success depends on our ability to retain and to continue to receive adequate attention from our key leaders, as well as on our ability to attract, retain and motivate qualified personnel.
- Our most advanced product candidate, OD-001, we have presented efficacy and supporting analyses from the 12-week induction period from our phase 2a clinical trial, and for OD-002, our next most advanced product

candidate, we have completed IND-enabling studies. We have never successfully completed any large-scale or pivotal clinical trials with our product candidates, and we may be unable to do so for any product candidates we develop.

- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome. We or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.
- We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.
- We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable time frames, or at all, would materially and adversely affect our business, financial condition, results of operations and prospects.
- Our stock price may be volatile, which could result in substantial losses for investors.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Odyssey Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data) (unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 80,641	$ 41,687
Short-term marketable securities	245,360	139,671
Prepaid expenses and other current assets	11,800	9,298
Total current assets	337,801	190,656
Property and equipment, net	4,626	7,209
Right-of-use assets	16,137	18,804
Goodwill	14,119	14,327
Intangible asset	-	262
Long-term marketable securities	60,987	35,198
Other non-current assets	4,430	3,332
Total assets	$ 438,100	$ 269,788
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 8,260	$ 7,872
Accrued expenses and other current liabilities	12,309	13,392
Lease liabilities, current	5,532	5,211
Total current liabilities	26,101	26,475
Contingent consideration and warrant liability	18,281	6,133
Lease liabilities, non-current	17,946	21,900
Total liabilities	62,328	54,508
Commitments and contingencies (see Note 13)		
Series A convertible preferred stock, $0.0001 par value: no shares and 43,749,045 shares authorized as of September 30, 2026 and December 31, 2025, respectively; and no shares and 43,732,797 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively (liquidation preference $0 and $84,796 as of September 30, 2026 and December 31, 2025, respectively)	-	216,503
Series B convertible preferred stock, $0.0001 par value: no shares and 26,601,360 shares authorized as of September 30, 2026 and December 31, 2025, respectively; and no shares and 26,601,360 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively (liquidation preference $0 and $66,100 as of September 30, 2026 and December 31, 2025, respectively)	-	167,765
Series C convertible preferred stock, $0.0001 par value: no shares and 24,901,598 shares authorized as of September 30, 2026 and December 31, 2025, respectively; and no shares and 24,901,598 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively (liquidation preference $0 and $49,065 as of September 30, 2026 and December 31, 2025, respectively)	-	123,259
Series D convertible preferred stock, $0.0001 par value: no shares and 142,016,823 shares authorized as of September 30, 2026 and December 31, 2025, respectively; and no shares and 141,950,377 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively (liquidation preference $0 and $213,631 as of September 30, 2026 and December 31, 2025, respectively)	-	196,031
Stockholders' equity (deficit):		
Common stock, $0.0001 par value: 500,000,000 and 365,081,240 shares authorized as of September 30, 2026 and December 31, 2025, respectively; 48,067,433 shares and 2,472,757 shares issued as of September 30, 2026 and December 31, 2025, respectively; 47,940,608 shares and 2,306,207 shares outstanding as of September 30, 2026 and December 31, 2025, respectively	5	-
Preferred stock, $0.0001 par value: 50,000,000 shares and no shares authorized as of September 30, 2026 and December 31, 2025; no shares issued and outstanding as of September 30, 2026 and December 31, 2025	-	-
Additional paid-in capital	1,089,000	79,616
Accumulated deficit	(712,248)	(568,139)
Accumulated other comprehensive income (loss)	(985)	245
Total stockholders' equity (deficit)	375,772	(488,278)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 438,100	$ 269,788

The accompanying notes are an integral part of these condensed consolidated financial statements.

Odyssey Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data) (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration revenue	$ —	$ 99	$ —	$ 2,976
Operating expenses:				
Research and development	42,121	26,325	110,668	95,326
General and administrative	11,240	10,156	29,101	31,327
Change in fair value of contingent consideration	3,307	1,872	12,149	(4,342)
Total operating expenses	56,668	38,353	151,918	122,311
Operating loss	(56,668)	(38,254)	(151,918)	(119,335)
Other income (expense), net:				
Interest income	3,864	2,198	8,404	4,226
Interest expense	(12)	(1)	(42)	(5)
Other income (expense), net	(194)	539	(449)	96
Total other income, net	3,658	2,736	7,913	4,317
Loss before income taxes	(53,010)	(35,518)	(144,005)	(115,018)
Income tax (benefit) provision	49	(56)	104	114
Net loss	$ (53,059)	$ (35,462)	$ (144,109)	$ (115,132)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	184	(410)	(9)	1,479
Unrealized loss on marketable securities, net of tax	(664)	(118)	(1,221)	(123)
Total other comprehensive (loss) income	(480)	(528)	(1,230)	1,356
Comprehensive loss	$ (53,539)	$ (35,990)	$ (145,339)	$ (113,776)
Net loss attributable to common stockholders (see Note 15)	(53,059)	(35,462)	(144,109)	(115,132)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.10)	$ (7.78)	$ (5.12)	$ (49.56)
Weighted-average common stock outstanding, basic and diluted	48,018,265	4,557,695	28,138,852	2,322,965

The accompanying notes are an integral part of these condensed consolidated financial statements.

Odyssey Therapeutics, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share and per share data) (unaudited)

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series D convertible preferred stock		Common stock		Additional paid-in	Accumulated	Accumulated other comprehensive income (loss)	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit		
Balance as of January 1, 2026	43,732,97	$ 216,503	26,601,360	$ 167,765	24,901,598	$ 123,259	141,950,377	$ 196,031	2,306,207	$ -	$ 79,616	$ (568,139)	$ 245	$ (488,278)
Exercises of common stock options	—	—	—	—	—	—	—	—	159,842	—	651	—	—	651
Vesting of restricted common stock	—	—	—	—	—	—	—	—	13,239	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,587	—	—	2,587
Exercise of common stock warrants	—	—	—	—	—	—	—	—	2,051	—	—	—	—	—
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	—	—	(392)	(392)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(38,262)	—	(38,262)
Balance as of March 31, 2026	43,732,97	$ 216,503	26,601,360	$ 167,765	24,901,598	$ 123,259	141,950,377	$ 196,031	2,481,339	$ -	$ 82,854	$ (606,401)	$ (147)	$ (523,694)
Exercises of common stock options	—	—	—	—	—	—	—	—	97,310	—	586	—	—	586
Vesting of restricted common stock	—	—	—	—	—	—	—	—	13,243	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	5,671	—	—	5,671
Issuance of common stock upon initial public offering, net of offering costs	—	—	—	—	—	—	—	—	17,488,889	2	288,172	—	—	288,174
Conversion of preferred stock and non-voting common stock into common stock and preferred stock warrants into common stock warrants, upon initial public offering	(43,732,797)	(216,503)	(26,601,360)	(167,765)	(24,901,598)	(123,259)	(141,950,377)	(196,031)	24,523,119	3	703,627	—	—	703,630
Conversion of common stock warrants into common stock upon initial public offering	—	—	—	—	—	—	—	—	3,287,352	—	—	—	—	—
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	—	—	(358)	(358)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(52,788)	—	(52,788)
Balance as of June 30, 2026	—	$ -	—	$ -	—	$ -	—	$ -	47,891,252	$ 5	$ 1,080,910	$ (659,189)	$ (505)	$ 421,221
Exercise of common stock options	—	—	—	—	—	—	—	—	36,113	—	152	—	—	152
Vesting of restricted common stock	—	—	—	—	—	—	—	—	13,243	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	7,938	—	—	7,938
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	—	—	(480)	(480)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(53,059)	—	(53,059)
Balance as of September 30, 2026	—	$ -	$ -	$ -	$ -	$ -	$ -	$ -	47,940,608	$ 5	$ 1,089,000	$ (712,248)	$ (985)	$ 375,772

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series D convertible preferred stock		Common stock		Additional paid-in	Accumulated	Accumulated other comprehensive income (loss)	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit		deficit
Balance as of January 1, 2025	45,414,682	$ 69	26,601,360	$ 65	24,901,598	$ 59	—	$ -	959,115	$ -	$ 38,306	$ (419,492)	$ (1,341)	$ (382,527)
Exercises of common stock options	—	—	—	—	—	—	—	—	8,985	—	235	—	—	235
Vesting of restricted common stock	—	—	—	—	—	—	—	—	23,967	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,989	—	—	2,989
Other comprehensive income, net	—	—	—	—	—	—	—	—	—	—	—	—	565	565
Net loss	—	—	—	—	—	—	—	—	—	—	—	(38,435)	—	(38,435)
Balance as of March 31, 2025	45,414,682	$ 69	26,601,360	$ 65	24,901,598	$ 59	—	$ -	992,067	$ -	$ 41,530	$ (457,927)	$ (776)	$ (417,173)
Vesting of restricted common stock	—	—	—	—	—	—	—	—	7,989	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,698	—	—	3,698
Issuance of Series D convertible preferred stock and common stock warrants, net of issuance costs of $860	—	—	—	—	—	—	79,518,143	109,095	—	—	9,657	—	—	9,657
Conversion of preferred stock into common stock	(1,681,885)	(7,366)	—	—	—	—	—	—	17,308	—	7,366	—	—	7,366
Exercise of common stock warrants	—	—	—	—	—	—	—	—	58,473	—	6	—	—	6
Other comprehensive income, net	—	—	—	—	—	—	—	—	—	—	—	—	1,319	1,319
Net loss	—	—	—	—	—	—	—	—	—	—	—	(41,235)	—	(41,235)
Balance as of June 30, 2025	43,732,797	$ 03	26,601,360	$ 65	24,901,598	$ 59	79,518,143	$ 95	1,075,837	$ -	$ 62,257	$ (499,162)	$ 543	$ (436,362)
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—		—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	4,894	—	—	4,894
Issuance of Series D convertible preferred stock and common stock warrants, net of issuance costs of $232	—	—	—	—	—	—	60,438,839	84,159	—	—	6,568	—	—	6,568
Exercise of common stock warrants	—	—	—	—	—	—	—	—	684,772	—	66	—	—	66
Exercise of common stock options	—	—	—	—	—	—	—	—	8,113	—	26	—	—	26
Other comprehensive loss, net	—	—	—	—	—	—	—	—	—	—	—	—	(528)	(528)
Net Loss	—	—	—	—	—	—	—	—	—	—	—	(35,462)	—	(35,462)
Balance as of September 30, 2025	43,732,797	$ 03	26,601,360	$ 65	24,901,598	$ 59	139,956,982	$ 54	1,768,722	$ -	$ 73,811	$ (534,624)	$ 15	$ (460,798)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Odyssey Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands) (unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (144,109)	$ (115,132)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,223	3,754
Loss from disposal of property and equipment	602	1,160
Right-of-use asset impairment expense	—	5,440
Amortization (accretion) of premium (discount) on marketable securities	115	(864)
Stock-based compensation expense	16,196	11,581
Non-cash lease expense	2,663	2,349
Change in fair value of contingent consideration and warrant liability	12,220	(4,386)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,495)	(1,123)
Other non-current assets	(854)	5,057
Accounts payable	338	313
Lease liabilities	(3,780)	(3,014)
Accrued expenses and other current liabilities	(1,204)	(9,274)
Net cash used in operating activities	(117,085)	(104,139)
Cash flows from investing activities:		
Maturities of marketable securities	113,675	70,950
Purchases of marketable securities	(246,489)	(185,772)
Proceeds from sale of property and equipment	302	357
Purchases of property and equipment	(838)	(1,004)
Net cash used in investing activities	(133,350)	(115,469)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	1,389	261
Proceeds from the exercise of common stock warrants	—	72
Principal payments on finance leases	(117)	(107)
Proceeds from the issuance of common stock upon IPO, net of offering costs	288,194	—
Proceeds from the issuance of convertible preferred stock, net of issuance costs	—	209,479
Net cash provided by financing activities	289,466	209,705
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	166	291
Increase (decrease) in cash, cash equivalents and restricted cash	39,197	(9,612)
Cash, cash equivalents and restricted cash, beginning of period	44,897	62,346
Cash, cash equivalents and restricted cash, end of period	$ 84,094	$ 52,734
Cash and cash equivalents, end of period	$ 80,641	$ 49,524
Restricted cash, included in other non-current assets, end of period	3,453	3,210
Total cash, cash equivalents and restricted cash, end of period	$ 84,094	$ 52,734
Supplemental cash flow information:		
Cash paid for income taxes	$ 251	$ 164
Cash paid for interest	$ 42	$ 5
Supplemental disclosure of non-cash financing and investing activities:		
Offering costs included in accounts payable and accrued expenses and other current liabilities	$ 20	$ —
Right-of-use assets obtained in exchange for new finance lease liabilities	$ 278	$ —
Conversion of preferred stock and preferred stock warrants into common stock and common stock warrants, upon initial public offering	$ 703,630	$ —
Conversion of preferred stock into common stock	$ —	$ 7,366
Property and Equipment in accounts payable and accrued expenses and other current liabilities	$ 179	$ —
Unrealized loss on marketable securities	$ 1,221	$ 153

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Description of Business and Liquidity

Business

Odyssey Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases by developing medicines that are designed to precisely target disease pathology.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion of preclinical studies and clinical trials, obtaining regulatory approval for product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and ability to secure additional capital to fund operations. Product candidates currently under development by the Company will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Reverse Stock Split

On May 1, 2026, the Company effected a 1-for-9.7170 reverse stock split of its issued and outstanding shares of voting common stock, which also resulted in a proportional adjustments to (i) the conversion ratio for its non-voting common stock, (ii) the existing conversion ratios of each series of its convertible preferred stock, and (iii) the exercise prices and number of outstanding common stock warrants and stock options. Accordingly, all shares of voting common stock, stock options and common stock warrants, the as converted preferred stock, and per share information presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split. The per share par value and authorized number of shares of the Company's common stock were not adjusted as a result of the split.

Initial Public Offering

In May 2026, the Company completed its initial public offering ("IPO"), in which the Company sold 15,500,000 shares of its common stock at a public offering price of $18.00 per share resulting in aggregate net proceeds of approximately $254.9 million, after deducting underwriter discounts and commissions and other offering expenses. Additionally, the Company sold 1,388,889 shares of its common stock in a concurrent private placement at a per share price equal to the public offering price paid in the IPO, resulting in additional net proceeds of approximately $23.3 million after deducting placement agent fees. In June 2026, the Company also sold an additional 600,000 shares of its common stock to the underwriters at a public offering price of $18.00 per share under the option granted to the underwriters, resulting in aggregate net proceeds of approximately $10.0 million, after deducting underwriter discounts and commissions.

Immediately prior to the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 24,596,000 shares of common stock, the Company's outstanding convertible preferred stock warrants converted into 1,742 warrants to purchase common stock, and the Company's outstanding common stock warrants were automatically exercised on a net exercise basis into 3,287,352 shares of common stock. Further, 81,240 shares of the Company's outstanding non-voting common stock were automatically converted into an aggregate of 8,359 shares of its common stock immediately upon the closing of the IPO. Following the closing of the IPO, no shares of convertible preferred stock were outstanding. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.0001 per share and 50,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Liquidity and Going Concern

The accompanying condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the ordinary course of business.

Since its inception, the Company has devoted substantially all of its resources to business planning, research and development activities, recruiting management and technical staff, raising capital, producing materials for preclinical studies and clinical trials, developing and establishing the Company's intellectual property portfolio, entering into collaboration agreements, acquiring companies or assets to further the Company's development programs and building infrastructure to support such activities. The Company has financed its operations primarily through the sale of shares of convertible preferred stock, the proceeds from research collaborations and license agreements, and through the sale of its common stock in its IPO and concurrent private placement completed in May 2026.

The Company believes that its existing cash, cash equivalents and marketable securities of $387.0 million as of September 30, 2026, will be sufficient to allow the Company to fund operations at least twelve months from the date that the condensed consolidated financial statements are issued.

2. Basis of Presentation and Summary of Significant Accounting Policies

The significant accounting policies are disclosed in Note 2 to the audited financial statements for the year ended December 31, 2025, included in the Company's final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"), with the Securities and Exchange Commission on May 8, 2026 (the "IPO Prospectus").

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025 have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Exchange Act of 1934, as amended. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed consolidated balance sheet at December 31, 2025 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2025 included in the IPO Prospectus. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Updates ("ASU"), of the Financial Accounting Standards Board ("FASB").

These condensed consolidated financial statements include the accounts of Odyssey Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Recently Issued Accounting Standards Updates Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB, or other standard-setting bodies that are adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. Unless otherwise

discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, or ASU 2024-03, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, and amortization) included in certain expense captions presented on the statement of operations. The guidance in ASU 2024-03 is effective for fiscal years beginning after December 15, 2026. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its consolidated financial statements and disclosures for fiscal years beginning after December 15, 2026.

3. Goodwill and Intangible Asset

The Company's goodwill and intangible asset relate to the purchase of Rahko Limited ("Rahko") in 2021, which was accounted for as a business combination.

Goodwill

Goodwill and the effect of foreign currency translation is as follows:

	Nine Months Ended September 30, 2026
Goodwill balance as of January 1, 2026	$ 14,327
Effect of foreign currency translation	(208)
Goodwill balance as of September 30, 2026	$ 14,119

Intangible Asset

The Company's intangible asset is comprised solely of developed technology and is being amortized using the straight-line method which reflects the pattern in which the economic benefits of the asset are consumed, over its estimated useful life of five years. The intangible asset was fully amortized as of September 30, 2026.

