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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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: 001-40431

DAY ONE BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2415215**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2000 Sierra Point Parkway, Suite 501 Brisbane, CA	**94005**
(Address of principal executive offices)	**(Zip Code)**

(650) 484-0899

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**DAWN**	**Nasdaq Global Select Market**

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

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

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

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

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

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

As of November 1, 2023, the registrant had 87,042,933 shares of common stock, $0.0001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of our product candidates, potential therapeutic benefits and economic value of our product candidates, use of net proceeds from our public offerings, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of nonclinical studies and clinical trials, commercial collaboration with third parties, and our ability to recognize milestone and royalty payments from commercialization agreements, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, cybersecurity incidents, instability in the global banking system, government shutdowns, uncertainty with respect to the federal budget and global regional conflicts on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “predict,” “target,” “intend,” “could,” “would,” “should,” “project,” “plan,” “expect,” and other similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context indicates otherwise, as used in this Quarterly Report on Form 10-Q, the terms “Day One,” “the Company,” “we,” “us,” and “our” refer to Day One Biopharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole, unless otherwise noted. “Day One” and all product candidate names are our common law trademarks. This Quarterly Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Table of Contents

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share amounts)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 241,179	$ 85,262
Short-term investments	164,359	257,007
Prepaid expenses and other current assets	7,753	5,605
Total current assets	413,291	347,874
Property and equipment, net	213	20
Operating lease right-of-use asset	442	699
Deposits and other long-term assets	233	469
Total assets	$ 414,179	$ 349,062
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,391	$ 260
Accrued expenses and other current liabilities	20,647	15,950
Current portion of operating lease liabilities	437	405
Total current liabilities	24,475	16,615
Long-term portion of lease liabilities	77	408
Total liabilities	24,552	17,023
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 87,042,933 and 73,458,176 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	9	7
Additional paid-in-capital	793,699	601,771
Accumulated other comprehensive loss	(7)	(71)
Accumulated deficit	(404,074)	(269,668)
Total stockholders' equity	389,627	332,039
Total liabilities and stockholders' equity	$ 414,179	$ 349,062

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 33,163	$ 22,035	$ 93,173	$ 59,598
General and administrative	18,275	17,664	53,374	44,568
Total operating expenses	51,438	39,699	146,547	104,166
Loss from operations	(51,438)	(39,699)	(146,547)	(104,166)
Investment income, net	5,291	1,895	12,163	2,086
Other (expense) income, net	(3)	9	(22)	8
Net loss attributable to common stockholders	(46,150)	(37,795)	(134,406)	(102,072)
Net loss per share, basic and diluted	$ (0.54)	$ (0.53)	$ (1.73)	$ (1.61)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	85,952,501	71,008,993	77,682,237	63,522,774

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (46,150)	$ (37,795)	$ (134,406)	$ (102,072)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	2	(389)	64	(392)
Total comprehensive loss	$ (46,148)	$ (38,184)	$ (134,342)	$ (102,464)

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Shares		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Equity
Balance at December 31, 2022	73,458,176	$ 7	$ 601,771	$ (71)	$ (269,668)	$ 332,039
Issuance of common stock upon exercise of stock options	75,184	—	1,184	—	—	1,184
Issuance of common stock upon release of restricted stock units	60,673	—	—	—	—	—
Unvested common stock forfeiture	(21,400)	—	—	—	—	—
Share-based compensation expenses	—	—	9,447	—	—	9,447
Unrealized gain on available-for-sale securities	—	—	—	138	—	138
Net loss attributable to common stockholders	—	—	—	—	(42,393)	(42,393)
Balance at March 31, 2023	73,572,633	7	612,402	67	(312,061)	300,415
Issuance of common stock pursuant to follow-on offering, net of issuance costs of $10,827	13,269,231	2	161,407	—	—	161,409
Issuance of common stock upon exercise of stock options	2,704	—	39	—	—	39
Issuance of common stock upon release of restricted stock units	69,020	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	57,740	—	653	—	—	653
Share-based compensation expenses	—	—	9,477	—	—	9,477
Unrealized loss on available-for-sale securities	—	—	—	(76)	—	(76)
Net loss attributable to common stockholders	—	—	—	—	(45,863)	(45,863)
Balance at June 30, 2023	86,971,328	9	783,978	(9)	(357,924)	426,054
Issuance of common stock upon exercise of stock options	10,571	—	115	—	—	115
Issuance of common stock upon release of restricted stock units	61,034	—	—	—	—	—
Share-based compensation expenses	—	—	9,606	—	—	9,606
Unrealized gain on available-for-sale securities	—	—	—	2	—	2
Net loss attributable to common stockholders	—	—	—	—	(46,150)	(46,150)
Balance at September 30, 2023	87,042,933	$ 9	$ 793,699	$ (7)	$ (404,074)	$ 389,627

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Shares		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Deficit	Equity
Balance at December 31, 2021	61,952,292	$ 6	$ 408,629	$ —	$ (127,487)	$ 281,148
Share-based compensation expenses	—	—	6,202	—	—	6,202
Unvested common stock forfeiture	(40,363)	—	—	—	—	—
Net loss attributable to common stockholders	—	—	—	—	(27,747)	(27,747)
Balance at March 31, 2022	61,911,929	6	414,831	—	(155,234)	259,603
Issuance of common stock pursuant to follow-on offering, net of issuance costs of $10,864	11,500,000	1	161,609	—	—	161,610
Issuance of common stock pursuant to Employee Stock Purchase Plan	49,171	—	320	—	—	320
Share-based compensation expenses	—	—	5,631	—	—	5,631
Unrealized loss on available-for-sale securities	—	—	—	(3)	—	(3)
Net loss attributable to common stockholders	—	—	—	—	(36,530)	(36,530)
Balance at June 30, 2022	73,461,100	$ 7	$ 582,391	$ (3)	$ (191,764)	$ 390,631
Issuance of common stock upon exercise of stock options	130,899	—	2,053	—	—	2,053
Issuance of common stock upon release of restricted stock units	51,030	—	—	—	—	—
Unvested common stock forfeiture	(131,106)	—	—	—	—	—
Share-based compensation expenses	—	—	8,576	—	—	8,576
Unrealized loss on available-for-sale securities	—	—	—	(389)	—	(389)
Net loss attributable to common stockholders	—	—	—	—	(37,795)	(37,795)
Balance at September 30, 2022	73,511,923	$ 7	$ 593,020	$ (392)	$ (229,559)	$ 363,076

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (134,406)	$ (102,072)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development assets	3,000	—
Share-based compensation expense	28,530	20,409
Depreciation expense	23	48
Accretion of discounts on short-term investments	(8,502)	(1,031)
Amortization of operating right-of-use assets	257	303
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,148)	(1,113)
Deposits and other long-term assets	236	(280)
Accounts payable	3,131	2,229
Accrued expenses and other current liabilities	4,697	7,127
Operating lease liabilities	(299)	(184)
Net cash used in operating activities	(105,481)	(74,564)
Cash flows from investing activities:		
Cash paid for purchase of short-term investments	(344,701)	(272,838)
Proceeds from maturity of short-term investments	445,915	20,000
Cash paid for purchase of property and equipment	(216)	(26)
Cash paid for acquired in-process research and development assets	(3,000)	—
Net cash provided by (used in) investing activities	97,998	(252,864)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	161,409	161,610
Proceeds from issuance of common stock upon stock option exercises	1,338	2,053
Proceeds from issuance of common stock upon Employee Stock Purchase Plan purchase	653	320
Cash provided by financing activities	163,400	163,983
Net increase (decrease) in cash and cash equivalents	155,917	(163,445)
Cash and cash equivalents, beginning of period	85,262	284,309
Cash and cash equivalents, end of period	$ 241,179	$ 120,864
Supplemental disclosures of noncash activities:		
Purchases of property and equipment included in accrued expenses and other current liabilities	$ 41	$ —
Lease liability obtained in exchange for right-of-use asset	$ —	$ 940

See accompanying notes to the condensed consolidated financial statements.

Day One Biopharmaceuticals, Inc.
Notes to the Condensed Consolidated Financial Statements

1. Description of Business and Organization

Organization and Business

Day One Biopharmaceuticals, Inc., or the Company, is a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases. The Company was formed as a limited liability company under the laws of the State of Delaware in November 2018, under the name Hero Therapeutics Holding Company, LLC. Subsequently, the Company changed its name to Day One Therapeutics Holding Company, LLC in December 2018 and to Day One Biopharmaceuticals Holding Company, LLC, or Day One Holding LLC, in March 2020.

On May 26, 2021, the Company completed a conversion by filing a certificate of conversion with the Secretary of State of the State of Delaware and changed its name to Day One Biopharmaceuticals, Inc.

2. Summary of Significant Accounting Policies

There have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's annual consolidated financial statements for the years ended December 31, 2022 and 2021, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of the Company's financial statements for interim periods presented in accordance with U.S. GAAP. The condensed consolidated balance sheet as of December 31, 2022 was derived from audited annual financial statements but does not include all disclosures required by U.S. GAAP. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2022 included in the Annual Report on Form 10-K for the year ended December 31, 2022. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the full year or any other future periods.

The Company's significant accounting policies are described in Note 2 of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, of the Financial Accounting Standards Board, or FASB.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to, the valuation of share-based awards, the valuation of deferred tax assets and income tax uncertainties, and accruals for research and development activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

Segments

The Company has determined that its chief executive officer is the chief operating decision maker, or CODM. The Company operates and manages the business as one reporting and one operating segment, which is the business of identifying and advancing targeted therapies for people of all ages with genomically defined cancers. The Company's CODM reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's assets are located in the United States.

Concentration of credit risk and other risks and uncertainties

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. Amounts on deposit may at times exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and short-term investments that are recorded on its balance sheet. Per policy, the Company mitigates its risk by investing in high-grade instruments and limiting the concentration in any one issuer, which limits its exposure. The Company has not experienced any losses on its cash, cash equivalents and short-term investments.

The Company is subject to certain risks and uncertainties and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position or results of its operations: ability to obtain future financing; regulatory requirements for approval and market acceptance of, and reimbursement for, product candidates; performance of third-party clinical research organizations and manufacturers upon which the Company relies; development of sales channels; protection of the Company's intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; changes to the market landscape; and the Company's ability to attract and retain employees necessary to support its growth.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. The JOBS Act also exempts **emerging growth** companies from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

The JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies. The Company expects to use the extended transition period for any other new or revised accounting standards during the period in which it remains an emerging growth company.

On the last business day of the second quarter of 2023, the aggregate market value of the shares of the Company's common stock held by non-affiliate stockholders exceeded $700 million. As a result, the Company will be considered a "large accelerated filer" as of December 31, 2023, and no longer qualify as an emerging growth company. Therefore, the Company will no longer be able to take advantage of the exemptions from various reporting requirements, beginning with its Annual Report on Form 10-K for the fiscal year ending December 31, 2023 to be filed in 2024.

3. Recurring Fair Value Measurements

The following table sets forth the Company's financial instruments as of September 30, 2023 and December 31, 2022, which are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 165,002	$ —	$ —	$ 165,002
U.S. treasury securities	—	150,963	—	150,963
U.S. government agency securities	—	82,164	—	82,164
Total assets measured at fair value	$ 165,002	$ 233,127	$ —	$ 398,129

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 18,765	$ —	$ —	$ 18,765
U.S. treasury securities	—	145,785	—	145,785
U.S. government agency securities	—	136,022	—	136,022
Total assets measured at fair value	$ 18,765	$ 281,807	$ —	$ 300,572

The Company's money market funds are classified as Level 1 because they are measured using observable inputs from active markets for identical assets.

The Company's U.S. treasury securities and U.S. government agency securities are classified as Level 2 because they are measured with inputs that are either directly or indirectly observable for the asset which include quoted prices for similar assets in active markets and quoted prices for identical or similar assets in markets that are not active.

There were no assets or liabilities classified as Level 3 as of September 30, 2023 and December 31, 2022.

There were no transfers between Level 1, Level 2 or Level 3 categories during the periods presented.

The following tables summarize the estimated fair value of the Company's cash equivalents, available-for-sale securities classified as short-term investments, and associated unrealized gains and losses (in thousands):

	September 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 165,002	$ —	$ —	$ 165,002
U.S. government agency securities	36,341	—	—	36,341
U.S. treasury securities	32,427	—	—	32,427
Total cash equivalents	233,770	—	—	233,770
Short-term investments				
U.S. treasury securities	118,544	6	(14)	118,536
U.S. government agency securities	45,821	5	(3)	45,823
Total short-term investments	$ 164,365	$ 11	$ (17)	$ 164,359

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 18,765	$ —	$ —	$ 18,765
U.S. government agency securities	24,800	—	—	24,800
Total cash equivalents	43,565	—	—	43,565
Short-term investments				
U.S. treasury securities	145,880	1	(96)	145,785
U.S. government agency securities	111,197	37	(12)	111,222
Total short-term investments	$ 257,077	$ 38	$ (108)	$ 257,007

The following table summarizes the maturities of our cash equivalents and available-for-sale securities (in thousands):

	September 30, 2023	
	Amortized Cost	Fair Value
Mature in one year or less	$ 398,135	$ 398,129
Total	$ 398,135	$ 398,129

	December 31, 2022	
	Amortized Cost	Fair Value
Mature in one year or less	$ 300,642	$ 300,572
Total	$ 300,642	$ 300,572

The following table presents the breakdown of the Company's available-for-sale securities with gross unrealized losses and the duration that those losses had been unrealized (in thousands):

	September 30, 2023					
	Unrealized Losses Less Than 12 Months		Unrealized Losses 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Financial assets:						
U.S. treasury securities	$ 57,367	$ (14)	$ —	$ —	$ 57,367	$ (14)
U.S. government agency securities	17,945	(3)	—	—	17,945	(3)
Total financial assets	$ 75,312	$ (17)	$ —	$ —	$ 75,312	$ (17)

	December 31, 2022					
	Unrealized Losses Less Than 12 Months		Unrealized Losses 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Financial assets:						
U.S. treasury securities	$ 140,822	$ (96)	$ —	$ —	$ 140,822	$ (96)
U.S. government agency securities	26,811	(12)	—	—	26,811	(12)
Total financial assets	$ 167,633	$ (108)	$ —	$ —	$ 167,633	$ (108)

The Company regularly reviews the changes to the rating of its securities and monitors the surrounding economic conditions to assess the risk of expected credit losses. As of September 30, 2023 and December 31, 2022, there were no securities that were in an unrealized loss position for more than 12 months. As of September 30, 2023, the unrealized losses on the Company’s investments in U.S. treasury securities and U.S. government agency securities were primarily caused by interest rate increases. The Company does not expect the issuers to settle any security at a price less than the amortized cost basis of the investment with the contractual cash flows of these investments guaranteed by the issuer. No allowance for credit losses has been recorded since it is not more-likely-than-not that the Company will be required to sell the investments before recovery of their amortized cost basis.