The following tables present the intangible asset, current amortization, and the effect of foreign currency translation:

	Nine Months Ended September 30, 2026
Intangible asset balance as of January 1, 2026	$ 1,749
Effect of foreign currency translation	(25)
Intangible asset balance as of September 30, 2026	1,724
Accumulated amortization	(1,724)
Intangible asset, net	$ -

4. Collaboration and License Agreements

Pfizer MTA

In December 2022, the Company entered into a material transfer and evaluation agreement (the "Pfizer MTA") with Pfizer, Inc. ("Pfizer") in which the Company granted to Pfizer a nonexclusive license to access the Company's intellectual property. Under the Pfizer MTA, the Company and Pfizer will jointly conduct research to identify novel hits using the Company's natural product platform to initiate a preclinical drug discovery program against an oncogenic transcription factor.

The Company determined that the Pfizer MTA represents a contract with a customer and consists of one combined performance obligation for the nonexclusive license and the promise to provide research and development services (“R&D services”) to Pfizer, as the license and promise are not capable of being distinct in the context of the contract. The Pfizer MTA provides that the term of the agreement would end following an initial period of two and one-half years or upon completion of the research, if completed or terminated earlier. In addition, the Pfizer MTA contains two options that require the Company to provide further R&D services to Pfizer (the “First Pfizer Option” and “Second Pfizer Option”, collectively the “Pfizer Options”). The Company evaluated the options to continue the R&D services and concluded that these options did not represent material rights, as they were deemed to be for additional R&D services that are at their standalone selling price.

In 2023, Pfizer paid the Company a nonrefundable upfront payment of $1.0 million in exchange for the nonexclusive license as well as R&D services performed by the Company over the initial period and the First Pfizer Option was exercised. In December 2024, the Second Pfizer Option was exercised. The total transaction price under the Pfizer MTA was determined to be $1.9 million after the exercises of the options. Revenue from the Pfizer MTA was recognized over the estimated performance of the R&D services using the time-elapsed input method. The Company recognized $0.5 million of revenue associated with the Pfizer MTA during the nine months ended September 30, 2025, which is included in collaboration revenue on the condensed consolidated statements of operations and comprehensive loss. The Company recognized $0.1 million of revenue associated with the Pfizer MTA during the three months ended September 30, 2025. The Company fulfilled all of its obligations under the Pfizer MTA during the year ended December 31, 2025 and, as such, no revenue has been recorded during the three and nine months ended September 30, 2026.

Strategic Collaboration, Option, and License Agreement

On March 29, 2024, the Company entered into a strategic collaboration, option and license agreement (the “J&J Agreement”) with Janssen Pharmaceutica NV, a Johnson & Johnson company (“J&J”) to jointly discover and optimize small-molecule medicines against select therapeutic targets using the Company’s artificial intelligence and machine learning capability.

Each party granted to the other party a non-exclusive, royalty-free, worldwide license (the “Research License”) to certain intellectual property in connection with the other party’s research activities under the J&J Agreement (the “Initial R&D Services”). The Company also granted J&J an option to obtain an exclusive commercial license with respect to each program within a specified time period. On a program-by-program basis, if J&J elects to exercise such option or if J&J initiates certain research activities for a program (without exercising such option), the Company would be entitled to a payment in the mid-single digit millions of dollars. J&J may elect up to four replacement targets prior to the earlier of the end of the research term or exercise of the option to obtain a commercial license.

J&J paid the Company a nonrefundable upfront payment of $6.5 million in connection with the entry into the J&J Agreement and the Company is also eligible to receive reimbursement for additional R&D services conducted incremental to the initial R&D services. The Company will be eligible to receive, subject to the achievement of certain research, development, commercialization approval and sales milestones and the option exercise described below, additional milestone payments in an aggregate amount of approximately $839.0 million from J&J. The Company will also be eligible to receive low to mid-single digit percentage tiered royalties based on the aggregate net sales of certain products, if approved, that arise from the J&J Agreement (subject to certain deductions). The applicable royalties will be payable to the Company in a given country commencing on the date of first commercial sale of a royalty product in such country and ending upon the latest of (i) the date of expiration of the last-to-expire valid claim included in certain intellectual property, (ii) a designated period of time following the first commercial sale in such country and (iii) the date of expiration of all regulatory exclusivity for the applicable product in such country.

The Company determined that the J&J Agreement represents a contract with a customer and consisted of two distinct and single performance obligations: (i) the grant of the research licenses, the transfer of the research materials, project governance through the joint research committee (the "JRC") and the promise to provide certain research services, which were combined as a single performance obligation (the “First Performance Obligation”), and (ii) the grant of the research licenses, the transfer of research materials, project governance through the JRC and the promise to provide certain other research services, which are combined as a single performance obligation (the “Second Performance Obligation”).

Revenue from the J&J Agreement was recognized over the estimated performance of the initial research and development services using the cost incurred input method, which the Company believes best depicts the transfer of

control to J&J. The Company recognized $0.0 million and $2.5 million of revenue associated with the J&J Agreement during the three and nine months ended September 30, 2025, respectively, which is recorded as collaboration revenue on the condensed consolidated statements of operations and comprehensive loss. The Company fulfilled all of its obligations under the J&J Agreement during the year ended December 31, 2025 and, as such, no revenue has been recorded during the three and nine months ended September 30, 2026.

To date there have been no development, commercial, and sales-based milestone payments or royalties based on sales achieved under the J&J Agreement.

Deferred Revenue and Accounts Receivable

Deferred revenue associated with collaboration and license agreements is recorded within accrued expenses and other current liabilities on the condensed consolidated balance sheets. There was no deferred revenue recorded as of December 31, 2025 and September 30, 2026. The following table summarizes the changes in deferred revenue for the nine months ended September 30, 2025:

	Nine Months Ended September 30, 2025
Beginning balance as of January 1, 2025	$ 2,877
Additions	99
Deductions	(2,976)
Ending balance as of September 30, 2025	$ —

There was no accounts receivable recorded as of December 31, 2025 and September 30, 2026. The following table summarizes the change in accounts receivable for the nine months ended September 30, 2025:

	Nine Months Ended September 30, 2025
Beginning balance as of January 1, 2025	$ 443
Additions	99
Deductions	(542)
Ending balance as of September 30, 2025	$ —

5. Fair Value Measurements

The following table sets forth by level, within the fair value hierarchy, the Company's financial assets and liabilities carried at fair value on a recurring basis:

	September 30, 2026			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial Assets:				
Cash equivalents:				
Money market funds	$ 71,228	$ 71,228	$ —	$ —
Marketable securities:				
U.S. Treasury bills and U.S. Treasury notes	306,347	—	306,347	—
Total financial assets	$ 377,575	$ 71,228	$ 306,347	$ —
Financial Liabilities:				
Contingent consideration	$ 18,281	$ —	$ —	$ 18,281
	$ 18,281	$ —	$ —	$ 18,281

	December 31, 2025			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial Assets:				
Cash equivalents:				
Money market funds	$ 30,032	$ 30,032	$ —	$ —
Marketable securities:				
U.S. Treasury bills and U.S. Treasury notes	174,869	—	174,869	—
Total financial assets	$ 204,901	$ 30,032	$ 174,869	$ —
Financial Liabilities:				
Contingent consideration	$ 6,132	$ —	$ —	$ 6,132
Warrant liability	1	—	—	1
	$ 6,133	$ —	$ —	$ 6,133

There were no changes in valuation techniques or transfers between Levels 1, 2 or 3 for the periods presented.

Marketable securities classified as Level 2 within the valuation hierarchy generally consist of U.S. Treasury bills and U.S. Treasury notes. The Company estimates the fair values of marketable securities by taking into consideration valuations obtained from third-party pricing sources.

The carrying values of accounts payable and accrued expenses and other current liabilities approximates their fair values due to the short-term nature of these instruments.

Valuation of Contingent Consideration

The contingent consideration in the below tables relates to the estimated fair value of future payments that may be made by the Company to the members of IFM Discovery, LLC (“IFM”) and Rahko as described below. The fair value of the contingent consideration was determined based on significant inputs not observable in the market, which represent Level 3 measurements.

IFM

In May 2022, the Company acquired all of the membership interests in IFM. The total purchase consideration was $3.1 million, which consisted of the following: (i) 81,240 shares of non-voting common stock at closing with the estimated fair value of $0.2 million, (ii) cash consideration of $0.9 million at closing, (iii) a deferred payment of $0.9 million, which was paid in June 2022, and (iv) contingent consideration in cash of up to $30.0 million, payable once for each of the NLR family pyrin domain containing 1 ("NLRP1") and melanoma differentiation-associated protein 5 ("MDA5") programs upon the first achievement of certain development, commercial, regulatory and sales milestones related to each such program. The estimated fair value of the contingent consideration was determined to be $1.1 million on the acquisition date. The contingent consideration is remeasured at each balance sheet date.

The fair value of the contingent consideration related to development, commercial, regulatory and sales milestones was based on the discounted cash flow valuation technique. The technique considered the following assumptions: (i) the probability and timing of achieving the specified milestones as of the valuation date and (ii) the market-based discount rates, with the most significant assumptions being the timing of the projected milestones and the probability of the milestones being achieved. The fair value of the contingent consideration could change in future periods depending on the prospects for the Company's MDA5 and NLRP1 drug discovery programs acquired as part of the IFM transaction achieving development, commercial, regulatory and sales milestones. The estimated fair value of the contingent consideration as of September 30, 2026 and December 31, 2025 related to the IFM acquisition was $1.0 million and $1.4 million, respectively.

The following table sets forth the significant inputs to the discounted cash flow technique used to value contingent consideration for IFM as of September 30, 2026 and December 31, 2025:

Significant Unobservable Inputs	**September 30, 2026**	**December 31, 2025**
Discount rate	24.9%	15.6%
Projected milestone timing	2.75 to 11 years	2.25 to 11.75 years
Probability of milestone achievement - NLRP1 program	5.0% - 35.0%	5.0% - 35.0%
Probability of milestone achievement - MDA5 program	5.0% - 35.0%	5.0% - 35.0%

Significant increases or decreases in these inputs could result in a significantly lower or higher fair value measurement of the contingent consideration liability.

Rahko

The Rahko acquisition included additional consideration payable of up to $30.0 million to the previous shareholders of Rahko upon the achievement of certain qualifying events, including (a) following the Company's completion of an IPO or public listing of the Company's shares on certain designated exchanges, and upon the first occurrence of the total market capitalization of the Company being equal to or in excess of $1.5 billion, or (b) an exit event such as (i) a transaction or transactions by which more than 50% of the combined voting power of then outstanding voting securities of the Company are acquired, (ii) consolidation or merger of the Company into another entity, or (iii) sale or disposition of substantially all of the assets of the Company, in each case for which the potential proceeds are equal to or in excess of $1.5 billion. The fair value of the contingent consideration was determined based on a Monte-Carlo simulation model that utilizes a geometric Brownian motion to estimate the equity value of the Company at expected qualifying event dates. The Company applied risk-free rate, volatility and discount rate assumptions to simulate the expected equity value of the Company as of the expected qualifying event dates. The risk-free rate was based upon the interest rates corresponding to the time period for U.S. Treasury notes published by the U.S. Federal Reserve. The volatility was estimated based on equity volatility indications from the guideline public companies and the capital structure of the Company.

The contingent consideration as of the date when the Company has met the certain market capitalization threshold following a certain qualifying event was discounted to the measurement date using a discount rate that is based on all-in market yields for publicly traded debt securities of comparable credit quality to the contingent consideration payments. The discounted amount of contingent consideration and the equity values are subject to the Monte-Carlo simulations for 100,000 trials to derive the fair value of the contingent consideration. The estimated contingent consideration liability as of September 30, 2026 and December 31, 2025, related to the Rahko acquisition was $17.3 million and $4.7 million, respectively.

The Company completed its IPO in May 2026 and, therefore, the probability of completing an IPO is no longer a significant input into the valuation of the Rahko contingent consideration. The following table sets forth the assumptions, which are significant inputs to the Monte-Carlo simulation used to value such contingent consideration as of September 30, 2026:

As of September 30, 2026			
Expected Term	**Discount Rates**	**Risk Free Rate Applied to Equity Value**	**Equity Volatility**
10 years	21.9% - 28.7%	5.3%	97.4%

As of December 31, 2025, given the Company was still a private entity, the following table sets forth the probability of completing an IPO (measured as a standalone metric separate from the other necessary triggers for the contingent consideration related to the Rahko acquisition), which was a significant input to the Monte-Carlo simulation used to value such contingent consideration:

As of December 31, 2025				
Expected IPO Date	**Probability of IPO Event**	**Discount Rates**	**Risk Free Rate Applied to Equity Value**	**Equity Volatility**
May 31, 2026	15%	15.3% - 16.1%	4.2%	96.2%
December 30, 2026	14%	15.3% - 16.0%	4.2%	96.4%
February 28, 2027	14%	15.3% - 16.0%	4.3%	96.5%
April 30, 2027	14%	15.3% - 16.0%	4.3%	96.5%
*	43%	Varies	4.3%	Varies

***Reflects the probability weighted expected term of 1.83 years for the remaining scenarios between August 2027 and December 2027 with each scenario weighted 14.2% overall, for an aggregate probability weight of 42.6%.**

Significant increases or decreases in these inputs could result in a significantly lower or higher fair value measurement of the contingent consideration liability.

Valuation of LSA Warrant Liability

In March 2022, the Company issued a warrant to purchase up to 64,992 shares of Series A-2 convertible preferred stock (the “LSA Warrant”). As of September 30, 2026, the LSA Warrant to purchase 1,742 shares of common stock was issued and outstanding.

As of May 7, 2026 and December 31, 2025, the estimated fair value of the LSA Warrant liability was determined using an option pricing model with the following assumptions:

Significant Unobservable Inputs	**May 7, 2026**	**December 31, 2025**
Expected term until a liquidity event (in years)	2	2
Volatility	97%	80%
Risk-free interest rate	3.9%	3.5%
Annual dividend rate	0%	0%

The following table presents a roll-forward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs:

	Warrant Liability	Contingent Consideration
Balance as of January 1, 2026	$ 1	$ 6,132
Change in fair value	-	109
Balance as of March 31, 2026	1	6,241
Change in fair value	71	8,733
Reclassification to equity	(72)	-
Balance as of June 30, 2026	-	14,974
Change in fair value	-	3,307
Balance as of September 30, 2026	$ —	$ 18,281

	Warrant Liability	Contingent Consideration
Balance as of January 1, 2025	$ 45	$ 10,179
Change in fair value	-	(5,648)
Balance as of March 31, 2025	45	4,531
Change in fair value	-	(566)
Balance as of June 30, 2025	45	3,965
Change in fair value	(44)	1,872
Balance as of September 30, 2025	$ 1	$ 5,837

6. Marketable Securities

The following tables summarize the Company's marketable securities held as of September 30, 2026 and December 31, 2025.

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities				
U.S. Treasury bills and U.S. Treasury notes	307,474	—	(1,127)	306,347
	$ 307,474	$ —	$ (1,127)	$ 306,347

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities				
U.S. Treasury bills and U.S. Treasury notes	174,776	93	—	174,869
	$ 174,776	$ 93	$ —	$ 174,869

The Company determined that there was no material credit risk associated with the above investments as of September 30, 2026 and December 31, 2025. The Company has the intent and ability to hold these securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable securities during the nine months ended September 30, 2026 and 2025. No available-for-sale debt securities held as of September 30, 2026 had remaining maturities greater than 15 months.

7. Property and Equipment, Net

Property and equipment and related accumulated depreciation consist of the following:

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 15,592	$ 18,651
Furniture, fixtures and equipment	686	686
Computer hardware and software	1,035	1,029
Finance lease	601	502
Leasehold improvements	575	501
	18,489	21,369
Less: accumulated depreciation	(13,863)	(14,160)
Total	$ 4,626	$ 7,209

Total depreciation expense was $0.9 million and $2.8 million for three and nine months ended September 30, 2026, respectively, and $1.1 million and $3.4 million for the three and nine months ended September 30, 2025, respectively. For the three and nine months ended September 30, 2026, the Company recognized losses on disposal of $0 and $0.6 million, respectively. For the three and nine months ended September 30, 2025, the Company recognized losses on disposal of $0.8 million and $1.2 million, respectively. Gain or loss on disposal of property and equipment is included in general and administrative expenses on the condensed consolidated statements of operations and comprehensive loss.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2026	December 31, 2025
Employee compensation, benefits, and recruiting	$ 4,919	$ 6,703
External research and supplies	5,260	3,076
Offering costs	20	64
Professional fees	1,271	3,175
Other	839	374
Total	$ 12,309	$ 13,392

9. Leases

In September 2021, the Company entered into an eight-year lease agreement for 45,632 square feet of space for its corporate headquarters located in Boston, Massachusetts. The Company is also party to several operating leases for office and laboratory space in San Diego, California, Ann Arbor, Michigan, New York, New York, and Frankfurt, Germany, as well as leases for certain laboratory equipment.

During the first quarter of 2025, the Company recorded an impairment loss of $5.4 million pertaining to the right-of-use ("ROU") asset for the San Diego lease as a result of the Company's decision to permanently cease use of the leased space. The impairment loss was measured as the excess of the carrying amount over the impaired asset group's estimated fair value, which was determined using a discounted cash flow model. The impairment is included as a component of research and development expenses in the condensed consolidated statements of operations and comprehensive loss.

In June 2025, the Company entered into a lease extension agreement for its Ann Arbor laboratory space for an additional one-year term. The Company accounted for the lease extension as a modification of the existing lease and remeasured the ROU asset and lease liability by calculating the present value of lease payments, discounted at 10.1%, the Company's incremental borrowing rate in June 2025, over the new lease term. The modification resulted in an increase in the ROU asset and lease liability of $0.3 million at the time of the modification.

During the third quarter of 2025, the Company entered into a sublease for its New York office space that commenced on October 15, 2025 and expires on February 28, 2029. The Company recognized sublease income of $0.1 million and $0.2 million for the three and nine months ended September 30, 2026, respectively, which was recorded as a reduction of lease cost in the condensed consolidated statements of operations and comprehensive loss.

The components of lease costs are recorded within the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 1,500	$ 1,522	$ 4,516	$ 4,847
Variable lease costs	1,135	1,074	2,660	2,557
Sublease income	(81)	—	(243)	—
Total lease costs, net	$ 2,554	$ 2,596	$ 6,933	$ 7,404

The Company recognized interest expense related to finance leases of $12 thousand and $37 thousand for the three and nine months ended September 30, 2026, respectively, and $1 thousand and $5 thousand for the three and nine months ended September 30, 2025, respectively, which is included within interest expense in the condensed consolidated statements of operations and comprehensive loss. Supplemental cash flow information related to the Company's leases for the three and nine months ended September 30, 2026 and 2025 are as follows:

	Nine Months Ended September 30,	
Supplemental cash flow information	2026	2025
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 5,641	$ 5,447
Operating cash flows for finance leases	$ 37	$ 5
Financing cash outflows for finance leases	$ 117	$ 107

10. Common Stock

In May 2026, the Company's stockholders approved the ninth amended and restated certificate of incorporation, which became effective upon its filing in connection with the closing of the Company's IPO on May 8, 2026, and which, among other things, increased the number of shares of common stock authorized for issuance from 365,081,240 to 500,000,000 shares of common stock. As of September 30, 2026, there were 47,940,608 shares of common stock issued and outstanding. In addition, the Company issued 126,825 shares of common stock that were subject to vesting as of September 30, 2026 (see Note 12). The Company's outstanding non-voting common stock automatically converted into an aggregate of 8,359 shares of its common stock immediately upon the closing of the IPO.

Each share of common stock entitles the holder to one vote on all matters on which stockholders have the right to vote. The holders of common stock are entitled to receive dividends, if any, as declared by the Company's Board of Directors, subject to the participation and priority rights of the Company's preferred stock. As of September 30, 2026 and December 31, 2025, no dividends have been declared or paid.

11. Warrants

In connection with entering into the Series D Preferred Stock Purchase Agreement in 2025, the Company issued an aggregate amount of warrants to purchase 4,056,164 shares of the Company's common stock, each with an exercise price of $0.10 per share (the "Common Warrants"). The Common Warrants were exercisable at any time by the holder and have a seven-year contractual term from their respective dates of issuance. Upon completion of the IPO, the outstanding Common Warrants were automatically net exercised pursuant to their terms and became shares of the Company's common stock, effective immediately prior to the consummation of the IPO. The Company determined that the Common Warrants were equity-classified, and recorded the amounts allocated to the Common Warrants within additional paid-in capital on the condensed consolidated balance sheets.

During the nine months ended September 30, 2026, 2,051 Common Warrants were exercised, resulting in the issuance of 2,051 shares of common stock and aggregate proceeds of a de minimis amount. The Company's outstanding Common Warrants were automatically exercised on a net exercise basis into 3,287,352 shares of common stock immediately prior to the closing of the IPO. As of September 30, 2026, no Common Warrants remain issued and outstanding.

12. Stock-Based Compensation

Stock Options

In August 2021, the Company's Board of Directors adopted the 2021 Equity Incentive Plan (the "2021 Plan") which provided for the granting of stock appreciation rights, incentive stock options, restricted stock awards, other stock-based awards to eligible employees, officers, directors, consultants, and advisors. The stock options issued under the 2021 Plan expire not more than ten years from their respective grant dates. The 2021 Plan was subsequently amended on various dates through September 2025 to increase the number of shares available for the issuance of awards. As of the effective date of the 2026 Long-Term Incentive Plan (the "2026 Plan") and as of September 30, 2026, there were no shares remaining available for future issuance under the 2021 Plan. Any options or other awards outstanding under the 2021 Plan remain outstanding and effective. The remaining shares reserved for issuance under the 2021 Plan ceased to be available for issuance at the time that the 2026 Plan became effective.

In May 2026, the Company's Board of Directors adopted the 2026 Plan and the 2026 Employee Stock Purchase Plan (the "ESPP"), which both became effective in connection with the IPO. The 2026 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance-based awards and other stock-based awards or cash incentives to employees, directors and consultants. A total of 6,232,376 shares of the Company's common stock have been reserved for future issuance under the 2026 Plan, in addition to any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2021 Plan that expire or are repurchased, forfeited, cancelled or withheld. The ESPP reserved a total of 516,400 shares for future issuance of common stock pursuant to purchase rights granted to employees, in addition to any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Upon the closing of the IPO, the Company granted 3,431,900 stock options to purchase shares of the Company's common stock under the 2026 Plan to certain employees and directors, with an exercise price equal to the IPO price of $18.00 per share.

The stock options granted under the plans generally vest over four years, with 25% of the award vesting at a one-year cliff with the remaining portion vesting in equal installments over the remaining period, or in equal monthly installments over four years. The stock options granted contain service-based vesting conditions and certain stock options granted contain performance-based vesting conditions. Awards with a service-based component require continued service with the Company over the requisite service period, while vesting for awards with performance-based conditions is tied to the achievement of certain research and development milestones.

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2026:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2026	4,631,713	$ 4.94	8.64	4,610
Granted	4,050,777	17.98		
Forfeited	(135,921)	11.92		
Expired	(92,140)	24.14		
Exercised	(293,265)	4.74		
Outstanding as of September 30, 2026	8,161,164	$ 11.09	8.84	$ 91,634
Exercisable as of September 30, 2026	2,189,935	$ 6.29	7.60	$ 35,015

In December 2025, 166,550 stock options to purchase shares of the Company's common stock were early exercised pursuant to approval by the Company's Board of Directors. The unvested common stock purchased pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest according to their respective terms.

The following table presents, on a weighted-average basis, the assumptions used in the Black Scholes option-pricing model to determine the grant date fair value of the stock options granted during the nine months ended September 30, 2026:

	September 30, 2026
Expected term (in years)	5.91
Risk-free interest rate	4.17%
Expected volatility	103.66%
Dividend yield	0%

There were no stock options granted during the nine months ended September 30, 2025. The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2026 was $14.71 per option. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was $0.7 million and $0.1 million during the nine months ended September 30, 2026 and 2025, respectively.

Restricted Stock

The summary of restricted stock award activity for the nine months ended September 30, 2026, is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of January 1, 2026	166,550	$ 13.60
Vested	(39,725)	15.44
Unvested as of September 30, 2026	126,825	$ 13.02

The Company recorded stock compensation expense of $0.2 million and $0.6 million related to the restricted stock awards during the three and nine months ended September 30, 2026, respectively. The Company recorded stock compensation expense of a de minimis amount related to the restricted stock awards during the three and nine months ended September 30, 2025.

As of September 30, 2026, total unrecognized compensation costs related to unvested stock options and restricted stock awards was $66.9 million, which is expected to be recognized over the remaining weighted average period of approximately 2.98 years.

The following table summarizes stock-based compensation expense included in operating expenses for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 2,265	$ 1,215	$ 4,361	$ 3,231
General and administrative	5,673	3,679	11,835	8,350
Total	$ 7,938	$ 4,894	$ 16,196	$ 11,581

13. Commitments and Contingencies

Contingent Consideration

In connection with the IFM acquisition, the Company is required to make future payments to the shareholders of IFM based on the occurrence of certain development, commercial, regulatory and sales milestones (see Note 5).

In connection with the Rahko acquisition, the Company has a contingent payment obligation to the shareholders of Rahko upon the occurrence of certain qualifying events. No qualifying event has occurred as of September 30, 2026 (see Note 5).

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred.

14. 401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the “401(k) Plan”). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. As currently established, the Company is not required to make and has not made any contributions to the 401(k) Plan.

15. Net Loss Per Share

The following table sets forth the computation of the Company’s basic and diluted net loss per share attributable to common stockholders for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (53,059)	$ (35,462)	$ (144,109)	$ (115,132)
Net loss attributable to common stockholders	$ (53,059)	$ (35,462)	$ (144,109)	$ (115,132)
Denominator:				
Weighted-average number of common shares used in computing net loss, basic and diluted per share—basic and diluted [1]	48,018,265	4,557,695	28,138,852	2,322,965
Net loss per share attributable to common stockholders—basic and diluted	$ (1.10)	$ (7.78)	$ (5.12)	$ (49.56)

[1] The weighted-average number of common shares used in computing net loss basic and diluted per share for the three and nine months ended September 30, 2025 includes 4,010,007 shares of common stock underlying Common Warrants issued as part of the Series D preferred stock financing during 2025.

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect is antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options to purchase common stock	8,161,164	5,225,231	8,161,164	5,225,231
Unvested restricted stock awards	126,825	—	126,825	—
Series A convertible preferred stock (as converted to common stock)	—	3,091,478	—	3,091,478
Series A-1 convertible preferred stock (as converted to common stock)	—	804,893	—	804,893
Series A-2 convertible preferred stock (as converted to common stock)	—	836,190	—	836,190
Series B convertible preferred stock (as converted to common stock)	—	2,865,387	—	2,865,387
Series C convertible preferred stock (as converted to common stock)	—	2,412,468	—	2,412,468
Series C-1 convertible preferred stock (as converted to common stock)	—	150,211	—	150,211
Series D convertible preferred stock (as converted to common stock)	—	14,403,312	—	14,403,312
Series A-2 warrants (as converted to common stock)	—	1,742	—	1,742
Common stock warrants (as converted to common stock)	1,742	—	1,742	—
Total	8,289,731	29,790,912	8,289,731	29,790,912

16. Segment Information

The Company operates and manages its business as one reportable segment and one operating segment, which is focused on the standard of care for patients suffering from autoimmune and inflammatory diseases. The chief operating decision maker (“CODM”) manages the Company’s operations on a consolidated basis, assesses performance for the operating segment and decides how to allocate resources based on consolidated net loss, which is reported on the condensed consolidated statements of operations and comprehensive loss.

The CODM uses consolidated net loss to evaluate the Company’s spend and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing the performance of the operating segment and in establishing resource allocation across the organization.

Factors used in determining the reportable segment include the nature of the Company’s operating activities, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance. The accounting policies of the segment are the same as those described in Note 2 of the notes to the condensed consolidated financial statements.

The measure of segment assets is reported on the condensed consolidated balance sheets as total assets. The following table presents certain financial data for the Company’s reportable segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration revenue	$ —	$ 99	$ —	$ 2,976
Research and development expenses associated with preclinical and clinical studies [1]	$ 28,145	$ 14,363	$ 70,693	$ 47,576
Facilities and related expenses, excluding depreciation and amortization [2]	$ 2,404	3,595	7,864	14,882
General and corporate expenses [3]	$ 2,773	2,510	9,166	12,787
Personnel-related expenses, excluding stock-based compensation	$ 11,122	9,897	32,609	36,072
Other segment items [4]	$ 8,615	5,196	23,777	6,791
Segment net loss	$ 53,059	$ 35,462	$ 144,109	$ 115,132

[1] Research and development expenses associated with preclinical and clinical studies includes research software, professional services and laboratory operations supporting the Company's research and development programs.

[2] Facilities and related expenses includes rent, common area maintenance costs, repairs and maintenance, utilities, real estate taxes, and the ROU impairment charge.

[3] General and corporate expenses include general and administrative costs associated with professional and consulting fees and other overhead costs.

[4] For the three and nine months ended September 30, 2026 and 2025, other segment items consist of interest income, stock-based compensation expense, depreciation and amortization expense, change in fair value of contingent consideration expense, income tax (benefit) provision and other (income) expense, net. Interest income consists of interest income earned on cash equivalents and marketable securities. Interest expense consists of interest expense on finance leases. Other (income) expense, net primarily consists of realized and unrealized gains and losses on marketable securities.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes included in our final prospectus for our initial public offering, or our IPO, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on May 8, 2026, or the IPO Prospectus. This discussion and other parts of this Quarterly Report contain forward-looking statements that are based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including, but not limited to those set forth under the section of this Quarterly Report titled "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the section of this Quarterly Report titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements."

Overview

Odyssey is a clinical-stage biopharmaceutical company led by a team and board of drug hunters seeking to transform the standard of care for patients suffering from autoimmune and inflammatory diseases. We believe our deep understanding of immunobiology, coupled with leading expertise in medicinal and computational chemistry, protein biochemistry, structural biology, genetics, and pharmacology, allows us to identify and drug key signaling nodes that drive disease. We have prioritized targets where we believe the underlying disease biology is understood through genetic, clinical, or translational evidence.

Our most advanced programs include OD-001, an oral small-molecule scaffolding inhibitor of receptor-interacting protein kinase 2, or RIPK2, and OD-002, an oral small-molecule inhibitor of solute carrier family 15 member 4, or SLC15A4. OD-001 has achieved proof-of-concept and we have completed OD-001 induction treatment in a phase 2a trial for the treatment of ulcerative colitis, or UC, one of the two main types of inflammatory bowel disease, or IBD. We have completed IND-enabling studies for OD-002, our second most advanced program, and expect to progress that program into clinical development. These programs have the potential to yield treatments for inflammatory and autoimmune diseases that have large, addressable patient populations globally and a lack of effective treatments, including IBD, systemic lupus erythematosus, and other disorders characterized either by the chronic overactivation of the type I interferon pathway, referred to as interferonopathies, or by pathogenic autoreactive B cells. In addition to our most advanced programs, we have a portfolio of wholly owned preclinical programs that include, but are not limited to, OD-003, a regulatory T cell-specific tumor necrosis factor receptor 2 agonist, OD-004, a bispecific antagonist of thymic stromal lymphopoietin and interleukin-33, and an interleukin-1 receptor-associated kinase 4 scaffolding inhibitor. We also have an interferon regulatory factor 5, or IRF5, inhibitor in preclinical development, which we are collaborating on with Terray Therapeutics, Inc., or Terray.

Since our inception in 2021, we have devoted substantially all of our resources to business planning, research and development activities, recruiting management and technical staff, raising capital, producing materials for preclinical studies and clinical trials, developing and establishing our intellectual property portfolio, entering into and performing under collaboration agreements, acquiring companies or assets to further our development programs and building infrastructure to support these activities. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant operating losses and negative cash flows since our inception. Our net loss was $144.1 million and $115.1 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $712.2 million and cash, cash equivalents, and marketable securities of $387.0 million. Since our inception, we have financed our operations primarily through the sale of shares of our convertible preferred stock, the proceeds from research collaborations and license agreements, and through the sale of our common stock as part of our IPO and concurrent private placement completed in May 2026.

Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities as of September 30, 2026 will be sufficient to fund our operating expenses and capital expenditures into the second half of 2028. We have based this estimate and our forecast of cash resources and planned operations on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner

than we expect. Additional funds will be necessary to maintain our current operations and to continue our research and development activities.

We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon the successful development, approval and commercialization of our product candidates and upon the receipt of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates and commercialize any such products. Because of the numerous risks and uncertainties associated with product development, we may never achieve profitability, and, unless we do, and until then, we will need to continue to raise additional capital.

We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- continue to progress the development of our product candidates, including our two most advanced programs: OD-001 and OD-002;
- invest in our target selection programs and develop any additional product candidates, including the cost of acquiring any necessary rights from third parties to develop those product candidates or entering into partnering relationships to further the development of any such product candidates;
- establish and expand the manufacturing of preclinical and clinical supply of our current and future product candidates;
- seek regulatory approvals for any of our current product candidates or any future product candidates;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval, if any;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and expand our rights in our intellectual property portfolio or acquire or in-license intellectual property and technologies from third parties;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates, including as a result of macroeconomic conditions, geopolitical conflicts or other factors; and
- incur additional legal, accounting or other expenses in operating our business, including the costs associated with operating as a public company.

We do not currently own or operate any manufacturing facilities. We rely on third-party contract manufacturing organizations, or CMOs, to produce our drug candidates in accordance with the U.S. Food and Drug Administration's, or the FDA, current good manufacturing practices, or cGMPs, for use in our clinical trials.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our product candidates, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce or discontinue the development and commercialization of our product candidates, scale back or terminate our pursuit of new in-licenses and acquisitions or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and prospects. See the subsection titled "*–Liquidity and Capital Resources*" below for additional discussion of our liquidity.

Components of Operating Results

Collaboration Revenue

We have not generated any revenue from product sales, and we do not expect to generate any revenue from the sale of products for the foreseeable future, if ever. Our ability to generate product revenues will depend on the successful development and eventual commercialization of any product candidates that we identify. If we fail to complete the development of any of our current or future product candidates in a timely manner or fail to obtain regulatory approval for those product candidates, our ability to generate future revenue and our business, results of operations, financial condition and prospects would be materially adversely affected.

We did not have any revenue for the three and nine months ended September 30, 2026. For the three and nine months ended September 30, 2025 our revenue consisted of collaboration revenue earned under the Material Transfer and Evaluation Agreement, dated December 20, 2022, or the Pfizer MTA, with Pfizer Inc., or Pfizer, which expired by its terms in 2025, and revenue earned under the Strategic Collaboration, Option and License Agreement, dated March 29, 2024, or the J&J Agreement, with Janssen Pharmaceutica NV, a Johnson & Johnson company, or J&J. For additional information about our revenue recognition policy related to our collaboration agreements, refer to Note 4 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) general and administrative expenses and (iii) change in fair value of contingent consideration.