4. Balance Sheet Items

Prepaid Expenses and Other Current Assets

Prepaid and other current assets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid research and development expenses	$ 4,075	$ 3,007
Prepaid insurance	1,453	1,592
Other prepaid expenses and other assets	2,225	1,006
Total prepaid expenses and other current assets	$ 7,753	$ 5,605

Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Leasehold improvements	$ 81	$ 26
Laboratory equipment	162	—
Property and equipment, gross	243	26
Less: accumulated depreciation	(30)	(6)
Property and equipment, net	$ 213	$ 20

Depreciation expense for each of the three and nine months ended September 30, 2023 and 2022 was immaterial.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued research and development expenses	$ 10,705	$ 7,554
Accrued payroll related expenses	$ 7,001	6,129
Accrued professional service expenses	$ 2,532	2,088
Other	$ 409	179
Total accrued expenses and other current liabilities	$ 20,647	$ 15,950

5. Significant Agreements

Research Collaboration and License Agreement with Sprint Bioscience AB

On August 15, 2023, the Company entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to the Company an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of Vaccinia Related Kinase 1, or VRK1.

The Company paid $3.0 million upfront in cash to Sprint, which was recorded as research and development expenses as the technology does not have an alternative future use, in the three and nine months ended September 30, 2023. The Company is required to make milestone payments of up to $74.0 million upon achievement of specified research, development, and regulatory milestones for each licensed product and sales milestone payments of up to $235.0 million upon achievement of specified sales milestones for each licensed product. Commencing on the first commercial sale of a licensed product in a country, the Company is obligated to pay tiered royalties ranging in the single-digit percentages on net sales of licensed products, if any. The obligation to pay royalties on a country-by-country and licensed product-by-licensed product basis commences on the first commercial sale in a country and continuing until the later of: (i) the expiration of the last valid claim of the Sprint or the Company's patents that claims the composition of matter of the licensed compound of such licensed product in such country, (ii) the 10th anniversary of the date of the first commercial sale of such licensed product in such country, and (iii) termination or expiration of regulatory exclusivity for such licensed product in such country. No milestones were achieved and due as of September 30, 2023.

The term of the Sprint License Agreement will expire on a licensed product and country basis upon the expiration of the royalty term with respect to such licensed product and such country, unless terminated earlier. The Company has the right to terminate the Sprint License Agreement in its entirety, or on a licensed product-by-licensed product basis, at will upon a specified notice period.

License Agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, DOT Therapeutics-2, Inc., or DOT-2, the Company’s subsidiary, entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Under the MRKDG License Agreement, Merck KGaA, Darmstadt, Germany granted to the Company an exclusive worldwide license, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to research, develop, manufacture and commercialize products containing and comprising the pimasertib and MSC2015103B compounds. The Company also received clinical inventory supplies to use in its research and development activities. The Company’s exclusive license grant is subject to a non-exclusive license granted by Merck KGaA, Darmstadt, Germany’s affiliate to a cancer research organization and Merck KGaA, Darmstadt, Germany retains the right to conduct, directly or indirectly, certain ongoing clinical studies relating to pimasertib.

Under the MRKDG License Agreement, the Company has obligations to use commercially reasonable efforts to develop and commercialize at least two licensed products in at least two specified major market countries by the year 2029.

In consideration for the rights granted under the MRKDG License Agreement and clinical supplies, the Company made an upfront payment of $8.0 million, which was recorded as research and development expenses, as the technology does not have an alternative future use and supplies are used for research activities. Additionally, the Company made a milestone payment of $2.5 million, which was recorded as research and development expenses due to the nature of the license agreement and the milestone event relating to the first dosing of a patient in a first clinical trial of a product containing pimasertib, in the year ended December 31, 2022. The Company may also be required to make additional payments of up to $364.5 million based upon the achievement of specified development, regulatory, and commercial milestones, as well as a high, single-digit royalty percentage on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due. No milestones were achieved and due as of September 30, 2023.

The term of the MRKDG License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company's obligation to pay royalties to the licensor with respect to such licensed product in such country and will expire in its entirety upon the expiration of all of the Company's payment obligations with respect to all licensed products and all countries under the MRKDG License Agreement.

Effective December 31, 2021, DOT-2 was merged with and into the Company, with the Company being the surviving corporation and assuming DOT-2's obligations under the MRKDG License Agreement.

Takeda Asset Purchase Agreement

On December 16, 2019, DOT Therapeutics-1, Inc., or DOT-1, the Company's subsidiary, entered into an asset purchase agreement, or the Takeda Asset Agreement, with Millennium Pharmaceuticals, Inc., a related party and an affiliate of Takeda Pharmaceutical Company Limited, or Takeda. Pursuant to the Takeda Asset Agreement, DOT-1 purchased certain technology rights and know-how related to TAK-580 (which is now tovorafenib (DAY101)) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. DOT-1 also received clinical inventory supplies to use in the Company's research and development activities of such RAF-inhibitor and an assigned investigator clinical trial agreement. Takeda also assigned to DOT-1 its exclusive license agreement, or the Viracta License Agreement, with Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.), or Viracta. Takeda also granted DOT-1 a worldwide, sublicensable exclusive license under specified patents and know-how and non-exclusive license under other patents and know-how generated by Takeda under the Takeda Asset Agreement. The Company also granted Takeda a grant back license, as defined in the Takeda Asset Agreement, which is terminable either automatically or by DOT-1 in the event Takeda does not achieve specified development milestones within the applicable timeframes set forth under the Takeda Asset Agreement. This grant back license to Takeda was terminated at the time of Conversion in connection with the Millennium Stock Exchange Agreement.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, DOT-1 made an upfront payment of $1.0 million in cash and issued 9,857,143 shares of Series A redeemable convertible preferred stock in DOT-1 in December 2019. The fair value of issued shares was estimated as $9.9 million, based on the price paid by other investors for issued shares in the Series A financing of DOT-1. Based on the terms of the Millennium Stock Exchange Agreement, Takeda exchanged the 9,857,143 shares of Series A redeemable convertible preferred stock of DOT-1 for 6,470,382 shares of the Company's common stock upon the effectiveness of the Conversion, on May 26, 2021.

The term of the Takeda Asset Agreement will expire on a country-by-country basis upon expiration of all assigned patent rights and all licensed patent rights in such country. Takeda may terminate the Takeda Asset Agreement prior to the Company's first commercial sale of a product if we cease conducting any development activities for a continuous and specified period of time and such cessation is not agreed upon by the parties and is not done in response to guidance from a regulatory authority. Additionally, Takeda can terminate the Takeda Asset Agreement in the event of the Company's bankruptcy. In the event of termination of the Takeda Asset Agreement by Takeda as a result of our cessation of development or bankruptcy, all assigned patents, know-how and contracts (other than the Viracta License Agreement) will be assigned back to Takeda and Takeda will obtain a reversion license under patents and know-how generated to exploit all such terminated products.

Effective December 31, 2021, DOT-1 was merged with and into the Company, with the Company being the surviving corporation and assuming DOT-1's obligations under the Takeda Assets Purchase Agreement.

Viracta License Agreement

On December 16, 2019, DOT-1 amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Under the Viracta License Agreement, DOT-1 received a worldwide exclusive license under specified patent rights and know-how to develop, use, manufacture, and commercialize products containing compounds binding the RAF protein family.

DOT-1 paid $2.0 million upfront in cash to Viracta, which was recorded as research and development expenses in 2019. DOT-1 made a milestone payment of $3.0 million to Viracta in February 2021, which was recorded as research and development expense when the milestone was achieved in April 2021. DOT-1 is also required to make additional milestone payments of up to $54.0 million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication to achieve a specified milestone event being lower than milestones payable for the first indication. Additionally, if DOT-1 obtains a priority review voucher with respect to a licensed product and sells such priority review voucher to a third party or uses such priority review voucher, DOT-1 is obligated to pay Viracta a specified percentage in the mid-teen digits of all net consideration received from any such sale or of the value of such used priority review voucher, as applicable. Commencing on the first commercial sale of a licensed product in a country, DOT-1 is obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products, if any. The obligation to pay royalties will end on a country-by-country and licensed product-by-licensed product basis commencing on the first commercial sale in a country and continuing until the later of: (i) the expiration of the last valid claim of the Viracta licensed patents, jointly owned collaboration patents or specified patents owned by the Company covering the use or sale of such product in such country, (ii) the expiration of the last statutory exclusivity pertaining to such product in such country or (iii) the tenth anniversary of the first commercial sale of such product in such country. No milestones were achieved and due as of September 30, 2023. Subsequent to September 30, 2023, a milestone related to the Viracta License Agreement was achieved and recorded to research and development expense as disclosed in Note 11.

The term of the Viracta License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company’s obligation to pay royalties to Viracta with respect to such product in such country. DOT-1 has the right to terminate the Viracta License Agreement with respect to any or all of the licensed products at will upon a specified notice period.

Effective December 31, 2021, DOT-1 was merged with and into the Company, with the Company being the surviving corporation and assuming DOT-1’s obligations under Viracta License Agreement.

6. Commitments and Contingencies

Leases

In April 2022, the Company entered into a lease agreement for approximately 12,000 square feet of general use office space in Brisbane, California. Such agreement was determined to be a lease since the right to control the use of the identified asset was conveyed to the Company for a period of time in exchange for consideration. The term of the lease is 31 months and commenced in May 2022. There is no option to extend the lease term nor is there an option to terminate the lease term prior to its expiration. The Company is obligated to pay monthly rent expense and its pro rata share of the landlord's operating expenses which include utilities, common area maintenance expenses, and property taxes. Such expenses are a non-lease component and a variable consideration and included in the Company's operating expenses as incurred. The Company concluded that this lease is also an operating lease. The total payments for base rent over the term of the lease is approximately $1.1 million. Upon execution of the agreement, the Company paid a security deposit of approximately $40,000 classified as deposits and other long-term assets on the condensed consolidated balance sheets.

The Company determined the lease incremental borrowing rate, or IBR, based on the information available at the applicable lease commencement date as the Company’s leases do not provide an implicit rate. The IBR is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment where the asset is located. As of September 30, 2023, the weighted-average remaining lease term and weighted-average discount rate were 1.2 years and 9.0%, respectively.

The Company’s lease does not require any contingent rental payments, impose financial restrictions, or contain any residual value guarantees.

Lease expense of right-of-use assets is recognized on a straight-line basis over the applicable lease term. Lease expense was $0.1 million for each of the three months ended September 30, 2023 and 2022 and was $0.3 million for each of the nine months ended September 30, 2023 and 2022. Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million and $0.2 million for the nine months ended September 30, 2023 and 2022, respectively. Variable payments expensed during the three and nine months ended September 30, 2023 and 2022 were immaterial.

As of September 30, 2023, the future lease obligations were as follows (in thousands):

	September 30, 2023
Remaining in 2023	$ 115
2024	424
Total future minimum lease payments	539
Less: Imputed interest	(25)
Present value of operating lease liabilities	514
Less: current portion of operating lease liabilities	(437)
Operating lease liabilities	$ 77

Research and Development Agreements

The Company enters into contracts in the normal course of business with clinical research organizations, contract manufacturing organizations, and other third-party vendors for clinical trial, manufacturing, testing, and other research and development activities. These contracts generally provide for termination on notice, with the exception of one vendor where certain costs are non-cancellable after the approval of the project. As of September 30, 2023 and December 31, 2022, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

The Company entered into the license agreements, as disclosed in Note 5, or the license agreements, pursuant to which the Company is required to pay milestones contingent upon meeting specific events. A milestone related to the MRKDG License Agreement was achieved and recorded to research and development during the nine months ended September 30, 2022. Subsequent to September 30, 2023, a milestone related to the Viracta License Agreement was achieved and recorded to research and development expense as disclosed in Note 11. The Company may be required to pay royalties on sales of products developed under these license agreements. All products are in development as of September 30, 2023, and no such royalties were due.

Purchase Commitments

To support product needs for tovorafenib (DAY101), the Company has entered into a manufacturing and supply agreement with Quotient Sciences - Philadelphia, LLC, or Quotient, in July 2023 that requires the Company to meet minimum purchase obligations on an annual basis. The amount of future minimum purchase obligations under the manufacturing and supply agreement over the next five years is approximately $17.2 million, in aggregate, as of September 30, 2023. For the three and nine months ended September 30, 2023, the Company has not yet made any purchases under the purchase obligation.

Legal Proceedings

The Company, from time to time, may be party to litigation, claims and assessments arising in the ordinary course of business. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not subject to any material legal proceedings, and to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Indemnification Agreements

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at its request in such capacities. There have been no claims to date, and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had not recorded any liabilities for these agreements as of September 30, 2023 and December 31, 2022.

7. Common Stock

Pursuant to its certificate of incorporation, the Company is authorized to issue 500.0 million shares of common stock at a par value of $0.0001 per share. As of September 30, 2023, 87,042,933 shares of common stock were issued and outstanding.