Research and Development Expenses

The largest component of our total operating expenses since our inception has been research and development activities, including costs incurred relating to discovery efforts and the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of internal personnel-related expenses, such as compensation and benefits for research and development employees, including stock-based compensation; external expenses associated with preclinical studies and clinical trials, including costs incurred under agreements with contract research organizations, or CROs, investigative sites that conduct preclinical studies and clinical trials, payments under licensing and research and development agreements and other outside services and consulting costs; costs of acquiring and manufacturing clinical trial materials and other supplies; software and information technology, or IT, costs; and allocated facility-related costs, such as rent, utilities and depreciation. Research and development costs are expensed as incurred.

We do not disaggregate external expenses associated with our preclinical studies from those associated with our clinical trials, because many of these external expenses relate to both preclinical studies and clinical trials across our development programs. We also do not allocate employee-related costs, laboratory supplies, and facilities, including other internal costs, to specific product candidates, because these costs are associated with multiple programs and, as such, are not separately classified. We use internal resources primarily for managing our product development, manufacturing and clinical development activities. We deploy our personnel across all of our research and development activities as our employees work across multiple programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and

development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs, travel and business expenses and stock-based compensation expense for our general and administrative personnel; professional fees for legal, consulting, accounting and tax services; software and IT costs; allocated overhead, including allocated facility-related costs, including rent, utilities and depreciation; and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will continue increasing, as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense, patent costs for our product candidates, expanded infrastructure and higher legal, consulting and accounting services associated with maintaining compliance with the listing requirements of the Nasdaq Stock Market LLC, or Nasdaq, and rules and regulations promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, investor relations costs and director and officer insurance premiums associated with being a public company.

Changes in fair value of contingent consideration

Expenses associated with changes in fair value of contingent consideration are driven by changes in the assumptions used by management in estimating the fair value of future payments that may be made by us to the previous members of IFM Discovery, LLC, or IFM, as a result of our acquisition of IFM in 2022, and Rahko Limited, or Rahko, as a result of our acquisition of Rahko in 2021.

For additional information about the changes in fair value of contingent consideration, refer to Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest income

Interest income consists primarily of interest generated on our interest-bearing cash and cash equivalent accounts and accretion of discounts and amortization of premiums related to our marketable securities.

Interest expense

Interest expense consists primarily of interest on our finance leases for certain lab equipment.

Other expense, net

Other expense, net consists primarily of realized and unrealized foreign currency transaction losses.

Income tax provision

Income tax provision consists of U.S. state and foreign taxes in jurisdictions in which we conduct business. Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that not all of our net operating loss carryforwards and tax credits will be realized. As of September 30, 2026, we have recorded a full valuation allowance against our net deferred tax assets.

Results of Operations

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

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

	Three Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Collaboration revenue	$ -	$ 99	$ (99)
Operating expenses:			
Research and development	42,121	26,325	15,796
General and administrative	11,240	10,156	1,084
Change in fair value of contingent consideration	3,307	1,872	1,435
Total operating expenses	56,668	38,353	18,315
Operating loss	(56,668)	(38,254)	(18,414)
Other income (expense), net:			
Interest income	3,864	2,198	1,666
Interest expense	(12)	(1)	(11)
Other income (expense), net	(194)	539	(733)
Total other income, net	3,658	2,736	922
Loss before income taxes	(53,010)	(35,518)	(17,492)
Income tax (benefit) provision	49	(56)	105
Net loss	$ (53,059)	$ (35,462)	(17,597)

Collaboration Revenue

Collaboration revenue decreased by $0.1 million, from $0.1 million for the three months ended September 30, 2025 compared to zero for the three months ended September 30, 2026. The decrease is related to the Company fulfilling all of its current obligations under the J&J Agreement and the expiration of the Pfizer MTA during the year ended December 31, 2025.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Three Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Internal personnel-related expenses (including stock-based compensation)	$ 10,791	$ 8,585	$ 2,206
External expenses associated with preclinical and clinical studies	23,455	11,027	12,428
Research software, professional services and laboratory operations	4,690	3,336	1,354
Facility-related costs (including depreciation)	3,185	3,377	(192)
Total research and development expenses	$ 42,121	$ 26,325	$ 15,796

Research and development expenses increased by $15.8 million, from $26.3 million for three months ended September 30, 2025 to $42.1 million for the three months ended September 30, 2026. This increase was primarily attributable to:

- a $12.4 million increase in external expenses associated with preclinical and clinical studies, primarily due to an increase in CRO expenses associated with start-up activities for our planned OD-001 phase 2b

monotherapy and phase 2a combination trials, as well as increased toxicology studies, external chemistry and chemistry, manufacturing, and controls activities supporting our pipeline programs;

- a $2.2 million increase in internal personnel-related expenses, primarily due to increased stock-based compensation from awards granted upon the IPO and higher headcount; and
- a $1.4 million increase in research software, professional services and laboratory operations, primarily due to the increase in research reagents and laboratory supplies to support increased level of research activity across the discovery programs.

These increases were partially offset by:

- a $0.2 million decrease in facility-related costs, primarily due to lower depreciation expense following the disposal of fixed assets.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods presented:

	Three Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Payroll and personnel-related expenses (including stock-based compensation)	$ 8,268	$ 6,206	$ 2,062
Professional and consulting fees	1,739	1,873	(134)
Software and IT costs	639	531	108
Facility-related costs (including depreciation)	199	1,440	(1,241)
Other general and administrative expenses	395	106	289
Total general and administrative expenses	$ 11,240	$ 10,156	$ 1,084

General and administrative expenses increased by $1.1 million, from $10.2 million during the three months ended September 30, 2025 to $11.2 million for the three months ended September 30, 2026. This increase was primarily attributable to:

- a $2.1 million increase in payroll and personnel-related expenses, primarily due to increased stock-based compensation from awards granted upon the IPO; and
- a $0.3 million increase in other general and administrative expenses, primarily due to additional corporate insurance expenses associated with operating as a public company.

These increases were partially offset by:

- a $1.2 million decrease in facility-related costs, primarily due to the loss on disposal of fixed assets recognized in the third quarter of 2025.

Changes in fair value of contingent consideration

The change in the fair value of contingent consideration resulted in expense of $3.3 million for the three months ended September 30, 2026, compared to expense of $1.9 million for the three months ended September 30, 2025. The change was driven by updates to the assumptions used in estimating the fair value of the Rahko contingent consideration, primarily due to an increase in the Company's market capitalization, following the completion of our IPO in May 2026.

Interest income

Interest income increased by $1.7 million from $2.2 million for the three months ended September 30, 2025 to $3.9 million for the three months ended September 30, 2026. The increase is primarily attributed to additional cash invested in marketable securities and interest-bearing accounts during 2026, given the proceeds received from our IPO.

Interest expense

Interest expense did not significantly fluctuate during the three months ended September 30, 2026 as compared to the three months ended September 30, 2025, and is attributable to interest on our finance leases for certain lab equipment.

Other income (expense), net

Other income (expense), net decreased by $0.7 million from income of $0.5 million during the three months ended September 30, 2025 compared to expense of $0.2 million during the three months ended September 30, 2026. The decrease primarily relates to a refundable tax credit recognized in the third quarter of 2025 and higher investment advisory fees in 2026 resulting from our larger investment portfolio.

Income tax (benefit) provision

Income tax (benefit) provision did not significantly fluctuate during the three months ended September 30, 2026 as compared to the three months ended September 30, 2025.

Comparison of the Nine Months Ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Collaboration revenue	$ -	$ 2,976	$ (2,976)
Operating expenses:			
Research and development	110,668	95,326	15,342
General and administrative	29,101	31,327	(2,226)
Change in fair value of contingent consideration	12,149	(4,342)	16,491
Total operating expenses	151,918	122,311	29,607
Operating loss	(151,918)	(119,335)	(32,583)
Other income (expense), net:			
Interest income	8,404	4,226	4,178
Interest expense	(42)	(5)	(37)
Other income (expense), net	(449)	96	(545)
Total other income, net	7,913	4,317	3,596
Loss before income taxes	(144,005)	(115,018)	(28,987)
Income tax (benefit) provision	104	114	(10)
Net loss	$ (144,109)	$ (115,132)	(28,977)

Collaboration Revenue

Collaboration revenue decreased by $3.0 million, from $3.0 million for the nine months ended September 30, 2025 compared to zero for the nine months ended September 30, 2026. The decrease is related to the Company

fulfilling all of its current obligations under the J&J Agreement and the expiration of the Pfizer MTA during the year ended December 31, 2025.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Internal personnel-related expenses (including stock-based compensation)	$ 29,473	$ 31,084	$ (1,611)
External expenses associated with preclinical and clinical studies	58,079	36,396	21,683
Research software, professional services and laboratory operations	12,614	11,180	1,434
Facility-related costs (including depreciation)	10,502	16,666	(6,164)
Total research and development expenses	$ 110,668	$ 95,326	$ 15,342

Research and development expenses increased by $15.3 million, from $95.3 million for the nine months ended September 30, 2025 to $110.7 million for the nine months ended September 30, 2026. This increase was primarily attributable to:

- a $21.7 million increase in external expenses associated with preclinical and clinical studies, primarily due to an increase in CRO expenses associated with our OD-001 phase 2a monotherapy trial and start-up activities for our planned OD-001 phase 2b monotherapy and phase 2a combination trials, as well as increased toxicology studies and external chemistry supporting our pipeline programs; and
- a $1.4 million increase in research software, professional services and laboratory operations, primarily due to the increase in research reagents and laboratory supplies to support increased level of research activity across the discovery programs.

These increases were partially offset by:

- a $6.2 million decrease in facility-related costs, primarily related to an impairment of our San Diego lease right-of-use asset in the first quarter of 2025; and
- a $1.6 million decrease in internal personnel-related expenses, primarily attributable to lower headcount, partially offset by increased stock-based compensation from awards granted upon the IPO.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods presented:

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Payroll and personnel-related expenses (including stock-based compensation)	$ 19,332	$ 16,569	$ 2,763
Professional and consulting fees	6,622	10,783	(4,161)
Software and IT costs	1,702	1,586	116
Facility-related costs (including depreciation)	603	1,971	(1,368)
Other general and administrative expenses	842	418	424
Total general and administrative expenses	$ 29,101	$ 31,327	$ (2,226)

General and administrative expenses decreased by $2.2 million, from $31.3 million during the nine months ended September 30, 2025 to $29.1 million for the nine months ended September 30, 2026. This decrease was primarily attributable to:

- a $4.2 million decrease in professional and consulting fees due to lower legal and accounting fees; and
- a $1.4 million decrease in facility-related costs, primarily due to losses on disposal of fixed assets recognized in 2025.

These decreases were partially offset by:

- a $2.8 million increase in payroll and personnel-related expenses, primarily due to increased stock-based compensation from awards granted upon the IPO; and
- a $0.4 million increase in other general and administrative expenses, primarily due to additional corporate insurance expenses associated with operating as a public company.

Changes in fair value of contingent consideration

The change in the fair value of contingent consideration resulted in expense of $12.2 million for the nine months ended September 30, 2026, compared to income of $4.3 million for the nine months ended September 30, 2025. The change was driven by updates to the assumptions management used in estimating the fair value of the Rahko contingent consideration following the completion of our IPO in May 2026.

Interest income

Interest income increased by $4.2 million from $4.2 million for the nine months ended September 30, 2025 to $8.4 million for the nine months ended September 30, 2026. The increase is primarily attributed to additional cash invested in marketable securities and interest-bearing accounts during 2026, reflecting proceeds received from the Series D convertible preferred stock financing completed in the second half of 2025 and our IPO in May 2026.

Interest expense

Interest expense did not significantly fluctuate during the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025, and is attributable to interest on our finance leases for certain lab equipment.

Other income (expense), net

Other income (expense), net decreased by $0.6 million from income of $0.1 million during the nine months ended September 30, 2025 compared to expense of $0.5 million during the nine months ended September 30, 2026. The decrease primarily relates to a non-recurring Australian tax refund recognized in 2025 and higher investment advisory fees and unrealized losses in 2026, partially offset by foreign currency gains.

Income tax provision

Income tax provision did not significantly fluctuate during the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have primarily funded our operations through the sale of shares of our convertible preferred stock, the proceeds from research collaborations and license agreements and through the sale of our common stock in our IPO and concurrent private placement completed in May 2026. We have not generated any revenue from product sales and have incurred significant annual operating losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the development of our product candidates. As of September 30, 2026, we had $387.0 million in cash, cash equivalents and marketable securities and an accumulated deficit of $712.2 million.

Future Funding Requirements

As of September 30, 2026, we had cash and cash equivalents, and marketable securities of $387.0 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and investments as of September 30, 2026, will be sufficient to fund our operations into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, incur costs associated with our efforts to discover new targets and engage in future collaborations, and the potential commercialization of our product candidates, if approved. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional financing to fund our continuing operations, which consist primarily of research and development expenditures related to our discovery programs and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and other current liabilities and prepaid expenses.

Our forecast of cash resources and planned operations involves risks and uncertainties, and the actual amount of expenses could vary materially as a result of a number of factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and planned clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans;
- the scope, prioritization and number of our research and development programs and clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- our ability to establish or maintain collaboration or license agreements and the achievement of milestones or occurrence of other developments that trigger payments under any existing or additional collaboration or license agreements;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the cost of continuing to invest in our drug discovery efforts and tools designed to identify novel targets and drugs;
- the potential increase in the number of our employees or expansion of our physical facilities to support preclinical studies and clinical trials;
- the cost associated with being a public company;
- the costs of securing manufacturing arrangements for clinical and commercial production and establishing or contracting for sales and marketing capabilities, if we obtain regulatory clearances to market our current or future product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and
- the impact of inflation, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, discovery tools, future revenue streams, research programs or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce or discontinue the development and commercialization of our product candidates, scale back or terminate our pursuit of new in-licenses and acquisitions or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Cash Flows

Nine months ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Net cash used in operating activities	$ (117,085)	$ (104,139)	$ (12,946)
Net cash used in investing activities	(133,350)	(115,469)	(17,881)
Net cash provided by financing activities	289,466	209,705	79,761
Effect of exchange rate changes on cash, cash equivalents, and restricted cash[(1)]	166	291	(125)
Increase (decrease) in cash, cash equivalents and restricted cash	$ 39,197	$ (9,612)	$ 48,809

(1) The balance sheet is affected by spot exchange rates used to translate local currency amounts into U.S. dollars. In accordance with generally accepted accounting principles in the United States, or GAAP, we have eliminated the effect of foreign currency throughout our cash flow statement, except for its effect on our cash and cash equivalents.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $117.1 million, primarily consisting of our net loss of $144.1 million and net changes in operating assets and liabilities of $8.0 million, which were partially offset by adjustments to reconcile net loss to net cash used in operating activities of $35.0 million.

Net cash used in operating activities for the nine months ended September 30, 2025 was $104.1 million, primarily consisting of our net loss of $115.1 million and net changes in operating assets and liabilities of $8.0 million,

which were partially offset by adjustments to reconcile net loss to net cash used in operating activities of $19.0 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2026 was $133.3 million, primarily consisting of $246.5 million of purchases of marketable securities, partially offset by $113.7 million of maturities of marketable securities.

Net cash used in investing activities for the nine months ended September 30, 2025 was $115.5 million, primarily consisting of $185.8 million of purchases of marketable securities, partially offset by $71.0 million of maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 was $289.5 million, primarily consisting of proceeds from our IPO and concurrent private placement, including the underwriters' partial exercise of their option to purchase additional shares.

Net cash provided by financing activities for the nine months ended September 30, 2025 was $209.7 million, primarily consisting of proceeds from the issuance of Series D convertible preferred stock.

License and Collaboration Agreement

Below is a summary of the key terms for our material license and collaboration agreement.

Terray Collaboration

In September 2024, we entered into a collaboration and license agreement, or the Terray Agreement, with Terray Therapeutics, Inc., or Terray, to discover, develop and commercialize or out-license products directed to IRF5. We and Terray have agreed to share all collaboration losses (generated in accordance with and subject to applicable budgets) and collaboration profits (including any payments received in connection with an out-licensing transaction) equally, beginning from the effective date of the Terray Agreement until the earlier of the date either party elects to opt-out, or the date the agreement expires or is terminated. The activities performed under the Terray Agreement are governed by a joint steering committee, made up of two employees designated by each party. No upfront payments were made upon the execution of the Terray Agreement and there have not been any payments made or received from the profit and loss share arrangement under the Terray Agreement as of September 30, 2026.

Contractual Obligations and Commitments

Leases

In September 2021, we entered into an operating lease agreement for our corporate headquarters located in Boston, Massachusetts, expiring in September 2029. We are also party to several operating leases for office and lab space, as well as finance leases for certain lab equipment. As of September 30, 2026, our non-cancellable lease obligations were $27.7 million and $0.6 million under our operating and finance leases, respectively, of which $7.4 million and $0.2 million related to operating and finance leases, respectively, are due within the next 12 months. Refer to Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for more information on our leases.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs for clinical trials, with CMOs for clinical manufacturing supplies and with other vendors for preclinical studies, supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party with 30 to 90 days' prior written notice and, therefore, we believe that our non-cancellable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancellable obligations under these agreements as of September 30, 2026.

IFM Acquisition Contingent Consideration

On May 6, 2022, we acquired all of the membership interests in IFM, or the IFM Acquisition. The total purchase consideration was $3.1 million, which consisted of the following: (i) 81,240 shares of our non-voting common stock at closing, with the estimated fair value of $0.2 million, (ii) cash consideration of $0.9 million at closing, (iii) a deferred payment of $0.9 million, which was paid in June 2022 and (iv) contingent consideration in cash of up to $30.0 million, payable once for each of our NLR family pyrin domain containing 1 and melanoma differentiation-associated protein 5 programs upon the first achievement of certain development, commercial, regulatory and sales milestones related to each such program, the estimated fair value of which was determined to be $1.1 million on the acquisition date. As of September 30, 2026, no milestones had been achieved or were deemed probable to occur.

See Note 5 and Note 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional details.

Rahko Acquisition Contingent Consideration

On October 6, 2021, we entered into the Rahko Purchase Agreements to purchase all of the issued share capital of Rahko, or the Rahko Acquisition, in exchange for a combination of cash, shares of our capital stock and additional contingent consideration of up to approximately $30.0 million. The contingent consideration would become payable to the former shareholders of Rahko upon either: (i) the first occurrence of our total market capitalization equaling or exceeding $1.5 billion based on a five-day volume-weighted average price of our publicly traded shares following the first public offering or public listing of our shares pursuant to applicable registration requirements on the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Global Market, the stock exchanges of Toronto, London or any other recognized investment exchange, or (ii) an exit event such as (1) a transaction or series of transactions in which any person (or persons acting in concert), other than a person who immediately prior to such transaction owned more than a majority of our voting securities, acquires more than 50% of the combined voting power of our then outstanding voting securities, (2) our consolidation or merger with or into another entity unless our stockholders immediately prior to such transaction continue to own, directly or indirectly, a majority of the combined voting power of the outstanding voting securities of the combined company, or (3) the sale or disposition of all or substantially all of our assets, in each case for which the potential proceeds are equal to or greater than $1.5 billion.

See Notes 5 and 13 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional details.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including, but not limited to, those related to revenue recognition, accrued research and development costs, stock-based compensation expense, and determination of the fair value of contingent consideration. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on 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 readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2026, there were no material changes to our critical accounting estimates and significant accounting policies described in our IPO Prospectus.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is provided in Note 2 to our audited consolidated financial statements included in our IPO Prospectus and Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an "emerging growth company," or an EGC, as defined in the JOBS Act and we may take advantage of certain exemptions from various disclosure and other requirements that are applicable to other public companies that are not EGCs, including (i) reduced disclosure about our executive compensation arrangements; (ii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iii) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and (iv) an exemption from compliance with the requirements of the PCAOB regarding the communication of critical audit matters in our auditor's report on the financial statements. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the time that we are no longer an EGC.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an EGC. We would cease to be an EGC on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have elected not to "opt out" of the extended transition period for new or revised accounting standards described above. As a result of these decisions, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company after our IPO if either (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company," as defined by Item 10 of Regulation S-K of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. In deciding whether to invest, you should carefully consider and read the following risk factors, as well as the financial and other information contained in this Quarterly Report, including in the section of this Quarterly Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us.

Risks Related to Our Business, Limited Operating History and Financial Position

We are a clinical-stage biotechnology company with a limited operating history and a history of incurring substantial net losses, have no products approved for commercial sale, have never generated revenue from product sales and may never be profitable.

We are a clinical-stage biotechnology company with a limited operating history. We were formed in April 2021 and have devoted substantially all of our resources since that time to research and development activities for our product candidates, including OD-001 and OD-002, and our other development programs, recruiting management and technical staff, raising capital, producing materials for preclinical studies and clinical trials, developing and establishing our intellectual property portfolio, developing our research and development tools and technologies, entering into collaboration agreements, acquiring companies or assets to further our development programs and building infrastructure to support such activities. Our most advanced product candidate, OD-001, achieved clinical proof-of-concept in a phase 2a monotherapy trial and we expect to report topline results from our phase 2b monotherapy and a phase 2a combination trials in the second half of 2027, and all of our other product candidates remain in preclinical or non-clinical development. We have completed IND-enabling studies for OD-002, our second most advanced program and expect to progress that program into clinical development.

We continue to incur significant research and development and other expenses related to our ongoing operations. The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates.

We do not have any products approved for sale and have not generated any revenue from product sales or royalties to date. We do not know whether we will be able to develop any product candidates that succeed through preclinical and clinical development or products of commercial value. All of our historical revenue was generated from certain collaboration agreements we had entered into. We do not expect to generate product revenues unless and until we obtain marketing approval for a product candidate. Consequently, it may be more difficult to evaluate our business and predictions about our future success and viability may not be as accurate as they could be if we had a longer operating history. Investing in biotechnology product development is highly speculative because of the significant risk that, despite significant investment, any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

We have incurred net losses since our inception through September 30, 2026. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. For the nine months ended September 30, 2026 and 2025, we reported a net loss of $144.1 million and $115.1 million, respectively. As of September 30, 2026, we had an accumulated deficit of $712.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue research

and development efforts for our product candidates, advance our product candidates through preclinical studies and clinical trials and seek regulatory approvals for our product candidates.

We anticipate that our expenses will increase substantially as we:

- continue to progress the development of our product candidates, including our two most advanced programs: OD-001 and OD-002;
- invest in our target selection programs and develop any additional product candidates, including the cost of acquiring any necessary rights from third parties to develop those product candidates or entering into partnering relationships to further the development of any such product candidates;
- establish and expand the manufacturing of preclinical and clinical supply of our current and future product candidates;
- seek regulatory approvals for any of our current product candidates or any future product candidates;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval, if any;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and expand our rights in our intellectual property portfolio or acquire or in-license intellectual property and technologies from third parties;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates, including as a result of macroeconomic conditions, geopolitical conflicts or other factors; and
- incur additional legal, accounting or other expenses in operating our business, including the costs associated with operating as a public company.

To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products if we obtain marketing approval, obtaining market acceptance for such products and satisfying any post-marketing requirements. We may not succeed in any or all of these activities and, even if we do, we may not generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and the price of our common stock, and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our common stock also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business, financial condition, results of operations and prospects. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since our inception. We expect to continue spending substantial amounts of cash to advance our current and future preclinical and clinical development programs and seek regulatory approval for our product candidates.

As of September 30, 2026, we had $387.0 million in cash, cash equivalents and marketable securities. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Additionally, because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and planned clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans or acquiring other therapies that are administered as part of our clinical trials;
- the scope, prioritization and number of our research and development programs and clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- our ability to establish or maintain collaboration or license agreements and the achievement of milestones or occurrence of other developments that trigger payments under any existing or additional collaboration or license agreements;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with acquisitions and licenses;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the cost of continuing to invest in our suite of tools and drug discovery efforts to identify novel targets and drugs;
- the potential increase in the number of our employees or expansion of our physical facilities to support preclinical studies and clinical trials;
- the costs associated with being a public company;
- the cost of securing manufacturing arrangements for clinical and commercial production and establishing or contracting for sales and marketing capabilities, if we obtain regulatory clearances to market our current or future product candidates, including the cost of any third-party products used as combination agents in our clinical trials;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage or adequate reimbursement from third-party payors; and
- the impact of inflation, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy. As a result, we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

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

Even if we believe that we will have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if there are specific strategic considerations for doing so. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted and the terms of those securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring and distributing dividends, and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, any of which may harm our business, financial condition, results of operations and prospects.

Further, if banks and financial institutions with whom we hold accounts enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash may be threatened and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our business depends entirely on the success of our product candidates and research and development programs, including OD-001 and OD-002, and we cannot guarantee that any or all of our current or future product candidates will successfully enter or complete clinical development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested the majority of our efforts and financial resources in the development of our product candidates and research and development programs, each of which is still in preclinical or clinical development, and expect that we will continue to invest heavily in the development of these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue are substantially dependent on our ability to develop, obtain regulatory approval for and then successfully commercialize our product candidates, which may never occur.

Our product candidates and research and development programs will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, the establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we will not be permitted to market or promote any of our product candidates until we receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or comparable foreign regulatory authorities, and we may never receive regulatory approval to allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

The FDA or comparable foreign regulatory authorities may also consider their approvals of competing products concurrently with their review of our investigational new drug applications, or INDs, clinical trial applications, or CTAs, or other submissions. That review may lead to changes in the review requirements that had been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate the withdrawal of our INDs, CTAs or other submissions.

If our product candidates are approved for marketing by applicable regulatory authorities, our ability to generate revenue from any approved products will depend on our ability to:

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- manufacture products through CMOs in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- price our products competitively such that third-party and government reimbursement supports broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our products through our own marketing and sales activities, and any other arrangements to promote these products that we may otherwise establish;
- establish and maintain agreements with wholesalers, distributors, pharmacies and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property rights and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations and guidance specific to commercialization, including interactions with healthcare professionals, patient advocacy groups and communication of healthcare economic information to payors and formularies;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- ensure that our product will be used as directed and that additional unexpected safety risks will not arise.

Our business entails a significant risk of product liability and an inability to obtain sufficient insurance coverage for those or other claims could adversely affect our business, financial condition, results of operations and prospects.

As we conduct preclinical studies and clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an investigation by the FDA or comparable foreign regulatory authorities focused on the safety and efficacy of our current or future product candidates, our manufacturing processes and facilities or our marketing programs. Such an investigation may potentially result in a recall of our products or a more serious enforcement action, limitations on the approved indications for which the product may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, product liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize products that we may develop and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain to cover product liability or other claims may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability or other claims that could adversely affect our business, financial condition, results of operations and prospects.

Our future success depends on our ability to retain and to continue to receive adequate attention from our key leaders, as well as on our ability to attract, retain and motivate qualified personnel.

We are highly dependent upon Gary D. Glick, Ph.D., our founder, President and Chief Executive Officer, and Jeffrey M. Leiden, M.D., Ph.D., the Chair of our board of directors, and losing the services of either of these individuals could

delay or prevent the successful development of our product candidates, the initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Dr. Glick's employment agreement with us is terminable by him at will and, therefore, we may not be able to retain his services as expected. Dr. Leiden serves as a director and must be re-elected by our stockholders to continue serving on our board of directors. He may also resign from service as a director at any time. In addition, because we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees, we may not have adequate compensation for the loss of the services of these individuals.

Our success also depends on our ability to continue to receive adequate attention from our key leaders as we execute on our growth strategy. For example, in addition to his services to Odyssey as CEO, Dr. Glick began serving as Executive Chair of Charm Therapeutics Limited, or Charm, a biotechnology company focused on developing a new generation of menin inhibitors for acute myeloid leukemia, in January 2022. While, to date, the amount of time Dr. Glick has devoted to Charm has not changed, Dr. Glick became interim CEO of Charm in June 2025. It is possible that, in the future, unforeseen developments at Charm could require Dr. Glick to divert his attention for a period of time from his role at Odyssey in order to fulfill his responsibilities at Charm. None of our other key leaders currently has an outside role that we believe could detract from their ability to fulfill their ongoing responsibilities to us.

Finally, our success also depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We may not be successful in continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses and academic institutions, particularly in the greater Boston area.

If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, or if members of our team are required to devote substantial amounts of time to other professional responsibilities that limit their ability to devote necessary time to our affairs, we may experience constraints that significantly impede the achievement of our business objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business, financial condition, results of operations and prospects.

We are a relatively small company and, as our development and commercialization plans and strategies progress, and as we continue to operate as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, as our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business, financial condition, results of operations and prospects.

We are exposed to the risk of fraud or other misconduct by our employees, contractors and partners. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with federal, state or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, to disclose unauthorized activities to us or to comply with comparable foreign requirements. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare

programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations and the curtailment or restructuring of our operations.

In the normal course of business, we periodically enter into commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our commercial agreements, we sometimes indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

If our obligations under an indemnification provision exceed or do not qualify for applicable insurance coverage or if we were denied insurance coverage, our business, financial condition, results of operations and prospects could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition, results of operations and prospects could be adversely affected.

We may be required to make contingent or deferred payments to collaborators or in connection with acquisitions and in-licenses of technology. Such payments may have an adverse impact on our business, financial condition, results of operations and prospects.

We have entered into, and may in the future enter into, collaborations, acquisitions and in-licensing arrangements that contemplate contingent or deferred payments. In the event we are deemed to have achieved certain milestones in connection with such contingent or deferred payments, we may be required to pay such amounts in full or in part. For example, if certain contingencies are satisfied, we may be required to make a payment of up to $30.0 million to the former shareholders of Rahko Limited, or Rahko, a company we acquired in 2021. Additionally, upon the achievement of certain development, commercial, regulatory and sales milestones for each of our NLRP1 and MDA5 programs, we may be required to pay up to $30.0 million in contingent payments once for each such program to the former members of IFM Discovery, LLC, a company we acquired in 2022. See the section of this Quarterly Report titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments*" for additional information regarding our deferred consideration obligations. Contingent or deferred payments may have an adverse impact on our business, financial condition, results of operations and prospects.

We may become subject to litigation, which could result in substantial costs and divert management's attention and resources from our business.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business or otherwise, including claims related to employment matters, security of patient and employee personal data, product liability, intellectual property rights and contractual relations with current or past collaborators or licensors. For example, we and the former shareholders of Rahko may disagree about when or whether the contractual prerequisites that would require us to make a substantial contingent consideration payment to them have been satisfied. In the event of a disagreement, the former Rahko shareholders could seek to recover for non-payment through litigation. See the section of this Quarterly Report titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments*" for additional information regarding our contingent consideration obligations. Any litigation we become party to could be costly and time-consuming and we cannot assure you that we would ultimately prevail. If we receive an adverse judgment in any litigation, we could be required to pay substantial damages that may not be covered by our insurance in full or at all. Expenses and damages relating to litigation can be difficult to predict. Regardless of its merit, litigation can be complex, extend for a protracted period of time, divert management's attention and resources and be expensive. Litigation initiated by us could also result in counterclaims against us, which could increase the costs associated with the litigation and result in our payment of damages or other judgments against us.

Our current operations are concentrated predominantly in two locations, and we or the third parties upon whom we depend may be adversely affected by natural or manmade disasters.

Our current operations are concentrated predominantly in Boston, Massachusetts and Ann Arbor, Michigan. Any unplanned event, such as a flood, explosion, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a

daily basis, and may have significant negative consequences on our financial condition, results of operations and prospects. Any similar impacts of natural or manmade disasters on our third-party CMOs, CROs, or other third parties on whom we rely could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial condition, results of operations and prospects. If any such natural or manmade accidents or incidents occurred and prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our artificial intelligence, or AI, and machine learning, or ML, platform leverages internal data as well as data from third parties. Defects in, or loss of access to, our databases or those of third parties may impair our ability to discover additional targets and develop our product candidates.

We use our AI/ML platform to improve our target discovery programs by improving the hit finding and lead optimization process for our small-molecule product candidates. Our AI/ML platform accesses third-party databases. If access to this data is lost or limited, or if this data becomes outdated, it may delay or otherwise adversely affect our ability to develop our product candidates. Our competitors may render our approach obsolete, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies.

Our proprietary software tools and data sets are inherently complex and may contain defects or errors. Errors may result from the interface of our hardware or proprietary software tools with our data or third-party systems and data. The risk of errors is particularly significant when new software or hardware is first introduced or when new versions or enhancements of existing software or hardware are implemented. Any errors, defects, disruptions or other performance problems with our software, hardware or data sets could hurt our ability to gather valuable insights that we intend to use to assist in developing our current and future product candidates and drive our drug discoveries. We outsource all of the core network infrastructure relating to our AI/ML platform to third-party hosting services. We have limited control, if any, over any of these third parties, and we cannot guarantee that such third-party providers will not experience system interruptions, outages or delays or deterioration in their performance. We have experienced, and expect that in the future we may again experience, interruptions, delays and outages in service and availability from time to time due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints.

Furthermore, the development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. For example, several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted or are considering laws governing the development and use of AI/ML. For example, the EU AI Act sets out a risk-based framework, subjecting certain AI technologies to numerous compliance obligations, including transparency, conformity and risk assessment, monitoring and human oversight requirements. Under the EU AI Act, non-compliant companies may be subject to administrative fines of up to 35 million Euros or 7% of a company's total worldwide annual turnover for the preceding financial year, whichever is higher. Certain of our activities subject us to the EU AI Act and, depending on how the EU AI Act is implemented and interpreted, we may have to adapt our business practices, contractual arrangements, and services to comply with such obligations. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices or retrain our AI/ML or prevent or limit our use of AI/ML. For example, the Federal Trade Commission, or the FTC, has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or our use is restricted, our preclinical research and development programs may be less efficient, or we may be at a competitive disadvantage.

The occurrence of any of these events could prevent us from leveraging our AI/ML capability and software to help us develop our product candidates more efficiently than existing industry tools and have a material adverse effect on our business, financial condition, results of operations or prospects.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, could adversely affect our business, financial condition, results of operations or prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years. A severe or prolonged economic downturn, or global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute on our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments, which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, continued market volatility or a general economic downturn could cause our stock price to decline.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. If any of the banks that hold our cash deposits were to be placed into receivership, we may be unable to access our cash and cash equivalents and short-term marketable securities, which would adversely affect our business. In addition, if any of the third parties on whom we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds through certain financial institutions, such parties' ability to fulfill their obligations to us could be adversely affected.