The Company has reserved shares of common stock for future issuances as follows:

	September 30, 2023
Common stock options issued and outstanding	10,183,440
Common stock available for future grants	2,689,562
Common stock available for ESPP	1,778,597
Restricted stock units issued and outstanding	1,094,563
Total	15,746,162

June 2023 Follow-On Offering

In June 2023, the Company completed a follow-on offering and issued and sold 13,269,231 shares of common stock (including the exercise by the underwriters of their option to purchase an additional 1,730,769 shares of common stock) at a price to the public of $13.00 per share for net proceeds of approximately $161.4 million, after deducting underwriting discounts, commissions, and offering costs.

At-The-Market Offering

In June 2022, the Company entered into an equity distribution agreement, or the Equity Distribution Agreement, with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of the Company's common stock for an aggregate offering price of up to $150.0 million under an at-the-market offering program, or the 2022 ATM.

In June 2023, the Company suspended and terminated the prospectus related to its common stock issuable pursuant to the terms of the Equity Distribution Agreement. In September 2023, in connection with the Company's filing of an automatic shelf registration statement on Form S-3, the Company filed a new prospectus relating to the Equity Distribution Agreement and the issuance and sale of shares of the Company's common stock having an aggregate offering price of up to $250.0 million under the 2022 ATM. The Company has no obligation to sell any shares and could at any time suspend solicitations and offers under the 2022 ATM. The Company has deferred offering costs consisting of accounting and legal fees directly attributable to the automatic shelf registration statement. Costs are deferred until shares are sold under the automatic shelf registration statement, at which time they will be reclassified to additional paid-in capital as a reduction against the proceeds received. No shares of the Company's common stock have been sold under the 2022 ATM as of September 30, 2023.

June 2022 Follow-On Offering

In June 2022, the Company completed a follow-on offering and issued and sold 11,500,000 shares of common stock (including the exercise by the underwriters of their option to purchase an additional 1,500,000 shares of common stock) at a price to the public of $15.00 per share for net proceeds of approximately $161.6 million, after deducting underwriting discounts, commissions, and offering costs.

8. Share-based Compensation

Share-based compensation expense recorded in the accompanying condensed consolidated statements of operations is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expense	$ 3,312	$ 2,020	$ 10,102	$ 6,242
General and administrative expense	6,294	6,556	18,428	14,167
Total share-based compensation expense	$ 9,606	$ 8,576	$ 28,530	$ 20,409

As of September 30, 2023, there was $86.6 million of unrecognized compensation cost related to unvested restricted stock, unvested restricted stock units, unvested stock options, and shares subject to purchase under the ESPP that is expected to be recognized over a weighted-average period of approximately 2.6 years.

As of September 30, 2023, there was $2.5 million of unrecognized compensation cost related to unvested PSOs and PSUs. The Company will recognize the PSO and PSU expense through the expected vesting dates when the achievement of the performance-based metrics is probable.

2022 Equity Inducement Plan

In October 2022, the board of directors and stockholders approved the 2022 Equity Inducement Plan, or the 2022 Plan. The 2022 Plan provides for the grant of non-statutory stock options and restricted stock units. The number of shares of common stock reserved for issuance under the 2022 Plan is 1,000,000 shares.

The following table provides a summary of stock option activity under the 2022 Plan during the nine months ended September 30, 2023.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	309,000	$ 21.14		
Granted	—	$ —		
Exercised	—	$ —		$ —
Forfeiture	—	$ —		
Outstanding at September 30, 2023	309,000	$ 21.14	9.1	$ —
Vested and expected to vest at September 30, 2023	309,000	$ 21.14	9.1	$ —
Exercisable at September 30, 2023	—	$ —	—	$ —

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

There was no fair value of options that vested during each of the nine months ended September 30, 2023 and 2022. There was no weighted-average grant date fair value of options granted since there were no options granted from the 2022 Plan during each of the nine months ended September 30, 2023 and 2022.

Unamortized share-based compensation for stock options as of September 30, 2023 was $3.6 million, which is expected to be recognized over a weighted-average period of 3.1 years.

The following table provides a summary of restricted stock units activity under the 2022 Plan during the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2022	47,400	$ 21.14
Granted	—	$ —
Vested	—	$ —
Forfeiture	—	$ —
Unvested restricted stock units at September 30, 2023	47,400	$ 21.14

Unamortized share-based compensation for restricted stock units as of September 30, 2023 was $0.8 million, which is expected to be recognized over a weighted-average period of 3.1 years.

2021 Equity Incentive Plan

Immediately prior to consummation of the Company's initial public offering, or the IPO, all the outstanding incentive shares were converted into common stock. The following table provides a summary of the unvested common stock awards activity during the nine months ended September 30, 2023.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested common stock as of December 31, 2022	1,722,744	$ 16.00
Vested	(744,625)	$ 16.00
Forfeiture	(21,400)	$ 16.00
Unvested common stock as of September 30, 2023	956,719	$ 16.00

In May 2021, in connection with the IPO, the board of directors and stockholders approved, the 2021 Equity Incentive Plan, or the 2021 Plan, which became effective on the day before the date of the effectiveness of the IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other share-based awards. The number of shares of common stock reserved for issuance under the 2021 Plan is equal to the sum of: (x) 6,369,000 shares of common stock; plus (y) 4,719,605 shares of common stock issued in respect of the Conversion of incentive shares that were subject to vesting immediately prior to the effectiveness of the registration statement for the IPO that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right. The number of shares available for grant and issuance under the 2021 Plan will be automatically increased on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including, the fiscal year commencing on January 1, 2031, by the lesser of (a) 5% of the number of shares of all classes of the Company's common stock, plus the total number of shares of Company common stock issuable upon conversion of any preferred stock or exercise of any warrants to acquire shares of Company common stock for a nominal exercise price issued and outstanding on each December 31 immediately prior to the date of increase or (b) such number of shares determined by the board of directors.

The following table provides a summary of stock option activity under the 2021 Plan during the nine months ended September 30, 2023.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	7,634,167	$ 16.42		
Granted	2,542,700	$ 19.14		
Exercised	(88,459)	$ 15.12		$ 643
Forfeiture	(357,468)	$ 18.84		
Outstanding at September 30, 2023	9,730,940	$ 17.06	8.4	$ 625
Vested and expected to vest at September 30, 2023	9,730,940	$ 17.06	8.4	$ 625
Exercisable at September 30, 2023	3,995,722	$ 16.63	7.9	$ 214

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

The total fair value of options that vested during the nine months ended September 30, 2023 and 2022 was $19.8 million and $15.6 million, respectively. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2023 and 2022 was $13.37 per share and $9.02 per share, respectively.

Unamortized share-based compensation for stock options as of September 30, 2023 was $60.7 million, which is expected to be recognized over a weighted-average period of 2.6 years.

The Company used the Black-Scholes option pricing model to estimate the fair value of stock option awards granted with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected term (in years)	5.65 - 6.14	5.27 - 6.33	5.27 - 6.25	5.27 - 6.33
Expected volatility	68.82% - 71.43%	68.96% - 70.71%	68.82% - 81.98%	65.20% - 70.71%
Risk-free interest rate	4.02% - 4.56%	2.65% - 4.09%	3.47% - 4.56%	1.47% - 4.09%
Expected dividend yield	—	—	—	—

The following table provides a summary of restricted stock units activity under the 2021 Plan during the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2022	485,351	$ 16.83
Granted	711,810	$ 20.46
Vested	(190,727)	$ 19.26
Forfeiture	(52,521)	$ 20.37
Unvested restricted stock units at September 30, 2023	953,913	$ 18.86

Unamortized share-based compensation for restricted stock units as of September 30, 2023 was $16.8 million, which is expected to be recognized over a weighted-average period of 3.1 years.

Performance Awards

In June 2022, the Company granted performance awards, consisting of performance stock options, or PSOs, and performance stock units, or PSUs, to non-executive employees pursuant to the 2021 Plan. Each performance award is earned through the achievement of a performance-based metric over a defined performance period determined by the compensation committee of the Company's board of directors. The estimated fair value of the equity awards that contain performance conditions is expensed over the term of the award once the Company has determined that it is probable that the performance conditions will be satisfied.

The following table provides a summary of PSO activity under the 2021 Plan during the nine months ended September 30, 2023.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	146,950	$ 15.25		
Granted	—	$ —		
Exercised	—	$ —		$ —
Forfeiture	(3,450)	$ 15.25		
Outstanding at September 30, 2023	143,500	$ 15.25	8.7	$ —
Vested and expected to vest at September 30, 2023	—	$ —	—	$ —
Exercisable at September 30, 2023	—	$ —	—	$ —

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money PSOs.

There was no fair value of PSOs that vested since there were no PSOs that vested during each of the nine months ended September 30, 2023 and 2022. There was no weighted-average grant date fair value of PSOs granted since there were no PSOs granted during the nine months ended September 30, 2023. The weighted-average grant date fair value of PSOs granted during the nine months ended September 30, 2022 was $7.78 per share.

As of September 30, 2023, there was $1.1 million of unrecognized compensation cost related to unvested PSOs. The Company will recognize the PSO expense through the expected vesting dates when the achievement of the performance-based metrics is probable.

The Company used the Black-Scholes option pricing model to estimate the fair value of the PSO awards granted with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected term (in years)	—	—	—	2.92 - 3.42
Expected volatility	—	—	—	72.72% - 72.98%
Risk-free interest rate	—	—	—	3.37%
Expected dividend yield	—	—	—	—

The following table provides a summary of PSU activity under the 2021 Plan during the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2022	95,500	$ 15.25
Granted	—	$ —
Vested	—	$ —
Forfeiture	(2,250)	$ 15.25
Unvested restricted stock units at September 30, 2023	93,250	$ 15.25

As of September 30, 2023, there was $1.4 million of unrecognized compensation cost related to unvested PSUs. The Company will recognize the PSU expense through the expected vesting dates when the achievement of the performance-based metrics is probable.

2021 Employee Stock Purchase Plan

In May 2021, the board of directors adopted, and the stockholders approved the 2021 Employee Stock Purchase Plan, or the ESPP, which became effective on May 26, 2021. A total of 603,000 shares of common stock were initially reserved for issuance under the ESPP. The number of shares of the common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including, the fiscal year commencing on January 1, 2031, by the lesser of: (a) 1% of the total number of outstanding shares of common stock of the Company (on an as converted basis outstanding on the immediately preceding December 31 (rounded down to the nearest whole share) and (b) an amount determined by the board of directors. 178,506 shares have been issued under the ESPP as of September 30, 2023. The Company recognized compensation expense related to the ESPP of $0.1 million and $17,000 for the three months ended September 30, 2023 and 2022, respectively, and $0.6 million and $0.1 million for the nine months ended September 30, 2023 and 2022, respectively.

The fair value of our common stock to be issued under the ESPP is estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2023	2022
Expected term (in years)	0.5	0.5
Expected volatility	63.57%	58.49%
Risk-free interest rate	5.24%	1.54%
Expected dividend yield	—	—

9. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss attributable to common stockholders	$ (46,150)	$ (37,795)	$ (134,406)	$ (102,072)
Net loss per share, basic and diluted	$ (0.54)	$ (0.53)	$ (1.73)	$ (1.61)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	85,952,501	71,008,993	77,682,237	63,522,774

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	As of September 30,	
	2023	2022
Stock options	10,039,940	7,447,808
Unvested common shares	956,719	2,240,702
Restricted stock units	1,001,313	435,570
Shares committed under ESPP	69,578	51,169
Total	12,067,550	10,175,249

10. Defined Contribution Plan

The Company maintains an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate provided that they meet the requirements of the plan. For each of the three months ended September 30, 2023 and 2022, the Company made matching contributions of $0.2 million and $0.3 million, respectively. For the nine months ended September 30, 2023 and 2022, the Company made matching contributions of $1.0 million and $0.8 million, respectively.

11. Subsequent Event

On October 30, 2023, the U.S. Food and Drug Administration, or the FDA, accepted for filing, the Company's New Drug Application, or NDA, for tovorafenib (DAY101) as a monotherapy in relapsed or progressive low-grade glioma, or pLGG. The FDA has granted priority review and assigned a Prescription Drug User Fee Act, or PDUFA, target action date of April 30, 2024. The FDA is not currently planning to hold an advisory committee meeting to discuss the application. Per the terms of the Viracta License Agreement, a $5.0 million payment is due to Viracta for achievement of this milestone, which will be recorded to research and development expense.

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 consolidated financial statements and related notes, our interim condensed consolidated financial statements and related notes, and other financial information appearing in our Annual Report on Form 10-K for the year ended December 31, 2022, or our Annual Report, and this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" in this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Day One was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Our name was inspired by the "The Day One Talk" that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. We aim to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

We are a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life threatening diseases. Initially, we have focused our clinical development efforts on pediatric patients living with cancer, a vulnerable population that has been underserved in the recent revolution in targeted therapeutics and immuno-oncology.

Our lead product candidate, tovorafenib (DAY101), is an oral, brain-penetrant, highly-selective type II rapidly accelerated fibrosarcoma, or RAF, kinase inhibitor. Tovorafenib (DAY101) has been studied in over 350 patients and has been shown to be generally well-tolerated as a monotherapy. Tovorafenib (DAY101) has demonstrated encouraging anti-tumor activity in pediatric and adult populations with specific genetic alterations that result in the over-activation of the RAS/mitogen-activated protein kinase, or MAPK, pathway leading to uncontrolled cell growth.

Tovorafenib (DAY101) was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration, or the FDA, in August 2020 for the treatment of relapsed or progressive low-grade glioma, or pLGG, based on initial results from a Phase 1 trial which showed evidence of rapid anti-tumor activity and durable responses in pLGG patients. Pediatric low-grade glioma is the most common brain tumor diagnosed in children for which there is no standard of care and for which there are no approved therapies for the vast majority of patients. We received orphan drug designation for the treatment of malignant glioma from the FDA in September 2020 and from the EU Commission for the treatment of glioma in May 2021. Additionally, the FDA granted Rare Pediatric Disease designation to tovorafenib (DAY101) for treatment of low-grade gliomas, or LGGs, harboring an activating RAF alteration in July 2021.