Risks Related to Research, Development and Commercialization

For our most advanced product candidate, OD-001, we have presented efficacy and supporting analyses from the 12-week induction period from our phase 2a clinical trial, and for OD-002, our next most advanced product candidate, we have completed IND-enabling studies. We have never successfully completed any large-scale or pivotal clinical trials with our product candidates, and we may be unable to do so for any product candidates we develop.

As of the date of this Quarterly Report, we have only one product candidate in clinical development and our next most advanced product candidate has completed IND-enabling studies. All of our other development programs are in the preclinical or drug discovery stage. We have not yet successfully completed any large-scale or pivotal clinical trials, obtained regulatory approvals, manufactured a commercial scale product (or arranged for a third party to do so on our behalf) or conducted sales and marketing activities necessary for successful commercialization of any of our product candidates. Our experience conducting clinical trials with our product candidates is limited. Aside from OD-001, our product candidate currently in clinical development for the treatment of ulcerative colitis, or UC, and OD-002, our product candidate that has completed IND-enabling studies, all of our other development programs will need to progress through IND-enabling studies and receive authorization from the FDA or a comparable foreign regulatory authority to proceed under an IND, CTA or other submission prior to initiating clinical development. We may not be able to file INDs, CTAs or other submissions for any of our other product candidates on the timelines we expect, or at all. Even if we submit an IND, CTA or other submission for a product candidate, the FDA or a comparable foreign regulatory authority may not clear the IND, CTA or other submission and allow us to begin clinical trials in a timely manner or at all. The timing of submissions of INDs, CTAs or other submissions for our product candidates will be dependent on further preclinical and manufacturing success. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and comparable foreign regulatory authorities. Any guidance we receive from the FDA or comparable foreign regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements; or
- be required to have the product removed from the market after obtaining marketing approval.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome. We or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are either in preclinical development or, in the case of OD-001, in a phase 2a monotherapy trial. The risk that our product candidates fail to successfully proceed through clinical development is high. We expect it will be many years before we commercialize any product candidate, if ever. The product candidates we are developing are novel and unproven, which makes it difficult to accurately predict the challenges we may face with respect to our product candidates as they proceed through development. It is also impossible to predict whether our clinical trials will proceed through registrational trials and when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authority could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our trial design, which may require us to complete additional studies or trials, amend our protocols or impose stricter conditions on the commencement of clinical trials.

We expect to continue to rely in part on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory authorities, Institutional Review Boards, or IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols or require that we modify or amend our clinical trial protocols;
- delays in reaching, or failing to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a biologic license application, or BLA, or new drug application, or NDA;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;

- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

We have and may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the IRBs of the institutions where such trials are being conducted, the FDA or comparable foreign regulatory authorities, or if a clinical trial is recommended for suspension or termination by a data safety monitoring board or data monitoring committee, or DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs to perform in accordance with good clinical practices, or GCPs, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also conduct preclinical and clinical research in collaboration with academic, pharmaceutical and biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our future costs and expenses.

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

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates or obtain limited regulatory approval, our business will be substantially harmed.

All of our current product candidates and any future product candidates will be subject to extensive governmental regulations relating to research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing, sale and distribution of products. Rigorous preclinical studies, clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product may be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them and any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or elsewhere until we receive regulatory approval of our product candidates through an NDA or BLA from the FDA or similar marketing application in another jurisdiction. The FDA and other comparable foreign regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other comparable foreign regulatory authorities that any of our product candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of any of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and clinical trials of any of our product candidates may not be sufficient to support the submission of an IND, CTA or other application for regulatory approval;
- the FDA may have difficulty scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, and foreign regulatory authorities may require a risk management plan, or RMP, as a condition of approval for new products, among other additional requirements;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations; and
- the FDA or comparable foreign regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Any of these regulatory authorities may also change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or comparable foreign regulatory authorities may require that we conduct additional clinical, preclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or comparable foreign regulatory authorities for granting approval.

In addition, the FDA or comparable foreign regulatory authorities may approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS, RMP or comparable foreign risk management approaches. The FDA or comparable foreign regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Further, the FDA or comparable foreign regulatory authorities may respond to any BLA, NDA or comparable marketing application that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of any of our product candidates or any future product candidates.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement, and may in the future become subject to additional ones. The regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval in foreign jurisdictions may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, financial condition, results of operations and prospects.

The successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in a trial until its conclusion. We may not be able to initiate, continue or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for any of our product candidates if we are unable to locate, enroll and retain a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- in the case of a combination study with another product, the ability of that product to be used as a combination therapy;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies; and
- other factors outside of our control, such as the effects of global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine, the conflicts in the Middle East and other geopolitical conditions.

For example, we enrolled patients in our phase 2a clinical trial for OD-001 at multiple sites, including sites in Ukraine. We are also considering, subject to the receipt of necessary approvals from the applicable regulatory authorities, enrolling patients at sites in the Middle East for future clinical trials. To the extent military conflicts, political unrest, unstable economic conditions or other events adversely impact our ability to enroll patients or complete enrollments in process or adversely impacts the ability of our suppliers to produce and distribute the supplies we need for our clinical trials, we may be required to enroll patients at other sites which could increase the cost or delay the timing for completing such trial.

We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting similar treatments, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, some of the diseases our product candidates are designed to address have existing treatments which may make it more difficult to recruit patients. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our clinical trials. We also rely on CROs and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance.

These factors may make it difficult for us to enroll and retain enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Positive results from preclinical studies and early clinical trials of our current or future product candidates are not necessarily predictive of the results of later clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies of our current or future product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. In addition, the data from our preclinical comparison studies may not be replicated in clinical trials, and our competitors may advance different compounds than those we studied. For example, historical remission rates observed in early clinical trials are not necessarily indicative of remission rates observed in future placebo-controlled clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Our RIPK2 phase 2a monotherapy trial utilizes an “open-label” trial design and we may utilize this for future clinical trials for this or future product candidates. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

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

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

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Others, including regulatory authorities, 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 value of the particular program, the approvability or commercialization of the particular product candidate or product and our value in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically a significant volume of data and other information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line 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 harmed, which could harm our business, financial condition, results of operations or prospects.

Our approach to clinical development relies on developing product candidates across a number of inflammatory diseases. We may not be successful in our efforts to discover additional product candidates or we may expend our limited resources to pursue a particular product candidate in specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Given our broad approach seeking to identify multiple novel targets in a wide variety of indications, we will need to carefully allocate our limited financial and managerial resources among our selected product candidates in certain selected indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. If we are unable to discover and develop additional product candidates, our ability to commercialize product candidates or partner product candidates may be negatively impacted. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.

We are currently developing product candidates targeting inflammatory bowel disease, or IBD, and a number of autoimmune diseases, including systemic lupus erythematosus. In the future, we may develop additional product candidates targeting a range of other inflammatory and autoimmune diseases. However, we have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory

approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, side effect profile, efficacy, tolerability, cost and ease of administration of our product candidates and any approved products we use as part of a combination treatment, if any;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to such product candidates or to which we agree as part of a mandatory REMS or RMP or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

The market opportunities for our product candidates and forecasts of market growth may not be accurate, and the actual market for our product candidates may be smaller than we estimate. Even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our estimates 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, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors' products, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our business. Further, new trials may change the estimated incidence or prevalence of these diseases. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States, other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to

treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability.

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

The development and commercialization of new drugs is highly competitive. We face and will continue to face competition from third parties, including larger and better-funded pharmaceutical, biopharmaceutical and biotechnological companies, developing treatments for the indications that we have decided to pursue. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of new drugs.

Many of our competitors have significantly greater financial, technical, manufacturing, supply, marketing and sales resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our programs may be delayed and our expenses may increase and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Use of our product candidates could be associated with side effects, adverse events or safety risks, which could cause us to suspend or discontinue clinical trials, cause us to abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations, financial condition and prospects.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our current product candidates, including OD-001 and OD-002, our lead product candidates, and any future product candidates are both safe, pure and potent and effective for use in such product candidate's target indication. Clinical testing is expensive, can take many years to complete and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to generate desired safety and efficacy data

despite having progressed through preclinical studies and initial clinical trials. It is not uncommon in the biopharmaceutical and biotechnology industries to suffer significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, results of operations, financial condition and prospects and may cause us to interrupt, delay or abandon the development of any such product candidate or limit development to more narrow uses or subpopulation.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. For example, while no serious adverse events, or SAEs, have been observed as of the date of this Quarterly Report, it is possible that testing in additional human subjects with IBD may, either in monotherapy or in combination with other agents, reveal greater side effects in our clinical program for OD-001 than observed in our clinical testing to date. We will continue to learn more about our product candidates and potential side effects as they advance through clinical development. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing other medical treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials.

We, the FDA, other comparable foreign regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA or comparable foreign regulatory authorities could require us to adopt a REMS or RMP, as applicable, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences include:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Changes in product candidate manufacturing, formulation or analytical methods may result in additional costs or delay, which could adversely affect our business, financial condition, results of operations and prospects.

As product candidates are developed through preclinical studies to later-stage clinical trials toward approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation or analytical methods, are altered in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization by, the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates or jeopardize our ability to commence product sales and generate revenue.

A variety of risks associated with conducting research and clinical trials abroad, including in China and Ukraine, and seeking to market our product candidates internationally, could materially adversely affect our business, financial condition, results of operations and prospects.

We plan to globally develop our product candidates. In addition, our enrollment timelines for our product candidates depend on initiating clinical trial sites outside of the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing standards with respect to data integrity;
- differing standards and privacy requirements for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates to the patient at the relevant trial site abroad;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions, tariffs and restrictions on currency exchange or the transfer of funds;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- 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 incident to doing business in another country;
- difficulties staffing, workforce uncertainty and managing foreign operations;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- challenges with obtaining any local supply of drugs or agents used with our product candidates, which are required by certain local clinical trial sites before conducting any study;
- business interruptions resulting from health epidemics or pandemics, or natural or man-made disasters, including earthquakes, tsunamis, fires, medical epidemics or geo-political developments, including war and terrorism;
- failure to observe local or international GCPs, including data integrity, rules leading to rejection of safety or effectiveness data by drug regulatory authorities; and
- failure to observe local data privacy or security rules leading to prohibitions on data transfer.

For example, our phase 1 healthy participant trial for OD-001 was conducted in Australia and we enrolled patients in our phase 2a clinical trial for OD-001 at multiple sites in Australia, Canada, Jordan, Moldova, New Zealand, Poland and Ukraine. We are also considering, subject to the receipt of necessary approvals from the applicable regulatory authorities, enrolling patients at sites in the Middle East and other jurisdictions globally for future clinical trials. To the extent military conflicts, political unrest, unstable economic conditions or other events adversely impact our ability to enroll patients or complete enrollments in process or adversely impact the ability of our suppliers to produce and distribute the supplies we need for our clinical trials, we may be required to enroll patients at other sites which could increase the cost or delay the timing for completing such trial.

We have also engaged CROs active in China and Ukraine to assist with discovery and research activities. Disruptions to our preclinical development programs or increased costs have in the past and may in the future result from changes in the policies of the U.S. or Chinese governments, political unrest, unstable economic conditions in China or Ukraine and disruption from the war in Ukraine. For example, a further trade war between the U.S. and China could lead to tariffs, legislation or regulations that impact our ability to continue relying on these CROs or increase the cost of doing so. Additionally, legislation and regulations, such as the BIOSECURE Act, could restrict our ability to enter into long-term commercial agreements with certain CMOs.

We are conducting and intend to conduct certain of our clinical trials globally. However, the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

Our phase 1 healthy participant trial for OD-001 was conducted in Australia and our phase 2a clinical trial for OD-001 includes sites in Australia, Canada, Jordan, Moldova, New Zealand, Poland and Ukraine. In addition, we currently intend to conduct additional future clinical trials in a number of countries around the world, including countries in the Middle East. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all, including as a basis for later-stage clinical trials. In cases where data from foreign clinical trials is intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (among other prerequisites) (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence in accordance with applicable GCPs; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign regulatory authority approval process, and we currently, and will need to continue to, contract with manufacturers who can meet our and all applicable FDA or comparable foreign regulatory authority requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and any contractors with which we contract for manufacturing must meet all applicable FDA or comparable foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or comparable foreign regulatory authority, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA or comparable foreign regulatory authority to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us (including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restrictions and criminal prosecutions), delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, any of which would have an adverse effect on our business, financial condition, results of operations and

prospects. Our future success depends on our ability to manufacture our products, on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality and complying with applicable regulatory requirements. An inability to do so could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

We rely on third-party CMOs to manufacture and supply drug substance and drug product for our clinical trial for OD-001 and we expect to rely on third-party CMOs for our future clinical trials.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured our product candidates ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates;
- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- international or multi-national activities that are related to business activities outside of our scope, but may have an impact on a CMO's ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and
- our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.

Should we continue to use CMOs, we may not succeed in maintaining our relationships with our current CMOs or establishing relationships with additional or alternative CMOs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. If our CMOs were to cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Moreover, if we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, recall, operating restrictions, suits under the civil False Claims Act, or FCA, corporate integrity agreements, consent decrees or withdrawal of product approval.

We intend to pursue the development of certain of our product candidates in combination with other therapies, and regulatory approval, safety or supply issues with these other therapies may delay or prevent the development and approval of our product candidates.

We have explored and may continue to explore the use of certain of our product candidates in combination with other therapies, including those that may not yet be approved. For example, we are planning to assess the effect of OD-001 in combination with vedolizumab. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with, the therapy used in combination with our product candidate. If the therapies we use in combination with our product candidates are replaced as the standard of care, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. The occurrence of any of these risks could result in our product candidates, if approved, being removed from the market or being less successful commercially.

While vedolizumab is approved by regulatory authorities in major markets, including the FDA and EMA, it has not received marketing approval in some countries where we intend to conduct our clinical trials. If we are unable to use the standard of care agents in our planned phase 2a combination trial for OD-001 in countries where the standard of care agents have not been approved or in any other clinical trial that includes a standard of care agent for a maintenance and induction period, we may be required to enroll additional patients at existing sites or identify new trial sites, resulting in potential delays in the trial and additional expenses. As a result, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, financial condition, results of operations and prospects.

If the FDA or comparable foreign regulatory authorities do not approve or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. We cannot assure you that any future issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can we assure you that the patents issued will not be infringed, designed around or invalidated by third parties, or that we can effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Public disclosures by us or third parties may preclude our ability to obtain or maintain patent applications and patents. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates. We may also depend on current or future collaborators or licensors to take necessary action to comply with patent protection requirements with respect to any licensed intellectual property. Noncompliance with such requirements could result in

abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We own an issued patent in the United States that claims the composition of matter of OD-001. However, composition of matter protection in foreign countries and for our other product candidates depends on pending patent applications, and we cannot be certain that the claims in our pending patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the methods claimed in the patents. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our patented indications, clinicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainty as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned or in-licensed patent applications may not result in patents being issued that protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we (or any collaborators or licensors) will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our pending patent applications, and those of any collaborators or licensors, may be challenged in the USPTO or patent offices abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review, or PGR, proceedings, oppositions, derivations, reexaminations, interferences, inter partes review, or IPR, proceedings or other similar proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our current or future owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our current or future owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We also rely upon a combination of trade secrets, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that any issued patents will not be challenged and rendered invalid or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any issued patent will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; or
- whether the patent applications will result in issued patents with claims that cover each of our product candidates or uses thereof in the United States or in other foreign countries.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in PGR procedures, oppositions, derivations, revocation, reexaminations, IPR or derivation proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may rely on more than one patent to provide multiple layers of patent protection for our product candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the product candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our product candidate could be adversely affected.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our product candidates. Further, in cases where a particular compound of interest is in the public domain, third parties may be able to obtain patents on improvements or other inventions relating to such compound if they were to discover the same patentable inventions relating to such compounds after us but manage to file a patent application before we do. In addition, we may enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, including any polymorphs and variants, such as our employees, collaborators, consultants, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. Furthermore, if third parties have filed patent applications related to our product candidates or technology, a derivation proceeding in the United States can be initiated by a third party to determine who invented any of the subject matter covered by the claims of our patent applications. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical ours. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and, in so doing, claim that future patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or may find that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.

Because some of our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Our product candidates also may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and expenses and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

In addition, we may have limited control over the maintenance and prosecution of any current or future in-licensed intellectual property. A licensor may not successfully prosecute any patent applications to which we are licensed in a manner consistent with the best interests of our business. We may also have limited control over the manner in which any licensor initiates an infringement proceeding against a third-party infringer or defends any intellectual property that is licensed to us. It is possible that a licensor's infringement proceeding or defense activities may be less vigorous than those we would have conducted ourselves. We may also enter into future license agreements under which we are a sub-licensee. If any sub-licensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which could terminate the sub-license. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all.

Additionally, we sometimes collaborate with academic institutions and governmental authorities to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, financial condition, results of operations and prospects could be adversely affected.

The licensing and acquisition of third-party intellectual property rights is a highly competitive area, and companies, which may be more established or have greater resources than we do, also may be pursuing strategies to license or acquire third-party intellectual property rights that we consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Any product candidates licensed from third parties may be subject to retained rights.

Third-parties who have collaborated with us by contributing intellectual property or with whom we may collaborate with or license intellectual property from in the future may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates or to develop or commercialize the licensed product candidates in certain regions.