We have initiated and fully enrolled a pivotal Phase 2 trial, or FIREFLY-1, of tovorafenib (DAY101) as a monotherapy for pediatric patients with relapsed or progressive low-grade glioma harboring an activating BRAF alteration. The first patient was dosed in FIREFLY-1 in May 2021 and we completed enrollment in the registrational arm in May 2022. The FIREFLY-1 trial has also been expanded to: (a) include two additional study arms to enable expanded access for eligible patients now that the primary cohort has completed enrollment, and (b) evaluate the preliminary efficacy of tovorafenib (DAY101) in patients aged six months to 25 years with a relapsed or progressive extracranial solid tumor with an activating RAF fusion.

We reported new data from the registrational Phase 2 FIREFLY-1 trial at the 2023 American Society of Clinical Oncology Annual Meeting in June 2023 and submitted an updated clinical study report with an additional six months of safety and efficacy data to the FDA. The data demonstrated an overall response rate, or ORR, of 67% in the 69 Response Assessment for Neuro-Oncology-High Grade Glioma, or RANO-HGG, evaluable patients, comprising 12 confirmed complete responses, or CR, and 34 partial responses, or PR, which is the primary endpoint of the trial. We observed an additional 18 patients with a best response of stable disease, or SD, resulting in a clinical benefit rate of 93% (CR+PR/uPR+SD of any duration).

Additional secondary analysis and exploratory endpoint analyses included the evaluation of responses by Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO-LGG, and Response Assessment in Neuro-Oncology Low-Grade Glioma, or RANO-LGG. RAPNO-LGG data demonstrated an ORR of 51% in the 76 RAPNO-LGG evaluable patients, comprising 28 PR and 11 minor responses, or MR. We observed an additional 23 patients with a best response of SD, resulting in a clinical benefit rate of 82% (PR/uPR+MR/uMR+SD of any duration).

RANO-LGG data demonstrated an ORR of 53% in the 76 RANO-LGG evaluable patients, comprising 20 PR and 20 MR. We observed an additional 23 patients with a best response of SD, resulting in a clinical benefit rate of 83% (PR/uPR+MR/uMR+SD of any duration). Safety data, based on 137 treated patients, indicated monotherapy tovorafenib (DAY101) to be generally well-tolerated. The vast majority of adverse events were Grade 1 or Grade 2, with the most common side effects reported related to tovorafenib being change in hair color (76%), fatigue (44%), maculopapular rash (41%), dry skin (33%), and dermatitis acneiform (30%).

We believe tumor reduction or stabilization is clinically meaningful for pLGG patients, as both are perceived as beneficial given the lack of approved therapies for the majority of patients. We completed the rolling NDA submission of tovorafenib (DAY101) for the treatment of patients with relapsed or progressive pLGG in September 2023, which included the submission an updated clinical study report with an additional six months of safety and efficacy data through June 2023. The NDA was accepted for filing and granted priority review by the FDA in October 2023, with a Prescription Drug User Fee Act, or PDUFA, target action date of April 30, 2024. The FDA is not currently planning to hold an advisory committee meeting to discuss the application.

We initiated a pivotal Phase 3 trial, or FIREFLY-2, evaluating tovorafenib (DAY101) as a front-line therapy in patients aged 6 months to 25 years with pLGG in June 2022. The first patient was dosed in FIREFLY-2 in March 2023. Patients continue to enroll in the United States, Canada, Europe, Australia and Asia, with approximately 70 sites activated.

Our second product candidate, pimasertib, is an oral, highly-selective small molecule inhibitor of mitogen-activated protein kinase kinases 1 and 2, or MEK, a well-characterized key signaling node in the MAPK pathway. Pimasertib has been studied in more than 10 Phase 1/2 clinical trials in over 850 patients with various tumor types, both as a monotherapy and in combination with standard of care therapies. Published preclinical studies indicated that pimasertib has higher central nervous system penetration than other MEK inhibitors.

We initiated an open-label, multicenter, Phase 1b/2a umbrella master trial, or FIRELIGHT-1, of tovorafenib (DAY101) monotherapy or combination therapy, which consists of two substudies. Substudy 1 is a Phase 2a trial of tovorafenib (DAY101) as a monotherapy in patients 12 years and older with relapsed, progressive, or refractory solid tumors harboring MAPK pathway aberrations. The Company has concluded enrollment in this substudy. Despite observing responses with a generally well tolerated therapy, a limited duration of response in this relatively rare patient population was observed. As such, the Company announced in November 2023 our decision to discontinue this monotherapy substudy and re-direct resources to other programs. Results from the substudy will be shared for presentation or publication after the final dataset becomes available. Substudy 2 is a Phase 1b/2 combination trial of tovorafenib (DAY101) and pimasertib in patients 12 years and older with various MAPK-altered solid tumors; the first patient was dosed in May 2022. Simultaneous inhibition of both RAF and MEK has been shown to lead to synergistic antitumor activity in preclinical models. This combination may demonstrate enhanced anti-tumor activity in a variety of adult solid tumors driven by MAPK alterations, including NRAS mutant melanoma and lung cancers, tumors driven by Class II BRAF alterations, tumors with BRAF wild-type fusions, and tumors driven by KRAS alterations.

In August 2023, we entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to us an exclusive, worldwide license, with the right to grant sublicenses through multiple tiers, to research, develop, and commercialize pharmaceutical products and to engage in research aimed at discovery, optimization and development of Vaccinia Related Kinase 1, or VRK1.VRK1 is a novel target involved in the regulation of cell division and DNA damage repair. Over-expression of VRK1 is linked to poor prognosis in a variety of adult and pediatric cancers, and VRK1 has been identified as a synthetic lethal target in tumors where expression of its paralog, VRK2, is lost. Silencing of VRK2 expression via promoter methylation has been noted in the majority of high-grade gliomas and high-risk neuroblastomas, providing a concrete approach for selecting patients with tumors sensitive to VRK1 inhibition. Preclinical research activities to advance the VRK1 program are ongoing.

We believe our business development capabilities combined with our extensive experience in oncology drug development and deep ties within the research and patient advocacy communities, particularly within the pediatric setting, positions us to be a leader in identifying, acquiring and developing therapies for patients of all ages. We hold exclusive worldwide rights to tovorafenib (DAY101) and to pimasertib for all therapeutic areas subject to certain milestone and royalty payments.

The following table summarizes our product candidate pipeline.

Since our inception in November 2018, we have devoted substantially all of our resources to identifying, acquiring and developing our product candidates and building our pipeline; organizing and staffing our company; business planning; establishing and maintaining our intellectual property portfolio; establishing arrangements with third parties for the manufacture of our product candidates; raising capital; preparing for commercial launch; and providing general and administrative support for these operations. We do not have any products approved for commercial sale and have not generated any revenues from product sales or any other source and have incurred net losses since commencement of our operations. For the nine months ended September 30, 2023 and 2022, we reported a net loss of $134.4 million and $102.1 million, respectively. We had an accumulated deficit of $404.1 million as of September 30, 2023. We expect a significant increase in expenses and substantial losses for the foreseeable future as we continue our development of, and seek marketing authorizations for our product candidates, commercialize any approved products, and seek to expand our product pipeline and invest in our organization.

To date, we have funded our operations through the sale of our redeemable convertible preferred shares, convertible notes and common stock in our IPO and subsequent public offerings.

Cash and cash equivalents and short-term investments totaled $405.5 million as of September 30, 2023. Based on our current operating plan, management believes we have sufficient capital resources to fund anticipated operations into 2026. Because of the numerous risks and uncertainties associated with product development, we may never achieve profitability, and unless and until then, we will need to continue to raise additional capital. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans. 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 or scale back or terminate our pursuit of new in-licenses and acquisitions.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing authorization. As we advance our product candidates through development, we will explore adding backup suppliers for the Active Pharmaceutical Ingredients, or APIs, formulation, finished drug product, and packaging of each of our product candidates to mitigate the effects of any potential supply disruptions.

Inflation Reduction Act

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which includes an Alternative Minimum Tax based on the Adjusted Financial Statement Income of Applicable Corporations. We do not believe the Inflation Reduction Act will have a material impact on our income tax provision and cash taxes. We continue to monitor the changes in tax laws and regulations to evaluate their potential impact on our business.

Significant Agreements

License Agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, DOT Therapeutics-2, Inc., or DOT-2, our subsidiary, entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Under the MRKDG License Agreement, Merck KGaA, Darmstadt, Germany granted to us an exclusive worldwide license, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for us to research, develop, manufacture and commercialize products containing and comprising the pimasertib and MSC2015103B compounds. We also received clinical inventory supplies to use in its research and development activities. Our exclusive license grant is subject to a non-exclusive license granted by Merck KGaA, Darmstadt, Germany's affiliate to a cancer research organization and Merck KGaA, Darmstadt, Germany retains the right to conduct, directly or indirectly, certain ongoing clinical studies relating to pimasertib.

Under the MRKDG License Agreement, we have obligations to use commercially reasonable efforts to develop and commercialize at least two licensed products in at least two specified major market countries by the year 2029.

In consideration for the rights granted under the MRKDG License Agreement and clinical supplies, we made an upfront payment of $8.0 million, which was recorded as research and development expenses, as the technology does not have an alternative future use and supplies are used for research activities. Additionally, we made a milestone payment of $2.5 million, which was recorded as research and development expenses due to the nature of the license agreement and the milestone event relating to the first dosing of a patient in a first clinical trial of a product containing pimasertib, in the year ended December 31, 2022. We may also be required to make additional payments of up to $364.5 million based upon the achievement of specified development, regulatory, and commercial milestones, as well as a high, single-digit royalty percentage on future net sales of licensed products, if any. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due. No milestones were achieved and due as of September 30, 2023.

The term of the MRKDG License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of our obligation to pay royalties to the licensor with respect to such licensed product in such country and will expire in its entirety upon the expiration of all of our payment obligations with respect to all licensed products and all countries under the MRKDG License Agreement.

Effective December 31, 2021, DOT-2 was merged with and into our company, with our company being the surviving corporation and assuming DOT-2's obligations under the MRKDG License Agreement.

Takeda asset agreement

On December 16, 2019, DOT Therapeutics-1, Inc., or DOT-1, our subsidiary, entered into an asset purchase agreement, or the Takeda Asset Agreement, with Millennium Pharmaceuticals, Inc., a related party and an affiliate of Takeda Pharmaceutical Company Limited, or Takeda. Pursuant to the Takeda Asset Agreement, DOT-1 purchased certain technology rights and know-how related to TAK-580 (which is now tovorafenib (DAY101)) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. DOT-1 also received clinical inventory supplies to use in our research and development activities of such RAF-inhibitor and an assigned investigator clinical trial agreement. Takeda also assigned to DOT-1 its exclusive license agreement, or the Viracta License Agreement, with Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.), or Viracta. Takeda also granted DOT-1 a worldwide, sublicensable exclusive license under specified patents and know-how and non-exclusive license under other patents and know-how generated by Takeda under the Takeda Asset Agreement. DOT-1 also granted Takeda a grant back license, as defined in the Takeda Asset Agreement, which is terminable either automatically or by DOT-1 in the event Takeda does not achieve specified development milestones within the applicable timeframes set forth under the Takeda Asset Agreement. This grant back license to Takeda was terminated at the time of Conversion in connection with the Millennium Stock Exchange Agreement.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, DOT-1 made an upfront payment of $1.0 million in cash and issued 9,857,143 shares of Series A redeemable convertible preferred stock in DOT-1 in December 2019. The fair value of issued shares was estimated as $9.9 million, based on the price paid by other investors for issued shares in the Series A financing of DOT-1. Based on the terms of the Millennium Stock Exchange Agreement, Takeda exchanged the 9,857,143 shares of Series A redeemable convertible preferred stock of DOT-1 for 6,470,382 shares of our common stock upon the effectiveness of the Conversion, on May 26, 2021.

The term of the Takeda Asset Agreement will expire on a country-by-country basis upon expiration of all assigned patent rights and all licensed patent rights in such country. Takeda may terminate the Takeda Asset Agreement prior to our first commercial sale of a product if we cease conducting any development activities for a continuous and specified period of time and such cessation is not agreed upon by the parties and is not done in response to guidance from a regulatory authority. Additionally, Takeda can terminate the Takeda Asset Agreement in the event of our bankruptcy. In the event of termination of the Takeda Asset Agreement by Takeda as a result of our cessation of development or bankruptcy, all assigned patents, know-how and contracts (other than the Viracta License Agreement) will be assigned back to Takeda and Takeda will obtain a reversion license under patents and know-how generated to

exploit all such terminated products.

Effective December 31, 2021, DOT-1 was merged with and into our company, with our company being the surviving corporation and assuming DOT-1's obligations under the Takeda Assets Purchase Agreement.

Viracta license agreement

On December 16, 2019, DOT-1 amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Under the Viracta License Agreement, DOT-1 received a worldwide exclusive license under specified patent rights and know-how to develop, use, manufacture, and commercialize products containing compounds binding the RAF protein family.

DOT-1 paid $2.0 million upfront in cash to Viracta, which was recorded as research and development expenses in 2019. DOT-1 made a milestone payment of $3.0 million to Viracta in February 2021, which was recorded as research and development expense when the milestone was achieved in April 2021. DOT-1 is also required to make additional milestone payments of up to $54.0 million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication to achieve a specified milestone event being lower than milestones payable for the first indication. Additionally, if DOT-1 obtains a priority review voucher with respect to a licensed product and sells such priority review voucher to a third party or uses such priority review voucher, DOT-1 is obligated to pay Viracta a specified percentage in the mid-teen digits of all net consideration received from any such sale or of the value of such used priority review voucher, as applicable. Commencing on the first commercial sale of a licensed product in a country, DOT-1 is obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products, if any. The obligation to pay royalties will end on a country-by-country and licensed product-by-licensed product basis commencing on the first commercial sale in a country and continuing until the later of: (i) the expiration of the last valid claim of the Viracta licensed patents, jointly owned collaboration patents or specified patents owned by the Company covering the use or sale of such product in such country, (ii) the expiration of the last statutory exclusivity pertaining to such product in such country or (iii) the tenth anniversary of the first commercial sale of such product in such country. No milestones were achieved and due as of September 30, 2023. Subsequent to September 30, 2023, a milestone related to the Viracta License Agreement was achieved and recorded to research and development expense as disclosed in Note 11 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

The term of the Viracta License Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the Company's obligation to pay royalties to Viracta with respect to such product in such country. DOT-1 has the right to terminate the Viracta License Agreement with respect to any or all of the licensed products at will upon a specified notice period.