We may also at times choose to collaborate with academic institutions to accelerate our preclinical research or development. The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates. We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing, or increase the costs of commercializing, our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents,

incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically 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. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our technologies or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our technologies and product candidates.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe but that we may ultimately be found to infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition, results of operations and prospects and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. 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 us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms, or at all. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to

prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition, results of operations and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition, results of operations and prospects. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property, or those of our collaborators or licensing partners. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). In addition, the U.S. Supreme Court recently has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Our future owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria, which also could make it more difficult to obtain patents. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations and prospects. Similarly, 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.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded.

We may not be able to detect infringement against our future owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we detect infringement by a third party of our future owned or in-licensed patents, we may choose not to pursue litigation against or

settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce our future owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our future owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an IPR, ex parte re-exam or PGR proceeding. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO proceedings, we may become a party to patent opposition proceedings at the European Patent Office or similar proceedings in other foreign patent offices, where either our future owned or in-licensed foreign patents are challenged.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain. An adverse determination in any such proceeding may result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial and may result in a loss of scope of some claims or a loss of the entire patent. Even if we ultimately prevail in any such claims or proceedings, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the claims or proceedings.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property or claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property, or those of our collaborators or licensors, as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable or invalid. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business, financial condition, results of operations and prospects. 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.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations and prospects.

In light of the advent of AI-assisted inventions, it is possible third parties could challenge our future patents as invalid for lack of a human inventor. The law regarding AI-assisted inventions and inventorship is evolving rapidly and allegations of improper inventorship of our AI-assisted inventions could pose a challenge to the validity and/or enforceability of our future patents throughout the world.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time. If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, any patents we may own or license may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, any issued U.S. patents that we may own in the future may be eligible for limited patent term restoration, or patent term extension, under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, an approved method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under a Supplemental Protection Certificate. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Obtaining and maintaining our patent protection is dependent on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel to pay these fees due to the USPTO and non-U.S. governmental patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the

Leahy-Smith America Invents Act, or the AIA, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that claims to certain DNA molecules are not patentable. In *Amgen Inc. v. Sanofi*, the Federal Circuit held that claims with functional language may pose high hurdles in fulfilling the enablement requirement. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. For example, the IRA passed by Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. Under recent legislative updates via the One Big Beautiful Bill Act, or the OBBBA, medicines that maintain one or more FDA orphan designations for rare diseases are exempt from this negotiation process, provided they are not approved for a non-orphan condition. Furthermore, if an exempt orphan medicine is subsequently approved for a broader, non-rare market indication, the 7-year negotiation countdown does not begin until the date of that non-orphan approval. While we do not believe that the IRA, these expanded orphan drug exemptions, or their combined effects will impact our ability to obtain patents in the near future, we cannot be certain whether it will affect our patent strategy in the long run. The laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. Additionally, in July 2025, the FDA announced its intent to increase transparency by publicly releasing portions of Complete Response Letters, or CRLs, issued to drug and biologic sponsors. While the FDA has stated that confidential information will be protected, it remains unclear how these disclosures will be implemented. Because CRLs often contain specific observations about study design, clinical endpoints, chemistry, manufacturing, and controls data, or other proprietary information, any public release could unintentionally disclose information that competitors may use to infer proprietary aspects of our product candidates or platform technologies. This could compromise the confidentiality of our trade secrets and know-how or facilitate third-party efforts to design around or challenge the validity, enforceability, or scope of our patents, or accelerate the development of generics or biosimilars. If we are required to modify or limit the information shared with the FDA to mitigate these risks, it could increase costs, slow our regulatory interactions, or delay product approval timelines.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new Unitary Patent system was introduced, which significantly impacts European patents, including those granted before the introduction of the system. Under the Unitary Patent system, after a European patent is granted, the default is that the patent will be a part of the Unitary Patent system, thereby resulting in a Unitary Patent having unitary effect; the patent proprietor, however, can, in some instances, opt out of the Unitary Patent system and opt for the traditional state-by-state national validation instead. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new Unitary Patent system.

Geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Government actions may also prevent filing, prosecution and maintenance of issued patents in various jurisdictions. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in such jurisdictions. If such an event were to occur, it could have a material adverse effect on our business. In addition, jurisdictions outside of the U.S. could also permit our patents to be exploited without consent or compensation. In those circumstances, we would not be able to prevent third parties from practicing our inventions or from selling or importing products made using our inventions in and into such jurisdictions. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Additionally, changes in U.S. trade policy, including the imposition of new or increased tariffs, as well as retaliatory measures by other countries, could adversely affect our patent strategy, such as where we choose to file, maintain, or enforce our patents. Also, if we are required to move our research or manufacturing activities to new regions, this may expose us to jurisdictions with weaker intellectual property enforcement, differing patent eligibility standards, or greater risk of compulsory licensing. These factors could compromise the protection or value of our proprietary technologies, including our core patents and related know-how.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary information and know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how or information. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future and we may require a license from the competitor to use our own technology or know-how. If the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Further, if the parties to our confidentiality agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a consequence of those breaches or violations. Our trade secrets could otherwise become known or be independently discovered by our competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occur or if we otherwise lose protection for our trade secrets, our business, financial condition, results of operation and prospects may be materially and adversely harmed.

In addition, we have entered into and may in the future enter into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as collaborators, CROs, third-party manufacturers, consultants, potential partners and other third parties. We may become subject to litigation where a third party asserts that we or our employees or other third parties inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of any such claims, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of resources from our business. We cannot predict whether we would prevail in any such claims. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, including the loss of valuable intellectual property rights or personnel, all of which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared merely descriptive or generic or determined to be infringing on other marks. The use of our registered and unregistered marks may also be limited by certain agreements with third parties. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. In the USPTO, cancellation proceedings may be filed against our trademarks, once registered, which may result in our trademarks not surviving those proceedings. In foreign jurisdictions, opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

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

The use of new and evolving technologies, such as AI, may require us to expend material resources and may present risks and challenges that can impact our business, including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We use AI, including generative artificial intelligence, or Gen AI, ML, and automated decision-making technologies. The use of AI technology, including Gen AI, can give rise to intellectual property risks, including uncertainty regarding ownership of AI-generated inventions, compromises to proprietary IP, inaccuracy, bias, data privacy and cybersecurity issues, data provenance disputes, and infringement or misappropriation claims. The legal landscape for AI-generated inventions remains uncertain, and development of the law in the U.S. and abroad could impact our ability to enforce proprietary rights or protect against infringing uses. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents.

Our employees may use AI including Gen AI in certain circumstances to perform portions of their work. There can be no assurance that our employees will not inadvertently or improperly input proprietary, confidential, or sensitive information, including trade secrets, into AI systems in a manner that results in unauthorized disclosure or loss of confidentiality. Many AI tools are provided by third-party vendors, and we may have limited ability to control or verify how information submitted by employees is processed, stored, retained, or used by such providers, including whether such information may be incorporated into model training or otherwise accessed or disclosed. Any failure to adequately prevent the disclosure or misuse of our proprietary or confidential information, whether due to employee error, inadequate controls, evolving AI system functionality, or third-party practices, could result in the loss of trade secret protection and the disclosure of confidential information related to our inventions and product candidates, which could impair or preclude our ability to obtain patent protection covering such inventions or product candidates,

or result in breaches of confidentiality obligations to our collaborators and other third parties, or violations of privacy laws.

AI, including Gen AI, may have errors or inadequacies that are not easily detectable. If the data used to train AI or the content AI applications assist in producing are deficient, inaccurate, or biased, our business may be adversely affected. We expect increasing government regulation of AI use (including the EU's AI Act which entered into force on August 1, 2024), which may significantly increase compliance costs. This legislation imposes significant obligations on providers and deployers of AI systems. The legal landscape for AI-related intellectual property remains uncertain, and development of the law could impact our ability to enforce proprietary rights.

The rapid evolution of AI (including Gen AI) may require the application of significant resources to design, develop, test and maintain these products and services to help ensure that any AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. We also may need to expend further resources to adjust our business practices, as these laws and regulations evolve, especially where requirements across jurisdictions are inconsistent. An increase in operating expenses of this nature, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our vendors or partners may in turn incorporate AI tools (including Gen AI) into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of Gen AI, to engage in illegal activities involving the theft and misuse of personal information, financial and other confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Any future proprietary technology platform may not yield protectable intellectual property. The components of such a platform, including proprietary hardware, software, and computational methods, may be difficult to protect through traditional patent means. Data rights and computational IP present unique challenges including potential for independent development by competitors using similar datasets or methodologies.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of our patent applications and any patents that we may own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we may own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we may own or license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- 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 not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than those in the United States. Moreover, obtaining this type of protection in a timely manner, or at all, may be affected by factors or events beyond our control, such as a prolonged economic downturn or global financial or political crises. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical 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. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Disclosure of this nature could have a material adverse effect on our business. In addition, certain countries outside of the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government authorities or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Government actions in certain jurisdictions, including sanctions-related measures and decrees directed at patent owners from countries such as the United States, may prevent us from obtaining, maintaining, or enforcing patent rights, or may allow third parties to use our patented inventions without compensation.

Governments may take actions that limit or eliminate patent protection or increase its cost. For example, in March 2022, the Russian government issued Decree No. 299, which provides that where the Russian government authorizes the use of a patented invention without the owner's consent, the compensation payable to owners from countries that Russia considers "unfriendly," which include the United States, is set at zero. As a result, we may be unable to obtain compensation for, or to enforce otherwise valid patent rights against, certain uses of our inventions in Russia, and we may not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions into Russia.

Sanctions imposed by the United States and other governments on Russia, and Russia's countermeasures, may also impede our ability to file, prosecute, maintain, and enforce patents in Russia. Although the U.S. Treasury Department's Office of Foreign Assets Control has authorized certain intellectual property-related transactions in Russia, including filing and prosecuting patent applications and paying maintenance fees, sanctions-related restrictions and the reluctance of financial institutions to process Russia-related payments may impede or prevent our

ability to pay local counsel and other intermediaries, which could result in the abandonment or lapse of patent applications or patents. These actions could result in the partial or complete loss of patent rights in Russia.

Other jurisdictions, including China and Brazil, also have laws under which patented inventions may be exploited without the patent owner's consent in certain circumstances, such as compulsory licensing. More generally, geopolitical developments in the United States and abroad, including sanctions, export controls, and trade measures, could increase the uncertainty and cost of prosecuting and maintaining patent applications and of maintaining, enforcing, or defending issued patents. Any of these developments could impair our competitive position in the affected jurisdictions and adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Government Regulation

Even if we are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products and biologics vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

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

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be certain that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will continue to be available for any product that we may develop that receives coverage and adequate reimbursement from one or more third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Accordingly, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. These groups have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that

coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. Specifically, the Centers for Medicare & Medicaid Services, or CMS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. The Department of Health and Human Services, or HHS, has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years and single-source biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year, up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program, and potential negative pricing effects in other market channels, on a per unit basis.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access, marketing cost disclosure, transparency measures and other measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Additionally, there may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs related to research and development, manufacturing and sale and distribution efforts. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services.

We expect to experience pricing pressures in connection with the sale of all of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Any arrangements we may have with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. Such laws and regulations may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our product candidates. In

particular, the research of our product candidates, as well as the promotion, sales, marketing and business arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other;
- the federal civil and criminal false claims laws, including the FCA, which prohibit individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to “cause” the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- furthermore, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, also imposes obligations on “covered entities,” including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective “business associates” and their respective subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the civil monetary penalties statute, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs that may be used in the calculation of reimbursement or discounts on approved products;
- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal 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 claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive licensing, record keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, financial condition, results of operations and prospects.

We may attempt to seek approval from the FDA for one or more of our product candidates through the use of the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval pathway, the FDA may approve a product candidate for a serious or life-threatening disease or condition with unmet medical need based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical

benefit. Products granted accelerated approval are subject to certain post-marketing requirements, which typically include a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product. In addition, during the pre-approval review period, FDA regulations require that sponsors of products granted accelerated approval submit copies of all promotional materials intended to be used within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the sponsor must submit all promotional materials at least 30 days prior to use. There can be no assurance that we will be able to use the accelerated approval pathway or any other form of expedited development, review or approval for any of our product candidates. For example, the FDA may not agree with our conclusion that an endpoint we select is reasonably likely to predict clinical benefit, and thus the FDA may not agree that accelerated approval is appropriate based on that endpoint (even if the results on that endpoint are statistically significant). Also, if any of our competitors were to receive full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval for any one of our product candidates, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need, and our product candidate may become ineligible for accelerated approval.

A failure to obtain accelerated approval would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Even if we are able to obtain accelerated approval, if we do not complete the required post-approval studies, or if the FDA determines that the completed post-approval studies do not confirm clinical benefit, then FDA may withdraw approval of our product using expedited procedures.

We may seek a Breakthrough Therapy or Fast Track designation for current or future product candidates, but we might not receive such designation, and even if we do, we may not maintain such designation. Such designation may not lead to faster development, regulatory review or approval, and will not increase the likelihood that the product candidate will receive marketing approval.

We may seek a Breakthrough Therapy or Fast Track designation for our current or future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biologics that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs or biologics designated as Breakthrough Therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA or BLA is submitted to the FDA. The FDA also has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. New drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied.

The FDA has broad discretion as to whether or not to grant Breakthrough Therapy or Fast Track designation to any product candidate. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy or a Fast Track designation, the FDA may disagree and instead determine not to make such a designation. Even if we receive a Breakthrough Therapy or Fast Track designation, the receipt of that designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a Breakthrough Therapy or for the Fast Track program, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. The failure to obtain a Breakthrough Therapy or Fast Track designation for any product candidates we may develop, or the inability to maintain that designation for the duration of the applicable period, could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Further, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress has considered, and may continue to consider, legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies, which create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer Most-Favored Nation, or MFN, pricing equal to or lower than those paid in other developed nations for certain prescription drugs under Medicaid and for certain newly launched products across all market channels in the U.S., with additional mandates for direct-to-patient discounts through a direct to consumer platform, or TrumpRx, and repatriation of certain foreign revenues. In January 2026, CMS launched the “GENErating cost Reductions fOr U.S.”, or GENEROUS, model under which manufacturers can provide MFN pricing to state Medicaid agencies on a voluntary basis, and CMS has announced that all state Medicaid programs, along with the District of Columbia and Puerto Rico, have applied to participate in the model. CMS also finalized the "Global Benchmark for Efficient Drug Pricing”, or GLOBE, model for products payable under Medicare Part B, set to begin January 1, 2027, and proposed the “Guarding U.S. Medicare Against Rising Drug Costs”, or GUARD, model for products covered under Medicare Part D. GLOBE implements, and GUARD, if finalized, would implement, a mandatory payment model under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of their units that are reimbursed by Medicare, with the rebate amount based on MFN pricing. The GLOBE model has been subject to legal challenge, and both the GLOBE model and the proposed GUARD model may face additional legal challenges, which could delay implementation or modify their impact on manufacturer pricing and revenue.

In addition, the current administration has taken other action that could affect our business such as (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on certain imported pharmaceutical products and components thereof; and (4) as part of the Make America Healthy Again, or MAHA, Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration has called on Congress to enact "The Great Healthcare Plan," to codify and expand MFN pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's *Loper Bright* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

We expect these and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. It is unclear what impact, if any, the current presidential administration may have on such measures. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our product candidates outside of the United States.

We plan to seek regulatory approval of our current or future product candidates outside of the United States in the future. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of any of our product candidates in certain countries. Regulatory and marketing approval in one country does not ensure regulatory and marketing approval in another, but a failure or delay in obtaining regulatory and marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The U.S. Congress, the current presidential administration or any new administration may make substantial changes to fiscal, tax, healthcare, trade and other federal policies that may adversely affect our business.

Changes to U.S. policy implemented by the U.S. Congress and new presidential administrations, including the current administration, have impacted and will in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, since the newest presidential administration has taken office, it has taken significant steps to, among other things, freeze some federal funding and reduce the size of the federal workforce. In addition, the current presidential administration has announced new tariffs on imported materials and goods from certain foreign countries, including Canada, Mexico and China. It is not possible to predict the outcome of this congressional, executive or regulatory activity, any of which could adversely affect us. Similarly, we cannot predict whether pending or future federal or state legislation or court proceedings will change various aspects of current government programs, nor can we predict the impact any changes of this nature will have on our business operations or financial results, but the effects could be materially adverse. In addition, changes in the leadership of the FDA and other federal agencies under the current presidential administration may result in changes in the funding, operations

and policies of the FDA and other federal agencies, which may negatively impact, among other things, our clinical development plans, timelines and the cost of product development.

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

Social media is increasingly being used to communicate about clinical development programs and the diseases our product candidates are being developed to treat. We may utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When disclosures of this nature occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

We are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws. Anti-corruption laws generally prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector.

We expect our non-U.S. activities to increase over time, including the engagement of third parties for clinical trials or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. persons, as well as their employees, agents and other collaborators, from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related parties for the purpose of influencing any act or decision of the foreign entity or to obtain, retain, or direct business. The FCPA also obligates companies whose securities are publicly listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all of the company's transactions, including those of its international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

Export control and economic sanctions laws may restrict, or even prohibit, the provision of certain items, technology and services to countries, governments and persons targeted by sanctions programs. Governmental regulation of the import or export of our product candidates, or our failure to obtain any required import or export authorization for our product candidates, when applicable, could harm our operations. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with Trade Laws may result in substantial civil and criminal fines and penalties, imprisonment, the loss of trade privileges, suspension or debarment from government contracting, reputational harm and other consequences. The Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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 adversely affect our business, financial condition, results of operations and prospects.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our future commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures used by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case, and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state, federal or other applicable authorities may curtail our use of certain materials or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes or our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the FDA 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.