Effective December 31, 2021, DOT-1 was merged with and into our company, with our company being the surviving corporation and assuming DOT-1's obligations under Viracta License Agreement.

Components of Results of Operations

Operating expenses

Research and development expenses

Research and development expenses consist primarily of external and internal expenses incurred for our research activities, including our discovery and in-licensing undertakings, and the development of our lead product candidate, tovorafenib (DAY101), and our second product candidate, pimasertib.

External expenses include:

- costs incurred under agreements with third-party contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other third parties that conduct clinical trials on our behalf;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses; and
- other operational costs not allocable to a specific product, including expenses for rent and facilities maintenance, travel and information technology.

Internal expenses include:

- employee-related costs, including salaries, bonuses, benefits and share-based compensation expense, for our research and development personnel.

We expense research and development expenses as incurred. We track external costs by program, which currently consist of expenses for our tovorafenib (DAY101) program and our pimasertib program. We do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to implement our business strategy; advance tovorafenib (DAY101) and pimasertib through clinical trials and conduct larger clinical trials; expand our research and development efforts; and identify, acquire and develop additional product candidates, particularly as more of our product candidates move into clinical development and later stages of clinical development.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot guarantee that results of clinical trials will be favorable or sufficient to support marketing authorizations for any of our product development programs. We could decide to abandon development or be required to spend considerable resources not otherwise contemplated. For additional discussion regarding the risks and uncertainties regarding our research and development programs, please refer to Part II, Item 1A “Risk Factors” in this Quarterly Report on Form 10-Q.

General and administrative expenses

General and administrative expenses consist primarily of employee-related costs, professional services and other operational costs. Employee-related costs include salaries, bonuses, benefits and share-based compensation expense for our general and administrative personnel. Professional service expenses include legal fees; professional fees for accounting, auditing, tax, human resources, business development, and other consulting services. Other operational costs include expenses for rent and facilities maintenance, travel, insurance and information technology.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we anticipate an increase in our personnel headcount to support expansion of research and development efforts for our product candidates and buildout of commercial capabilities, as well as to support our operations generally. We also expect continued expenses associated with being a public company, including costs related to compliance with the requirements of the Nasdaq Global Select Market, or Nasdaq, and the Securities and Exchange Commission, or the SEC; and investor and public relations costs.

Results of operations

Comparison of three months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (unaudited):

	Three Months Ended September 30,			
	2023	2022	$ Change	% Change
Operating expenses:				
Research and development	$ 33,163	$ 22,035	$ 11,128	50.5 %
General and administrative	18,275	17,664	611	3.5 %
Total operating expenses	51,438	39,699	11,739	29.6 %
Loss from operations	(51,438)	(39,699)	(11,739)	29.6 %
Investment income, net	5,291	1,895	3,396	*
Other (expense) income, net	(3)	9	(12)	*
Net loss attributable to common stockholders	$ (46,150)	$ (37,795)	$ (8,355)	22.1 %

* Amount and/or percentage not meaningful

Research and development expenses

Research and development expenses increased $11.1 million, from $22.0 million for the three months ended September 30, 2022 to $33.2 million for the three months ended September 30, 2023. In the three months ended September 30, 2023 as compared to the three months ended September 30, 2022, third-party expenses increased by $5.8 million, due primarily to an increase in clinical trial, manufacturing, and other product development expenses and personnel related expenses increased by $2.3 million driven by headcount growth. Additionally, our expense increased by $3.0 million due to the upfront license payment to Sprint during the three months ended September 30, 2023, with no license-related payments made during the same period in 2022.

The following table summarizes our external and internal research and development expenses for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,	
	2023	2022
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 17,929	$ 13,740
Upfront payment related to the Sprint License Agreement	3,000	—
Other research and development costs	2,256	675
Internal costs:		
Employee related expenses	9,978	7,620
Total research and development expenses	$ 33,163	$ 22,035

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib (DAY101) program, the pimasertib program, and the VRK1 program were $16.3 million, $1.0 million, and $0.6 million for three months ended September 30, 2023 compared to $12.2 million, $1.5 million, and $0, respectively, for the three months ended September 30, 2022.

General and administrative expenses

General and administrative expenses increased $0.6 million, from $17.7 million for the three months ended September 30, 2022 to $18.3 million for the three months ended September 30, 2023. The increase in general and administrative expenses was primarily due to $1.2 million in personnel related expenses driven by headcount growth, offset by a decrease of $0.6 million in external consulting services.

Comparison of nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (unaudited):

	Nine Months Ended September 30,			
	2023	2022	$ Change	% Change
Operating expenses:				
Research and development	$ 93,173	$ 59,598	$ 33,575	56.3 %
General and administrative	53,374	44,568	8,806	19.8 %
Total operating expenses	146,547	104,166	42,381	40.7 %
Loss from operations	(146,547)	(104,166)	(42,381)	40.7 %
Investment income, net	12,163	2,086	10,077	*
Other (expense) income, net	(22)	8	(30)	*
Net Loss attributable to common stockholders	$ (134,406)	$ (102,072)	$ (32,334)	31.7 %

* Amount and/or percentage not meaningful

Research and development expenses

Research and development expenses increased $33.6 million, from $59.6 million for the nine months ended September 30, 2022 to $93.2 million for the nine months ended September 30, 2023. In the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022, third-party expenses increased by $22.8 million, due primarily to an increase in clinical trial, manufacturing, and other product development expenses and personnel related expenses increased by $10.3 million resulting from additional headcount and stock-based compensation. License expense increased by $0.5 million due to the $3.0 million upfront license payment to Sprint during the nine months ended September 30, 2022 compared to the $2.5 million milestone payment to Merck KGaA related to the first dosing of a patient in a clinical trial of a product containing pimasertib during the three months ended September 30, 2022.

The following table summarizes our external and internal research and development expenses for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 53,426	$ 33,909
Upfront payment related to the Sprint License Agreement	3,000	—
License milestone payment related to the MRKDG License Agreement	—	2,500
Other research and development costs	5,539	2,248
Internal costs:		
Employee related expenses	31,208	20,941
Total research and development expenses	$ 93,173	$ 59,598

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib (DAY101) program, the pimasertib program, and the VRK1 program were $50.0 million, $2.8 million, and $0.6 million, respectively, for nine months ended September 30, 2023 compared to $29.8 million, $4.1 million, and $0, respectively, for the nine months ended September 30, 2022.

General and administrative expenses

General and administrative expenses increased $8.8 million, from $44.6 million for the nine months ended September 30, 2022 to $53.4 million for the nine months ended September 30, 2023. The increase in general and administrative expenses was primarily due to $9.5 million in employee compensation costs driven by headcount growth.

Liquidity and Capital Resources

Sources of liquidity

In June 2023, we completed a follow-on offering and issued and sold 13,269,231 shares of common stock (including the exercise by the underwriters of their option to purchase an additional 1,730,769 shares of common stock) at a price to the public of $13.00 per share for net proceeds of approximately $161.4 million, after deducting underwriting discounts, commissions, and offering costs.

In June 2022, we entered into an equity distribution agreement, or the Equity Distribution Agreement, with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of our common stock for an aggregate offering price of up to $150.0 million under an at-the-market offering program, or the 2022 ATM. In June 2023, we suspended and terminated the prospectus related to our common stock issuable pursuant to the terms of the Equity Distribution Agreement. In September 2023, in connection with our filing of an automatic shelf registration statement on Form S-3, we filed a new prospectus relating to the Equity Distribution Agreement and the issuance and sale of shares of our common stock having an aggregate offering price of up to $250.0 million under the 2022 ATM. No shares of our common stock have been sold under the 2022 ATM as of September 30, 2023.

In June 2022, we completed a follow-on offering and issued and sold 11,500,000 shares of common stock (including the exercise by the underwriters of their option to purchase an additional 1,500,000 shares of common stock) at a price to the public of $15.00 per share for net proceeds of approximately $161.6 million, after deducting underwriting discounts, commissions and offering costs.

In June 2021, we completed our IPO and sold an aggregate of 11,500,000 shares of common stock at a price to the public of $16.00 per share, which included 1,500,000 shares issued upon the full exercise by the underwriters in May 2021 of their option to purchase additional shares of common stock. We received aggregate net proceeds from the IPO of $167.0 million, after deducting underwriting discounts, commissions, and offering costs of $17.0 million. Prior to our IPO, we had funded our operations through the sale of our redeemable convertible preferred shares and convertible notes. We had previously raised approximately $192.0 million in gross proceeds from the sale and issuance of our Series A and Series B redeemable convertible preferred shares and convertible notes.

As of September 30, 2023, we had an accumulated deficit of $404.1 million and $405.5 million in cash and cash equivalents and short-term investments. We believe our cash and cash equivalents and short-term investments will be sufficient to satisfy our cash requirements over the next 12 months and into 2026.

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures 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 and accrued expenses. Our material cash requirements include the following contractual and other obligations.

Leases

We have an operating lease obligation for office space. As of September 30, 2023, we had fixed lease payment obligations of approximately $0.5 million payable within 12 months.

Contract Research Organizations and Contract Manufacturing Organizations

We have entered into contracts in the normal course of business with CROs, CMOs, and other third-party vendors for clinical trial, manufacturing, testing, and other research and development activities. These contracts generally provide for termination on notice, with the exception of one vendor where certain costs are non-cancellable after the approval of the project. As of September 30, 2023, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

We have entered into licensing agreements, or the licensing agreements, which require us to pay milestones contingent upon meeting of specific events. We made a milestone payment of $2.5 million related to the first dosing of a patient in a first clinical trial of a product containing pimasertib in the year ended December 31, 2022. Subsequent to September 30, 2023, a milestone related to the Viracta License Agreement was achieved and recorded to research and development expense as disclosed in Note 11 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We are required to pay royalties on sales of products developed under these license agreements. All our products are in development as of September 30, 2023 and no such royalties are due. As of September 30, 2023, we do not have any contingent payment obligations since the amount, timing and likelihood of such payments are not known.

Purchase Commitments

We have entered into a manufacturing and supply agreement with Quotient Sciences - Philadelphia, LLC in July 2023 to support our product needs for tovorafenib (DAY101) that requires the Company to meet minimum purchase obligations on an annual basis. As of September 30, 2023, we had aggregate future minimum purchase obligations of $17.2 million.

Cash flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (105,481)	$ (74,564)
Net cash provided by (used in) investing activities	97,998	(252,864)
Cash provided by financing activities	163,400	163,983
Net increase in cash and cash equivalents	$ 155,917	$ (163,445)

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $105.5 million, consisting of our net loss of $134.4 million, non-cash charges of $23.3 million and net changes in operating assets and liabilities of $5.6 million. Non-cash charges are primarily related to share-based compensation expense of $28.5 million and $3.0 million for acquired in-process research and development assets, which was partially offset by accretion of discounts on short-term investments of $8.5 million. Net changes in operating assets and liabilities are primarily related to an increase in accrued expenses and other current liabilities of $4.7 million, an increase in accounts payable of $3.1 million, and a decrease in deposits and other long-term assets of $0.2 million, which were partially offset by an increase in prepaid expenses and other current assets of $2.1 million and a decrease in operating lease liabilities of $0.3 million.

Net cash used in operating activities for the nine months ended September 30, 2022 was $74.6 million, consisting of our net loss of $102.1 million, changes of approximately $7.8 million in net operating assets and liabilities and by non-cash charges of $19.7 million, which is primarily comprised of stock-based compensation expense of $20.4 million. Changes in operating assets and liabilities were primarily related to an increase in accrued expenses and other current liabilities of $7.1 million and an increase of accounts payable of $2.2 million. This was partially offset by an increase to prepaid expenses and other assets of $1.1 million, an increase to deposits and other long-term assets of $0.3 million, and an increase to operating lease liabilities of $0.2 million.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2023 was $98.0 million related to the proceeds from the maturity of short-term investments of $445.9 million, partially offset by the purchase of short-term investments of $344.7 million and $3.0 million for acquired in-process research and development assets.

Net cash used in investing activities for the nine months ended September 30, 2022 was $252.9 million related to the purchase of short-term investments and property and equipment expenditures of $272.9 million. This was partially offset by the proceeds from the maturity of short-term investments of $20.0 million.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $163.4 million, primarily attributable to the net proceeds from the issuance of common stock in connection with our follow-on offering of common stock of $161.4 million. Additionally, there was $2.0 million of net cash provided by financing activities related to proceeds from the issuance of common stock upon stock option exercises and purchases made under our 2021 Employee Stock Purchase Plan.

Net cash provided by financing activities for the nine months ended September 30, 2022 was $164.0 million, primarily attributable to the net proceeds from the issuance of common stock in connection with our follow-on offering of common stock. Additionally, there was $2.4 million of net cash provided by financing activities related to proceeds from the issuance of common stock upon stock option exercises and purchases made under our 2021 Employee Stock Purchase Plan.

Funding requirements

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our ongoing activities.

We believe our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be imprecise, and we could use our available capital resources sooner than we currently expect.

As a result of anticipated expenditures, we will need to obtain substantial additional financing in connection with our continuing operations. Until such time, if ever, as we cannot generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Adequate additional funds may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions, and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from inflation, changing interest rates, recent turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget, global regional conflicts, public health epidemics, such as the COVID-19 pandemic, or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure that we will ever be profitable or generate positive cash flow from operating activities.

Critical accounting policies and use of estimates

Our critical accounting policies are disclosed in our audited consolidated financial statements for the year ended December 31, 2022, and the related notes, included in our Annual Report.

New Accounting Pronouncements

Refer to Note 2 of the Notes to our Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of recently issued and adopted accounting pronouncements.

Emerging Growth Company Status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to

delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. On the last business day of the second quarter of 2023, the aggregate market value of the shares of our common stock held by non-affiliate stockholders exceeded $700 million. As a result, we will be considered a “large accelerated filer” as of December 31, 2023, and no longer qualify as an emerging growth company. Therefore, we will no longer be able to take advantage of the exemptions from various reporting requirements, beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2023 to be filed in 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

On the last business day of the second quarter of 2023, the aggregate market value of the shares of our common stock held by non-affiliate stockholders exceeded $700 million. As a result, as of December 31, 2023, we will no longer qualify as a smaller reporting company. Therefore, we will no longer be able to take advantage of the scaled disclosure requirements, beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2023 to be filed in 2024.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2023, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed 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, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of September 30, 2023, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the nine months ended September 30, 2023 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 be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this quarterly report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Summary of Risk Factors

Our business is subject to several risks and uncertainties, including those immediately following this summary. Some of these risks are:

- We have a limited operating history, have not completed any clinical trials beyond Phase 1, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses since our inception and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.
- We are substantially dependent on the success of our lead product candidate, tovorafenib (DAY101), for which the FDA accepted our NDA and granted priority review. To the extent tovorafenib (DAY101) is not commercially successful, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery or identification, development and commercialization of our product candidates.
- We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.
- Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive marketing authorization.
- We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial (PNOC014), and we do not control the trial operations or reporting of the results of such trials.
- The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain marketing authorizations for tovorafenib (DAY101), pimasertib or any future product candidates, on a timely basis or at all.
- The manufacture of pharmaceutical products, including our product candidates, such as tovorafenib (DAY101), is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, our products for commercial sale.
- Our future success depends on our ability to retain our executive officers and key employees and to attract, retain and motivate qualified personnel and manage our human capital.
- We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

- If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under our patents (owned, co-owned or licensed) is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials beyond Phase 1, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, have no products approved for commercial sale and have never generated any revenue. Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have devoted substantially all of our resources to identifying, acquiring and developing our product candidates and building our pipeline, organizing and staffing our company, business planning, establishing and maintaining our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates, raising capital and providing general and administrative support for these operations.

Since our inception, we have focused substantially all of our efforts and financial resources on the clinical development of our lead product candidate, tovorafenib (DAY101), initially for relapsed or progressive low-grade gliomas, or pLGGs, and our other current product candidate, pimasertib, an orally available small molecule inhibitor of MEK kinase, which we are studying in combination with tovorafenib (DAY101) for the treatment of RAS- and RAF-dependent tumors. To date, we have financed our operations primarily through the sale and issuance of redeemable convertible preferred shares, convertible notes, the completion of our IPO and follow-on public offerings of our common stock.

We have not yet demonstrated an ability to successfully complete any clinical trials beyond Phase 1, obtain marketing authorizations, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since our inception and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements of our redeemable convertible preferred shares, our convertible notes, the completion of our IPO and follow-on offerings of our common stock. For the nine months ended September 30, 2023 and 2022, we reported a net loss of $134.4 million and $102.1 million, respectively. We had an accumulated deficit of $404.1 million as of September 30, 2023. We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we advance tovorafenib (DAY101) and pimasertib through clinical development. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our additional planned clinical trials for our lead product candidate and other product candidates, including our ongoing pivotal Phase 2 FIREFLY-1 trial for tovorafenib (DAY101), our ongoing pivotal Phase 3 FIREFLY-2 trial of tovorafenib (DAY101) as a potential front-line therapy in pLGG, our ongoing Phase 1b/2 FIRELIGHT-1 umbrella master trial of tovorafenib (DAY101) in adult RAS/RAF-altered solid tumors as a monotherapy and in combination with pimasertib, and development of and subsequent Investigational New Drug Applications, or INDs, for any future product candidates we may choose to pursue. In October 2023, the FDA accepted our NDA and granted priority review for tovorafenib (DAY101) as a monotherapy in relapsed or progressive pediatric low-grade glioma. If we obtain marketing authorization for tovorafenib (DAY101), pimasertib, or another product candidate, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of tovorafenib (DAY101), pimasertib, or such other product candidate. We have also incurred, and will continue to incur, additional costs associated with operating as a public company.

As a result, we expect to continue to incur significant and increasing net losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. In addition, we expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We are substantially dependent on the success of our lead product candidate, tovorafenib (DAY101), for which the FDA accepted our NDA and granted priority review. To the extent tovorafenib (DAY101) is not commercially successful, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.

Our future success is highly dependent on our ability to timely complete successful clinical trials, obtain marketing authorization for, and then successfully commercialize, our product candidates. We are early in our development efforts and our lead product candidate, tovorafenib (DAY101), is currently in pivotal Phase 2 and Phase 3 clinical trials. Our other current product candidate, pimasertib, is in an earlier stage of development. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that tovorafenib (DAY101), pimasertib or any future product candidates we develop, if any, will achieve success in their clinical trials or obtain marketing authorization.

Our ability to generate product revenue, which we do not expect will occur in the near future, if ever, will depend heavily on the successful development and eventual commercialization of our lead product candidate, tovorafenib (DAY101). If the launch or commercialization of tovorafenib (DAY101) is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product candidate and our company could be harmed.

The success of tovorafenib (DAY101) will depend on several factors, including the following:

- successful and timely completion of current and future clinical trials resulting in attractive, competitive target product profiles, including our frontline pivotal Phase 3 FIREFLY-2 trial of tovorafenib (DAY101) as a front-line therapy for patients with pLGG;
- the results of our ongoing clinical trial for tovorafenib (DAY101) and Phase 1b/2 umbrella master trial of tovorafenib (DAY101) as a monotherapy and in combination with pimasertib meeting clinical endpoints;
- approval of NDAs by the U.S. Food and Drug Administration, or FDA, including our NDA submission for tovorafenib (DAY101), which was accepted for filing and granted priority review as a monotherapy in relapsed or progressive pLGG, by the FDA in October 2023, or other similar clinical trial applications from foreign regulatory authorities for our future clinical trials for our pipeline product candidates;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, effectiveness and acceptable risk-benefit profiles of our product candidates to the satisfaction of the FDA and foreign regulatory agencies and attractiveness of our product candidates to physicians, patients, advocates, payors and caregivers;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of complementary or companion diagnostics, if any, on a timely basis, or at all, and an adequate supply of these diagnostics and access to these diagnostics that outpaces demand;
- receipt and related terms of marketing authorizations from applicable regulatory authorities, including potential restrictions or limitations on the conditions of use of our products;
- the successful completion of any required or committed post-marketing studies and available funding to perform any such post-marketing requirements or post-marketing commitments;
- raising additional funds necessary to complete clinical development of and commercialize our product candidates, including tovorafenib (DAY101);
- obtaining and maintaining patent, trade secret and other intellectual property protection and statutory exclusivities for our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates and ensuring a resilient, effective supply chain that produces supply that outpaces demand;

- developing and implementing marketing, pricing, and reimbursement strategies, as well as adequate demand forecasts for supply and sales planning;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others in a market where promotional sales approaches are rapidly moving to digital platforms and access of sales representatives to major institutions remains uncertain;
- acceptance of our products, if and when approved, by patients, physicians, the medical community and third-party payors underpinned by adequate health economic data and a meaningful value proposition;
- obtaining and maintaining third-party payor coverage and adequate reimbursement in both public and private payor spaces across multiple countries;
- effectively competing with other therapies, including those that have not yet entered the market;
- effectively competing with other companies in the pharmaceutical and biotechnology industries, which are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates;
- obtaining appropriate support from patient advocacy organizations;
- effectively shaping the market in the early years following launch to help providers understand a new way of thinking about treating these patients;
- addressing any delays in our ongoing and planned clinical trials resulting from factors related to any macroeconomic conditions, major natural disaster, public health epidemic or significant political event, including inflation, changes in interest rates, turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget and global regional conflicts, as well as any delays due to recent supply chain issues impacting the availability of certain standard-of-care chemotherapy drugs;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain marketing authorization even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery or identification, development and commercialization of our product candidates.

Our business depends entirely on the successful discovery or identification, development and commercialization of product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next 12 months, if ever. We do not expect to generate significant revenue unless and until we obtain marketing authorization for, and begin to sell, tovorafenib (DAY101), pimasertib, or another product candidate. Our ability to generate revenue and achieve profitability depends on several factors, including, but not limited to, our ability to:

- complete a successful pivotal Phase 2 FIREFLY-1 trial with tovorafenib (DAY101) that achieves a competitive, clinically meaningful and generally well-tolerated target product profile for the treatment of relapsed or progressive pLGG;
- complete a successful pivotal Phase 3 FIREFLY-2 trial with tovorafenib (DAY101) that achieves a competitive, clinically meaningful and generally well-tolerated target product profile for the front-line treatment of pLGG;
- complete a successful Phase 1b/2 FIRELIGHT-1 umbrella master trial of tovorafenib (DAY101) as a monotherapy and in combination with pimasertib in patients 12 years and older with tumors having activated RAF signaling;
- initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain U.S. and foreign marketing authorization for tovorafenib (DAY101) as a treatment for patients with pLGGs;
- initiate and complete successful later-stage clinical trials that meet their clinical endpoints;
- obtain favorable results from our clinical trials and apply for and obtain marketing authorization for tovorafenib (DAY101) and pimasertib from applicable regulatory authorities, including NDAs, from the FDA, and maintaining such approvals;
- establish licenses, collaborations or strategic partnerships that allow for the commercialization of our product candidates and/or may increase the value of our programs;

- establish and maintain viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successfully commercialize tovorafenib (DAY101), pimasertib, and any future product candidates we may develop, if approved, by building a sales force and/or entering into collaborations with third parties;
- satisfy any post-marketing requirements imposed by, or post-marketing commitments made to, applicable regulatory authorities;
- demonstrate an acceptable safety profile of our product candidates, including tovorafenib (DAY101) and pimasertib, and continue to maintain a continued acceptable safety profile following marketing authorization, if any;
- identify, assess and develop new product candidates;
- establish and maintain patent and trade secret protection, statutory exclusivities, and other intellectual property protections for our products;
- obtain, maintain, protect and defend our intellectual property portfolio, including any necessary licenses from third parties;
- address any competing therapies and technological and market developments;
- achieve market acceptance of tovorafenib (DAY101) or pimasertib and our other successful product candidates, if approved, with patients, the medical community and third-party payors, both in the United States and internationally; and
- attract, hire and retain qualified personnel.

To become and remain profitable, we must succeed in designing, developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials for our product candidates, designing and/or acquiring additional product candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our product candidates, obtaining marketing authorization for our product candidates, obtaining and retaining patents, trade secrets, statutory exclusivities, and other intellectual property protections and marketing and selling products for which we may obtain marketing authorization, if any. We are in the earlier stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining marketing authorizations to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing authorizations, the pricing for the product, the duration of treatment with our product, the adoption of our product in treatment guidelines and by prescribers, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the approved indication is narrower than expected, or the treatment population is narrowed by competition, physician choice, payor decisions, or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

If we decide to or are required by the FDA or regulatory authorities in other jurisdictions to perform studies or clinical trials in addition to, those currently expected, or to modify ongoing or planned clinical trials, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our current and planned clinical trials for, or in the development of, any of our product candidates, our expenses could increase significantly and profitability could be further delayed.

Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our lead product candidate, tovorafenib (DAY101), pimasertib, and any future product candidates through clinical development. We expect increased expenses as we continue our research and development, initiate additional clinical trials, seek to expand our product pipeline, seek marketing authorization for our lead programs and future product candidates, if any, and invest in our organization. In addition, if we obtain marketing authorization for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company, such as acquiring and retaining experienced personnel, developing new information technology systems, and other costs associated with being a public company. Also, we expect to experience ongoing and additional costs related to preparing and filing patent applications, maintaining our intellectual property and potentially expanding our office facilities. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations. Our ability to raise capital may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from inflation, changes in interest rates, recent turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget, global regional conflicts, public health epidemics, such as the COVID-19 pandemic, or otherwise.

We had $405.5 million in cash, cash equivalents and short-term investments as of September 30, 2023. We believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses, and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for our current or any future product candidates;
- the extent to which we develop, in-license or acquire other pipeline product candidates or technologies;
- the number and development requirements of current or future product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of obtaining marketing authorization for our current or future product candidates or the modification of ongoing or planned clinical trials;
- the successful development of and marketing authorization for any complementary or companion diagnostics that may be useful to or necessary for the commercialization of our product candidates;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- to the extent we pursue strategic collaborations, including collaborations to commercialize tovorafenib (DAY101), pimasertib, or any of our future pipeline product candidates, if any, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations or our current licenses;
- the cost associated with commercializing any approved product candidates, including establishing sales, marketing, market access and distribution capabilities;
- the cost associated with completing any post-marketing studies or trials requested or required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of tovorafenib (DAY101), pimasertib or any of our future product candidates if any are approved, or any future pipeline product candidates that receive marketing authorization;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation; and
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims.

We will require additional capital to complete our planned clinical development programs for our current product candidates to obtain marketing authorization, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our team's attention from their day-to-day activities, which may adversely affect our business, including our ability to develop and commercialize our current and future product candidates, if approved. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. In June 2022, we entered into the Equity Distribution Agreement with Piper Sandler & Co. and JonesTrading Institutional Services LLC, as sales agents, relating to the issuance and sale of shares of our common stock for an aggregate offering price of up to $150.0 million under the 2022 ATM. In June 2023, we suspended and terminated the prospectus related to our common stock issuable pursuant to the terms of the Equity Distribution Agreement. In September 2023, in connection with our filing of an automatic shelf registration statement on Form S-3, we filed a new prospectus relating to the Equity Distribution Agreement and the issuance and sale of shares of our common stock having an aggregate offering price of up to $250.0 million under the 2022 ATM. No shares of our common stock have been sold under the 2022 ATM as of September 30, 2023. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to our 2022 ATM, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from inflation, changes in interest rates, recent turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget, global regional conflicts, public health epidemics, including the COVID-19 pandemic, or otherwise.