Further, the current presidential administration has undertaken efforts to reduce the size and spending of the federal government. As part of this initiative, the administration has taken action aimed at reducing the workforce of the federal government and eliminating other expenditures, such as facility leases used by the federal government and its component agencies. While these and other actions taken by the current presidential administration could be viewed as a part of a larger goal of de-regulation, a consequence of these developments and other actions taken by the current presidential administration generally could be reduced resources, employees and contractors at the FDA. In addition, these efforts have led to a number of experienced government officials being fired, resigning from or otherwise departing government service, including many with significant institutional knowledge.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business, financial condition, results of operations and prospects. For example, over the last several years, the U.S. government has shut down several times, including for an extended period in 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If another prolonged government shutdown occurs or there are other changes which limit the FDA's ability to perform its necessary activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Data Privacy and Information Security

If our information technology systems, or those used by our CROs, CMOs, clinical sites or other vendors, contractors or consultants with whom we work, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory

investigations or action, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse consequences.

In the ordinary course of our business, we, and the third parties with whom we work, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share, which we collectively refer to as process, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions and financial information, which we collectively refer to as sensitive data. As a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems, and those of the third parties with whom we work.

Our information technology systems and those of our CROs, CMOs, clinical sites and other vendors, contractors and consultants with whom we work are vulnerable to cyberattacks, computer viruses, bugs, worms or other malicious codes, malware (including as a result of advanced persistent threat intrusions) and other attacks by computer hackers, brute force attacks, application security attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks facilitated or enhanced by AI, telecommunications failures, earthquakes, fires, floods and other similar threats. Remote work has increased these risks to our information technology systems and sensitive data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit, and in public locations.

These types of threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays or outages in our operations, loss of sensitive data, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of attacks for geopolitical reasons, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain and ability to continue our research and development efforts or produce, sell and distribute our product candidates, if approved. For example, certain third parties with whom we work to support our business are located in potentially unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts, including Ukraine, which was attacked by Russia in February 2022 through various means, including cyberattacks. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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

It may be difficult or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

In addition, our reliance on third-party partners could introduce new cybersecurity risks and vulnerabilities. We rely on third-party partners and technologies to operate critical business systems and to process sensitive data in a variety of contexts, including cloud-based infrastructure, encryption and authentication technology, employee email and other functions. We also rely on third-party partners to assist with our clinical trials, provide other products or services or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party partners experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service partners fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover any such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

We actively implement measures designed to identify, protect, detect, respond to and recover from vulnerabilities within our information systems, including those related to hardware, software and third-party providers. Despite our efforts, we have not and may not in the future detect and remediate all such vulnerabilities including on a timely basis. In some cases, we have and may in the future experience delays in developing and deploying necessary remediation measures and security patches. These undetected or unaddressed vulnerabilities could be exploited, potentially leading to security incidents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. The introduction of AI has increased the sophistication of incoming attacks. We have introduced new tools to protect Odyssey from evolving threats that target human behavior. At times, however, threat actors evolve more rapidly than the tools meant to protect against them. As such, evolving threats pose a risk to the integrity of our data and cyber infrastructure.

Any of the previously identified or similar threats have in the past and may in the future cause another security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption or disclosure of, or access to, our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services, including clinical trials, or continue our target discovery programs.

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

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other vendors, contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

If any incidents of this nature were to occur and cause interruptions in our operations, it could result in a disruption of our business, operations and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in the loss of or damage to our sensitive data or applications, or inappropriate disclosure of sensitive data, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, future customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements or oversight, restrictions on processing sensitive data, litigation, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, financial loss and other similar harms. Security incidents and material attendant consequences may negatively impact our ability to grow and operate our business and may result in a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Our contracts may not always contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all or that such coverage will pay future claims. Additionally, our sensitive data could be leaked, disclosed or revealed as a result of, or in connection with, our employees', personnel's or vendors' use of generative AI and/or automated decision-making technologies.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Any actual or perceived failure to comply with these obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation (including class claims), negative publicity or other adverse consequences that could negatively affect our operating results and business.

In the ordinary course of business, we and our partners process sensitive data. As a result, we and our partners are subject to numerous data privacy and security obligations, such as various federal, state and foreign laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, numerous federal, state and local governments have enacted laws and regulations, including state data breach notification laws, state health information privacy laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or the FTCA) and other similar regulations (e.g., wiretapping) that govern the processing of sensitive data, including health-related information. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information.

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

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

privacy impact assessments. Failure to comply with these laws, where applicable, can result in significant statutory fines. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants to recover significant statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar privacy laws are being considered at the federal level, which may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Outside the United States, an increasing number of laws and regulations, including Australia's Privacy Act, the European Union's General Data Protection Regulation, or the EU GDPR, and the United Kingdom's General Data Protection Regulation, or UK GDPR, and, together with the EU GDPR, the GDPR, also apply to our processing of sensitive data, including health-related and other personal data.

The GDPR imposes stringent requirements for processing personal data. The GDPR, together with national legislation, regulations and guidelines of the European Economic Area, or EEA, member states and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements, temporary or definitive bans on data processing, private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, and potential fines for noncompliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA's standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework, or the Framework, and the United Kingdom extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom or other jurisdictions to the United States, or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA member states and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects. In addition to the foregoing, a

breach of the GDPR or other applicable data privacy, data protection and security laws and regulations could result in regulatory investigations, reputational damage and orders to cease or change our use of data, enforcement notices or potential civil claims including class-action-type litigation.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in certain transactions or agreements with certain third parties in the future.

Our employees and personnel use AI modeling and/or automated decision-making tools to assist in our discovery efforts and product development. The disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions and lawsuits. If we are unable to use AI and/or automated decision-making technologies, our drug discovery efforts may be less efficient and our ability to further expand our pipeline may be impaired.

We are bound by other contractual obligations related to data privacy and security, and our efforts to comply with those obligations may not be successful.

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

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

Compliance with U.S. and foreign data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose sensitive data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Any actual or perceived failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation or adverse publicity and could negatively affect our operating results and business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Reliance on Third Parties

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be

delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have if we were to conduct them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, these parties may have contractual relationships with other entities (some of whom may be our competitors), which may draw time and resources from our programs. For example, we rely on CROs located or operating in China and Ukraine, among others, to conduct certain of our preclinical research and discovery activities and/or our clinical trials. It is unknown how the status of current or future U.S.-China relations or the ongoing conflict in Ukraine will affect our ability to rely on these CROs to conduct our current and future preclinical studies or clinical trials.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with good laboratory practices, or GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA or BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties, including CROs. If we, our CROs, clinical trial sites or other third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCPs. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors or vendors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

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

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business, financial condition, results of operations and prospects.

We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials, samples, components and other materials for our product candidates.

Reliance on third-party CMOs may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices, including as we expand the size and number of clinical trials. In addition, replacing a CMO could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidates is subject to review by the FDA and other foreign regulatory authorities to the extent applicable. We and our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current good manufacturing practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory requirements. If any of our manufacturers fail to comply with those requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, delayed, interrupted or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do in a timely manner or on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on a CMO or require us to obtain a license from that CMO to enable us to manufacture, or to have another third party manufacture, our product candidates. If we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new CMO could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party CMOs if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory

requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMPs, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our, or a third party's, failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or other applicable foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- a delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- a loss of the cooperation of existing or future collaborators;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and
- regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, requirements to cease distribution of the products, product seizure, detention or recall, operating restrictions, suits under the civil FCA, corporate integrity agreements, consent decrees or withdrawal of product approval.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes, unstable political environments, natural disasters, epidemics or outbreaks, among other things. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants if approved, would be jeopardized.

The operations of our suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Certain of our suppliers are located outside of the United States. As a result, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, inhibit our suppliers' ability to procure certain materials or delay or increase the cost of certain preclinical development programs, any of which could harm our business, financial condition, results of operations and prospects.

We have entered, and may in the future enter into additional, collaborations or licensing arrangements, which are important to our business. If we are unable to enter into new collaborations or licenses, or if we fail to realize the benefits of any current or future collaborations or licensing arrangements, our business, financial condition, results of operations and prospects could be adversely affected.

A key part of our strategy is to strategically evaluate and, as we deem appropriate, enter into collaborations or partnerships, including with major biotechnology or pharmaceutical companies to advance our current or future product candidates. We have previously entered into collaborations with Pfizer Inc., or Pfizer, J&J and Terray to conduct various research and development activities. Our agreement with Pfizer expired by its terms in 2025 and, as of the date of this Quarterly Report, we do not anticipate generating any additional revenue from our agreements with either Pfizer or J&J. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may continue to enter into collaborations with other companies in the future to provide us with funding for our programs and technology. Any of our existing or future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our current product candidates are designed to address targets that we believe are of high interest to pharmaceutical partners.

Our current collaborations and any future collaborations we enter into pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial or test results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates, if approved;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing, manufacturing and distribution rights to one or more of our product candidates that achieve regulatory approval, if any, may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out the marketing and distribution of such product or products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or future commercialization of product candidates, if approved, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may seek to amend or modify the terms of any collaboration;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in such a way as to invite actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or future commercialization of any product candidate licensed to it by us.

If our collaborations do not result in the successful discovery, development and future commercialization of product candidates, if approved, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments we are owed under such collaboration and could be required to raise additional capital to pursue further development or future commercialization of the applicable product candidates. Additionally, if one of our collaborators terminates its agreement with us, we may lose rights that are important to our business or find it more difficult to attract new collaborators, and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies.

Collaborations are complex, expensive and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Additionally, our collaboration agreements may contain non-competition provisions that could limit our ability to enter into strategic collaborations with future collaborators or restrict our ability to commercialize products on our own, if approved.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, if approved, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or future commercialization activities at our own expense. If we elect to increase our expenditures to fund development or future commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and future commercialization activities, we may not be able to further develop our product candidates, bring them to market, if approved, and generate revenue from sales of drugs or continue to develop our technology, and our business, financial condition, results of operations and prospects could be adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of any approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and future commercialization of our product candidates, if approved, and reduce their competitiveness even if they reach the market.

Risks Related to Ownership of Our Common Stock

If we fail to maintain an effective system of internal control over financial reporting or disclosure controls, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which is likely to negatively affect our business and the market price of our common stock.

As a public company, we are subject to the periodic reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which requires that we maintain effective disclosure controls and

procedures and internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States. Effective internal control over financial reporting and disclosure controls are necessary for us to provide reliable financial reports, prevent fraud and comply with our Exchange Act reporting obligations, and efforts to ensure that there are effective internal control over financial reporting and disclosure controls are costly, time-consuming, and need to be re-evaluated frequently. In addition, any testing conducted by us, or any testing conducted by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

We must also design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any failure to remediate any material weakness or develop or maintain effective controls when we become subject to this requirement could negatively affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that we will be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline as a result. In addition, if we are unable to continue to meet these requirements, we may be delisted from Nasdaq.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of (i) our second annual report or (ii) the first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the JOBS Act or a “smaller reporting company” as defined by the SEC.

Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, we may not be able to produce timely and accurate financial statements or detect acts of fraud. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

Our stock price may be volatile, which could result in substantial losses for investors.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- volatility and instability in the financial and capital markets;
- announcements by competitors that impact our competitive outlook;
- developments with respect to our product candidates, or similar products or product candidates against which we compete;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates;
- additions or departures of key personnel;
- developments with respect to patents or other intellectual property rights;

- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, dispositions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equity research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales or the perception of potential sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- regulatory developments within, and outside of, the United States, including changes in the structure of healthcare payment systems;
- litigation or arbitration;
- pandemics, natural disasters or major catastrophic events; and
- general economic, political and market conditions and other factors, including any such changes specific to the pharmaceutical and biotechnology sectors.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention.

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is likely to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Our directors or officers may in the future also become involved in securities or other litigation in the context of any roles with other public companies. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from, any such proceeding) can be expensive and time-consuming, damage our reputation and divert our management's and board of directors' attention from other business concerns, which could seriously harm our business, financial condition, results of operations and prospects.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations that may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including, among other things, the results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such preclinical studies or clinical trials.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our Certificate of Incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Certificate of Incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

We may engage in a variety of strategic transactions, including acquisitions, dispositions, joint ventures or making investments in other companies or technologies, that could negatively affect our operating results, dilute our stockholders' ownership, create or increase indebtedness or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, or businesses, dispose of certain of our product candidates or businesses and enter into strategic alliances, joint ventures and collaborations, all in order to expand our existing technologies and operations or otherwise generate capital to advance our product candidates.

Any potential transaction may entail numerous risks, including:

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

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we engage in a disposition, we may have difficulty replacing the assets we sold or in separating our continuing operations from those of the business we sold. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a

cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance certain transactions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our common stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Upon the expiration of lock-up and market standoff agreements entered into prior to or in connection with our IPO, an additional 27,098,614 shares of our common stock became eligible for sale in the public market (some of which are held by directors, executive officers and other affiliates and remain subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act).

In addition, the shares of our common stock that are subject to outstanding options under our 2021 Plan and 2026 Plan are eligible for sale in the public market, to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 29,662,867 shares of our outstanding common stock, or approximately 59.9% of our total outstanding common stock following our IPO, have certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading price of our common stock.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into or exercisable for common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

Our principal stockholders and management own a significant percentage of our common stock and will be able to control matters subject to stockholder approval.

Following our IPO, our executive officers and directors collectively own a significant percentage of our outstanding voting stock. As a result, any stockholders who own more than 5% or more of our capital stock, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation, or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent our change of control, even if a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or of our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may

adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We plan to hire additional financial reporting, internal control and other finance personnel or consultants in order to develop and implement appropriate internal control and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

Our ability to use our net operating loss, or NOL, carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had U.S. federal NOL carryforwards of approximately $240.4 million and research and development credits of approximately $16.8 million, and state NOL carryforwards of approximately $171.0 million and research and development credits of approximately $7.4 million. Under the Internal Revenue Code of 1986, as amended, or the Code, our U.S. federal NOL carryforwards will not expire and may be carried forward indefinitely but the deductibility of such NOL carryforwards is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study; however, we have completed several fundraises in recent years, increasing the likelihood that there have been changes in our ownership that would limit our ability to utilize our tax attribute carryforwards. Furthermore, there may be additional ownership changes in the future, some of which may be outside of our control. If we have undergone or undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase our state taxes owed. As a result, even if we attain profitability, we may be unable to use all

or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect us.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect us. For example, the Tax Cuts and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act, the Inflation Reduction Act of 2022, or the IRA, and the OBBBA enacted many significant changes to U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission) have proposed, recommended or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in this Quarterly Report and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700.0 million, measured on the last business day of our second fiscal quarter, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year, in which cases we would no longer be an emerging growth company as of the last day of the fiscal year, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

Anti-takeover provisions in our organizational documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Each of our Certificate of Incorporation and Bylaws contain provisions that could delay or prevent a change in control of Odyssey. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our Bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our capital stock entitled to vote generally in the election of directors, voting as a single class;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock entitled to vote generally in the election of directors, voting as a single class, for a stockholder amendment to our Bylaws (absent approval of our board of directors) and to amend specific provisions of our Certificate of Incorporation; and
- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, Section 203 of General Corporation Law of the State of Delaware, or the DGCL, may discourage, delay or prevent a change in control of us. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Our Certificate of Incorporation designates certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation provides that, to the fullest extent permitted by law, derivative actions brought in our name or actions against directors, officers and employees for breach of fiduciary duty, arising pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws, or governed by the internal affairs doctrine, or actions brought by stockholders that do not constitute internal corporate claims under the DGCL, if such claim relates to our business, the conduct of our affairs, or our rights or powers or our stockholders, directors or officers, may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel except any action (i) as to which the Court of Chancery in the State of Delaware determines that there is an indispensable party

not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within 10 days following such determination), (ii) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or (iii) for which the Court of Chancery does not have subject matter jurisdiction. In addition, our Certificate of Incorporation designates the federal district courts of the United States as the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act; however, such exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act. The validity and enforceability of such provision is uncertain in a number of courts other than the Delaware Supreme Court and certain other state courts.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations promulgated thereunder.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the frequency of or content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us or do not publish reports on us on a regular basis, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Ninth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-43270), filed on May 11, 2026).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-295141), filed on April 17, 2026).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-295141), filed on April 17, 2026).
4.2	Warrant to Purchase Stock, issued to Banc of California (formerly Pacific Western Bank) (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-295141), filed on April 17, 2026).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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.

Odyssey Therapeutics, Inc.

Date: November 4, 2026

By: /s/ Gary D. Glick
Gary D. Glick, Ph.D.
President and Chief Executive Officer

Date: November 4, 2026

By: /s/ Jason Haas
Jason Haas
Chief Financial Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary D. Glick , certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Odyssey Therapeutics 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 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 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: November 4, 2026

By: /s/ Gary D. Glick

Gary D. Glick, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason Haas, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Odyssey Therapeutics 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 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 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: November 4, 2026

By: /s/ Jason Haas
Jason Haas
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

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 on Form 10-Q of Odyssey Therapeutics Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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: November 4, 2026

By: /s/ Gary D. Glick

Gary D. Glick, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 on Form 10-Q of Odyssey Therapeutics Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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: November 4, 2026

By: /s/ Jason Haas
Jason Haas
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)