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, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, clinical trials or future commercialization efforts.

Risks Related to Development and Commercialization of Our Product Candidates

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive marketing authorization.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing authorization. To obtain the requisite marketing authorizations to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. We have limited clinical data for our product candidates. Product candidates in later stages of clinical trials may fail to show similar or desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of discontinuation among clinical trial participants. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and marketing authorization and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

Tovorafenib (DAY101) has only been studied in a limited number of patients. Should the FDA grant approval for market authorization, tovorafenib (DAY101) will be available to a much larger number of patients, and we do not know whether the results of tovorafenib's use in such larger number of patients will be consistent with the results from our clinical studies.

Tovorafenib (DAY101) has been administered only to a limited number of patients in clinical studies. While the FDA accepted our NDA and granted priority review for tovorafenib (DAY101), we do not know whether the results when a larger number of patients are exposed to tovorafenib (DAY101), including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of tovorafenib (DAY101) that served as the basis for the FDA's acceptance of our NDA and grant of priority review for tovorafenib (DAY101). New data relating to tovorafenib (DAY101), including from adverse events reports and our post-marketing commitments in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of tovorafenib (DAY101) from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing tovorafenib (DAY101)'s marketing applications for additional indications and/or in other jurisdictions, or impose post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial (PNOC014), and we do not control the trial operations or reporting of the results of such trials.

From time to time, we may rely on certain clinical data from investigator-sponsored clinical studies, and we do not control the trial operations or reporting of the results of such trials. This was the case for the initial Phase 1 study for our lead product candidate, tovorafenib (DAY101) (PNOC014), which was run as an investigator-initiated, multi-center trial in patients with relapsed/refractory pLGG that is being conducted by the Dana Farber Cancer Institute in collaboration with the Pacific Pediatric Neuro-Oncology Consortium, or PNOC. The last data reported from that trial was in January 2023. It is possible that additional data, when reported, will not demonstrate similar results. We have no control over the timing of such clinical data announcements. Our pivotal Phase 2 FIREFLY-1 trial tovorafenib is a Day One-sponsored trial. Although we expect that our pivotal Phase 2 FIREFELY-1 trial in pLGG will provide a sufficient dataset to support approval based on preliminary discussions with regulatory agencies, we cannot assure you that the FDA will not require data from additional patients or additional follow-up data from existing patients on PNOC014 to support approval. In addition, in later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization for their products.

Furthermore, we do not control the design or administration of investigator-sponsored trials, nor the submission or approval of any IND or foreign equivalent required to conduct these trials, and the investigator-sponsored trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing authorization from the FDA or other applicable regulatory authorities. To the extent the results of this or other investigator-sponsored trials are inconsistent with, or different from, the results of our planned company-sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the results of the company-sponsored trial or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing authorization of our product candidates. While investigator-sponsored initiated trials could be useful to inform our own clinical development efforts, we do not control the data or timing of data releases for investigator-sponsored trials, and there is no guarantee that we will be able to use the data from these trials to form the basis for marketing authorization of our product candidates.

Our compassionate use programs could subject us to additional risks, including delays in our clinical trial programs, impacts to our supply capabilities, or adverse publicity.

Some patients receive access to investigational drugs outside of clinical trials through compassionate use programs, which refer to expanded access or right to try programs. These patients generally have life-threatening illnesses for which there are no alternative therapies or they have exhausted all other available therapies. There are a number of risks that we may face as a result of our compassionate use programs. For example, the risk for serious adverse events in this patient population is high, which, if those adverse events are determined to be drug-related, could have a negative impact on the safety profile of our drug candidates and/or cause significant delays, result in an inability to successfully commercialize our drug candidates, and/or materially harm our business. Additionally, if we were to provide patients with any of our drug candidates under a compassionate use program, our supply capabilities may limit the number of patients who are able to enroll in the program. It also may become challenging to enroll patients in randomized trials if product candidates are being supplied to patients under expanded access programs. These factors may result in the need to restructure or pause any compassionate use program in order to enroll sufficient numbers of patients in our clinical trials required for marketing authorization and successful commercialization of our drug candidates. If we were to restructure or pause our compassionate use programs, we could face adverse publicity or disruptions related to current or potential participants in our programs.

Our clinical trials may be suspended, delayed, or fail to adequately demonstrate the safety and effectiveness of any of our product candidates, which would prevent or delay development, marketing authorization and commercialization.

Before obtaining marketing authorization from the FDA or comparable foreign regulatory authorities for the sale of our current product candidates, we must demonstrate through lengthy, complex and expensive clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. Failure can occur at any time during the clinical trial processes and for any number of reasons, and, because our product candidates are in earlier stages of development, there is a high risk of failure and we may never succeed in developing marketable products.

We may experience numerous challenges and unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing authorization or our ability to commercialize our product candidates, including:

- FDA or other regulators refusing to permit our clinical studies to proceed or placing studies on hold before or after the studies begin;
- a failure to demonstrate that the dose for a product candidate has been optimized;
- failure of our product candidates in clinical trials to demonstrate important functional, quality, or patient-reported outcomes;
- changes in the competitive landscape preventing marketing authorization in one or several subsets studied in our programs, including in relapsed or front-line pLGG;
- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research and/or drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- unanticipated delays in our preclinical studies or clinical trials;
- third-party contractors failing to comply with regulatory requirements, including Good Clinical Practice, or GCP, regulations, or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- failure of our clinical trials to demonstrate the safety or effectiveness of our product candidates;
- regulators revising the requirements for approving our product candidates; and
- receipt of feedback from regulatory authorities that would require us to include data from additional patients or longer term efficacy and safety data.

We may also face unanticipated regulatory hurdles in our drug development program that may require additional data generation or delay our existing or planned trials and the timing of applications for marketing authorization. For instance, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Additionally, FDA may determine that it has questions or concerns about our trials and may not permit our proposed clinical studies to move forward by imposing a partial or full clinical hold.

Further, we, FDA or an institutional review board, or IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including Good Clinical Practices, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if FDA finds deficiencies in our INDs or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials.

We may also conduct clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Further, data from trials conducted outside of the United States may be subject to additional scrutiny by FDA, which may require that additional U.S. data be generated.

Because our product candidates are initially targeted towards the pediatric population, we may face additional hurdles and be subjected to greater scrutiny by regulatory agencies. Trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric studies are more dependent on a smaller number of specialized clinical trial sites, which in turn can limit site availability and make the trials more expensive to conduct. In addition, as interest in pediatric indications grows as a result of the Research to Accelerate Cures and Equity (RACE) for Children Act and other market forces, trial recruitment may become even more difficult due to competition for eligible patients. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Our inability to enroll a sufficient number of pediatric patients for our clinical trial could result in significant delays, require us to abandon one or more clinical trials altogether, impact our ability to raise additional capital, and delay or prevent our ability to obtain necessary marketing authorizations for any drug product candidate.

We cannot predict the outcome of our clinical trials, nor can we guarantee that the data we generate from our clinical trials will be acceptable to regulatory authorities so as to support marketing authorization.

The outcome of clinical trials is uncertain, and, because our product candidates are in earlier stages of development, there is a significant risk of failure. If we complete our clinical trials but the results of our clinical trials are inconclusive or only modestly positive, if there are safety concerns or serious adverse events associated with our product candidates, or if our clinical trials are delayed or require unplanned changes, we may:

- incur additional, unplanned drug development and/or commercialization costs;
- be delayed in obtaining or unable to obtain marketing authorization;
- be required to perform additional clinical trials to support approval;
- obtain approval for indications or patient populations that are not as broad as intended or desired or may have contraindications, limitations of use, or other restrictions that affect the market for the product;
- obtain marketing authorization with labeling that includes safety warnings a risk evaluation and mitigation strategy, or REMS, and/or other restrictions on distribution or use that could affect market access;
- be subject to additional post-marketing testing requirements or commitments;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose post-marketing safety labeling changes or a REMS;
- be subject to civil or criminal investigations and litigation; or
- experience damage to our reputation.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

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 FDA or comparable foreign regulatory authorities. FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or has affected the conduct or interpretation of the study. FDA or a comparable foreign regulatory authority 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 FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing authorization of one or more of our product candidates.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, we may be delayed in or prevented from obtaining necessary marketing authorization for any or all of our product candidates.

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. In our tovorafenib (DAY101) program, we utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. We cannot be certain (i) how many patients will have the requisite alterations for inclusion in our clinical trials, (ii) that the number of patients enrolled in each program will suffice for marketing authorization or (iii) whether each specific BRAF mutation targeted will be included in the approved drug labeling. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of, and perceptions as to, the potential advantages and risks of our product candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the availability, expertise, and selection of contract research organizations, or CROs, to manage operations related to clinical trial enrollment;
- competing studies or trials with similar eligibility criteria;
- invasive procedures required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- ongoing shortages of chemotherapy standard of care, which may be used in the control arm of certain of our clinical trials, including FIREFLY-2;
- eligibility criteria defined in the protocol for the trial in question;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians or patient advocacy organizations to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

In addition, the conditions for which we currently plan to evaluate our product candidates are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. Further, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as our clinical product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Moreover, if any of our competitors receive FDA approval for a product, it may limit our ability to enroll patients in our clinical trials if they decide to seek treatment with an approved product. For example, Novartis recently received approval for dabrafenib in combination with trametinib, which could in the future limit our ability to enroll patients in clinical trials for tovorafenib (DAY101).

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials or clinical programs altogether. There may be competing trials, as well as the limited bandwidth of pediatric oncology institutions for running trials, which can lead to the prioritization of certain trials, resulting in delays in our clinical trials. In addition, because our product candidates are initially targeted to pediatric populations, we may face additional challenges. For example, parents may be reluctant to enroll their children in our clinical trials or may decide to withdraw their children from our clinical trials to pursue other therapies.

Preliminary, interim, initial and topline 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, interim or topline data from our clinical trials, such as the initial interim data and the topline data analysis for the pivotal Phase 2 of our tovorafenib (DAY101) trial. These updates are 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 study. Additionally, 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. Therefore, positive interim or initial results in any ongoing clinical trial may not be predictive of such results in the completed study. Initial or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. For example, our FIREFLY-1 clinical trial was designed to use the Response Assessment for Neuro-Oncology – High Grade Glioma, or RANO-HGG, to measure the primary endpoint of ORR, in alignment with FDA, with overall response rate, or ORR, using Response Assessment for Pediatric Neuro-Oncology – Low-Grade Glioma, or RAPNO-LGG, as a secondary endpoint. Following discussions with FDA and the March 2023 approval of dabrafenib, in combination with trametinib in BRAF V600E pLGG, we have structured the primary endpoint in our FIREFLY-2/LOGGIC trial to be assessed using the Response Assessment for Neuro-Oncology-Low Grade Glioma, or RANO-LGG, and have included RANO-LGG as an exploratory endpoint in FIREFLY-1.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline 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, operating results, prospects or financial condition.

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize, including tovorafenib (DAY101), may compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of competing product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing, or may in the future develop, product candidates. In addition, our product candidates may need to compete with drugs that are prescribed off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates.

We also compete with these organizations to recruit and retain qualified scientific, management and sales and commercial and marketing personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions.

We expect to face competition from existing products and products in development for each of our programs. Drug discovery efforts focused on V600 mutations have led to clinical success in some cancers. Three BRAF inhibitors have been approved by the FDA for the treatment of tumors containing V600E or V600K mutations. These first-generation BRAF inhibitors, known more generally as Type I RAF inhibitors, are vemurafenib, marketed as Zelboraf® by Genentech; dabrafenib, marketed as Tafinlar® by Novartis; and encorafenib, marketed as Braftovi® by Pfizer. Dabrafenib, in combination with trametinib, marketed as Mekinist® by Novartis, has been approved for the treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This includes BRAF V600E pLGG, a subset of the greater RAF-altered pLGG clinical scope of the tovorafenib (DAY101) development program. We believe that current data indicates that the BRAF V600E subset represents 10%-20% of BRAF-altered pLGG, but additional epidemiologic data may emerge as more patients are profiled. Further, dabrafenib, in combination with trametinib, was granted full approval in the BRAF V600E pLGG indication in March 2023 to include the treatment of pediatric patients 1 year of age and older with low-grade glioma, or LGG, with a BRAF V600E mutation who require initial systemic therapy.

Four MEK inhibitors have been approved by the FDA. Three have been approved for the treatment of tumors containing BRAF V600E or V600K mutations, including cobimetinib, marketed as Cotellic® by Genentech; trametinib, marketed as Mekinist® by Novartis; and binimetinib, marketed as Mektovi® by Pfizer. A fourth MEK inhibitor—selumetinib, marketed as Koselugo® by AstraZeneca—has been approved for the treatment of pediatric patients, two years of age and older, with neurofibromatosis type 1, or NF1, who have symptomatic, inoperable plexiform neurofibromas. While MEK inhibitors as monotherapy have been shown to be active in BRAF altered pLGG (both BRAF V600E mutant pLGG and BRAF fusion-driven pLGG), no MEK inhibitors have been FDA approved as monotherapy for the treatment of pLGG patients.

There are a number of next-generation BRAF inhibitors in clinical development. BeiGene has two next-generation BRAF programs: Lifirafenib (BGB-283), which is currently in a Phase 1/2 trial in combination with mirdametinib, and BGB-3245 which is currently in a single agent in Phase 1 dose escalation study. Hanmi/Genentech are developing belvarafenib in combination with cobimetinib in a Phase 1b clinical trial. Fore Therapeutics (formerly NovellusDx) is developing the RAF dimer breaker PLX8394 in a Phase 1/2 trial in combination with cobicistat. Kinnate is developing KIN-2787 in a monotherapy Phase 1 clinical trial as well as in combination with the MEK inhibitor binimetinib in a Phase 1b clinical trial. Black Diamond Therapeutics have next-generation BRAF inhibitors in various stages of preclinical development. Jazz Pharmaceuticals and Redx have announced that the pan-RAF inhibitor JZP815 has entered clinical development in a Phase 1 trial. Erasca recently announced that it has entered into an exclusive worldwide license agreement with Novartis for naporafenib, a Phase 2 pivotal-ready pan-RAF inhibitor with a potential first-in-class and best-in-class profile in NRAS mutant melanoma and other RAS/MAPK pathway-driven tumors.

With regard to the treatment of pLGG, some MEK inhibitors' and some type I RAF inhibitors' other targeted therapies have been studied, or are being studied, in academic investigator-initiated clinical trials, and in some regions may be being used in an off-label manner. The off-label use of these agents may represent competition for tovorafenib (DAY101) when it enters the market.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining marketing authorizations and reimbursement and marketing approved products than we do.

Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining marketing authorizations, recruiting patients and manufacturing biotechnology product candidates. These companies also have significantly greater research, marketing and sales capabilities than we do and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs.

As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market or could make our development more complicated.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than tovorafenib (DAY101) or our other product candidates. Even if the product candidates we develop achieve marketing authorization, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Safety risks or other side effects associated with tovorafenib (DAY101), pimasertib or any future product candidates we may develop could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the use of an approved product, or result in significant negative consequences following marketing authorization, if any.

As is the case with pharmaceuticals generally, we have observed side effects and adverse events associated with our lead product candidate, tovorafenib (DAY101), and our other product candidates. The most common side effects (adverse events) observed to date with tovorafenib included maculopapular rash, anemia, headache, elevation in blood creatinine phosphokinase, or CPK, nausea, skin and hair discoloration and fatigue.

Results of our ongoing and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. These side effects or unexpected characteristics may be subject to regulatory reporting requirements before and/or after approval. Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug.

Additionally, patients treated with our product candidates have undergone, or may also be undergoing, medical, surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non-treatment related reasons, which could impact development of tovorafenib (DAY101), pimasertib or our other product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from such product candidate will be delayed or eliminated. Serious adverse events, or SAEs, observed in clinical trials could hinder or prevent market acceptance of any approved products or reduce the duration of time that physicians expect to use our product in particular patients. Any of these occurrences may significantly harm our business, prospects, financial condition and results of operations.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our product candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many drugs that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions, require additional testing to confirm these determinations, require more restrictive labeling, or deny marketing authorization of the product candidate.

It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our product candidates becomes more widespread following any marketing authorization, illnesses, injuries, discomforts and other adverse events that were observed, did not occur or went undetected in earlier trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may significantly harm our business, financial condition, results of operations and prospects significantly.

If any of our product candidates receive marketing authorization, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings in the labeling, such as a contraindication or a boxed warning, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may impose additional restrictions on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- we may be subject to regulatory investigations and government enforcement actions;

- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market authorization or acceptance of our product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

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

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

The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

We plan to seek approval of tovorafenib (DAY101) as a treatment of both front-line and relapsed/progressive pLGG. In October 2023, the FDA accepted our NDA and granted priority review for tovorafenib (DAY101) as a monotherapy in relapsed or progressive pLGG. However, there is no guarantee that our product candidates would be approved for either line of treatment, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. For example, pLGG is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with pLGG who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and/or market research. These estimates may prove to be incorrect. Additionally, new studies may change the estimated incidence or prevalence of the cancers that we are targeting. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing authorization for additional indications.

Our clinical development activities are primarily focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.

The discovery and development of targeted therapeutics for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover, identify and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our product candidates' preclinical trial results and our clinical work, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population. In some cases, the target patient populations may not be completely defined. We will need to screen and identify appropriate patients with the targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for RAF-driven cancers for our tovorafenib (DAY101) program, we may never successfully identify additional oncogenic alterations sensitive to tovorafenib (DAY101) in other MAPK-driven tumors. Therefore, we do not know if our approach of treating patients with genomically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

Our product candidates, including tovorafenib (DAY101), may not achieve adequate market acceptance among physicians, healthcare professionals, patients or their families, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive marketing authorization, they may not gain adequate market acceptance among physicians, patients or their families, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy, durability and safety profile as demonstrated in clinical trials compared to alternative treatments, in addition to functional, quality, or patient-reported outcomes;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments and the cost/benefit ratios of each;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities, and timing of relevant formulary decision-making resulting in this coverage and reimbursement;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration in relation to competition;
- the willingness of the target patient population (which may include willingness of our pediatric patients' parents) to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales, marketing efforts and market access;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

With respect to tovorafenib (DAY101) specifically, successful commercialization will depend on whether and to what extent physicians and pharmacies, over whom we have no control, determine to utilize tovorafenib (DAY101) at the price we have selected. Tovorafenib (DAY101) would be made available to patients. Because of this, it is particularly difficult to estimate tovorafenib (DAY101)'s market potential and how physicians, payors and patients will respond to the pricing of tovorafenib (DAY101).

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as price restrictions.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates, including tovorafenib (DAY101), that receive marketing authorization will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors, as patients who are prescribed medicine for the treatment of their condition generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Further, coverage and adequate reimbursement from governmental healthcare programs such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing authorization. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing authorization.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, particularly pediatric products. The payor mix for pediatric products in the United States is a fragmented combination of state-specific Medicaid policies and a broad universe of private insurance companies. There is no consistent policy or leading payor to inform other price-setting entities. National payor policies are expected to be critical to our ability to achieve broad payment coverage. Further, to the extent our products obtain coverage by one third-party payor, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We plan to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost-effective. Moreover, third-party payor coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

In addition, complementary and companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for related pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, or EU, medicinal product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing authorization. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing authorization, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing, commercializing tovorafenib (DAY101) and any future products and marketing of therapeutic 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 FDA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing our product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain 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 claims that could have an adverse effect on our business and financial condition.

Risks related to Government Regulation

The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain marketing authorizations for tovorafenib (DAY101), pimasertib or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to tovorafenib (DAY101) and pimasertib, currently our only product candidates in planned or ongoing clinical trials, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing authorization of drugs in the United States requires the submission of an NDA to FDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. We are not permitted to market any product candidate in the United States until we obtain approval from FDA of the NDA for that product.

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

FDA approval of an NDA is not guaranteed, and the review and approval process is an expensive and uncertain process, over which the FDA has substantial discretion, that may take several years. The number and types of preclinical studies and clinical trials that will be required for NDA approval vary depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA marketing authorization process and will be commercialized. The FDA approved our NDA and granted priority review for tovorafenib (DAY101) as a monotherapy in relapsed or progressive pLGG. However, there can be no assurance that any of our product candidates will receive marketing authorization in the United States or in other jurisdictions. Additionally, in connection with the FDA's approval of tovorafenib (DAY101) for market authorization, if granted, we may be subject to certain approval requirements or other post-marketing commitments. If we fail to comply with such requirements or if the results of our clinical trials are negative, the FDA could withdraw approval, add warnings or narrow the approved indication in the product label.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, in May 2022, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing authorization. On the basis of our clinical trials, the FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA may:

- not deem our product candidate to be safe and effective;
- determine that the product candidate does not have an acceptable benefit-risk profile;
- determine in the case of an NDA seeking accelerated approval that the NDA does not provide evidence that the product candidate represents a meaningful advantage over available therapies and, therefore, may deny approval;
- determine that ORR as the primary endpoint, complemented by key secondary endpoints, is insufficient to reliably define clinical benefit;
- not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing authorization, and may impose requirements for additional preclinical studies or clinical trials;
- determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- determine that the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- disagree regarding the formulation, labeling and/or the specifications;
- not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- change approval policies or adopt new regulations; or
- not file a submission due to, among other reasons, the content or formatting of the submission.

We have not yet obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our clinical product candidates. Furthermore, even if we receive FDA approval, there is no assurance that we will receive similar approval from comparable regulatory authorities in foreign jurisdictions, which may limit our addressable market and could adversely affect our business, prospects, financial condition and results of operations.

If we experience delays in obtaining approval or if we fail to obtain approval of tovorafenib (DAY101) or pimasertib, or our future product candidates, if any, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired, which would adversely affect our business, prospects, financial condition and results of operations.

If we seek to utilize any of FDA's expedited programs, FDA may not find our product candidates to be eligible for these programs and, if granted, these programs may not lead to faster development, regulatory review or approval of our product candidates.

FDA has several expedited programs, including Fast Track, Priority Review, Breakthrough Therapy, and Accelerated Approval, which are authorized by the Federal Food, Drug and Cosmetic Act, or FD&C Act, and implemented pursuant to FDA regulations and guidance. None of these programs change the standard for FDA approval of a pharmaceutical product. We still must demonstrate substantial evidence of effectiveness and an acceptable safety profile to obtain marketing authorization. In October 2023, the FDA accepted our NDA and granted priority review for tovorafenib (DAY101) as a monotherapy in relapsed or progressive PLGG. We may seek to avail ourselves of priority review with respect to one or more of our product candidates in the future or of another of the FDA's expedited programs.

For example, we may seek Fast Track Designation for one or more of our product candidates.

FDA may grant a Fast Track designation to a drug that is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrates the potential to address unmet medical needs for this condition. FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that FDA would decide to grant it. FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We have applied for and have been granted Breakthrough Therapy Designation for tovorafenib (DAY101) in patients with advanced pLGG, and we may apply for Breakthrough Therapy Designation for other product candidates or indications. FDA may designate a drug as a potential breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between 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 designated as breakthrough therapies by FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA. FDA may withdraw Breakthrough Therapy Designations if it determines that the criteria for the designation is no longer met.

In October 2023, the FDA accepted our NDA and granted priority review for tovorafenib (DAY101) as a monotherapy in relapsed or progressive pLGG. We may seek Priority Review of one or more of our other applications for marketing authorization, or we may receive Priority Review as part of other designations we may seek for one or more of our other product candidates. FDA may grant Priority Review to an application if an application is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. FDA may also grant Priority Review to supplements that propose a labeling change pursuant to a report on a pediatric study under Section 505A of the FD&C Act. Additionally, FDA may grant Priority Review to any application or supplement for a drug submitted with a priority review voucher. We cannot assure you that FDA would decide to grant Priority Review of any of our product candidates.

Even if we do receive Fast Track Designation, Breakthrough Therapy Designation, or Priority Review for any of our product candidates, we may not experience expedited development, review or faster action on our applications for marketing authorization compared to products without such designations.

The accelerated approval pathway may be unavailable or, if available, may not lead to faster development, regulatory review, or marketing authorization, and the use of the accelerated approval pathway does not necessarily increase the likelihood that our product candidates will receive marketing authorization.

Under FDA's Accelerated Approval Program, and subject to the conditions set forth in section 506(c) of the FD&C Act and FDA regulations, FDA may approve a product for a serious or life-threatening disease or condition 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, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. FDA generally reserves the use of accelerated approvals for situations in which the product candidate at issue provides a meaningful therapeutic benefit over existing treatments.

We may seek accelerated approval for one or more of our product candidates on the basis of a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, such as overall response rate, or ORR. FDA may not agree with our conclusion that an endpoint we select is reasonably likely to predict clinical benefit, and thus FDA may not agree that accelerated approval is appropriate based on that endpoint (even if the results on that endpoint are statistically significant), which could delay or preclude accelerated approval.

Products granted accelerated approval are subject to certain post-marketing requirements, which typically includes a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product, which must be completed with due diligence. By the time of approval of the product, FDA must set forth the conditions for the post-marketing studies which may include specific conditions and deadlines relating to the study protocol, enrollment targets, target completion date, and other milestones. FDA generally expects—and may require, as appropriate—the confirmatory study or studies to be underway at the time of the accelerated approval or within a specific time frame following approval. FDA may disagree with our proposed clinical study designs for post-marketing confirmatory studies, and may require study conditions that are unfavorable to us, which could delay approval or lead to the withdrawal of a product approved under the accelerated approval pathway.

In addition, FDA regulations require that sponsors of products granted accelerated approval submit during the pre-approval review period 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 FDA, the sponsor must submit all promotional materials at least 30 days prior to use.

The accelerated approval pathway has come under scrutiny within FDA, by Congress, and by other stakeholders. FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA has convened its Oncologic Drugs Advisory Committee to review what FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, in 2021, the Oncology Center of Excellence announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and

innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies.

Finally, Congress recently passed the Food and Drug Omnibus Reform Act of 2022, or FDORA, which implemented key reforms to FDA's authorities with respect to accelerated approval, including strengthening requirements around post-approval studies, codifying procedures for withdrawal of a product approved under the expedited approval pathway, and establishing an intra-agency Accelerated Approval Council to address accelerated approval policy. FDORA also added the failure to conduct post-approval studies with due diligence or to submit timely progress reports on such studies to the list of prohibited acts under the FD&C Act, which means that any such failures, whether they result from our actions or the actions of third parties, could provide the basis for enforcement actions to be brought against us, which may be costly to defend or we may be unsuccessful in our defense.

FDA also has the authority to withdraw products approved under the accelerated approval pathway using expedited withdrawal procedures. Circumstances that may lead to such withdrawal include:

- we fail to conduct any required post-approval study of our product candidate with due diligence, including with respect to conditions specified by FDA;
- a study required to verify and describe the predicted clinical benefit of our product candidate fail to verify and describe such benefit;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

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, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need, and accelerated approval of our product candidate would be more difficult or may not occur at all.

Even though we have received Breakthrough Therapy Designation by the FDA for tovorafenib (DAY101) in treating pLGG, such designation may not lead to a faster development or regulatory review or approval process, it does not increase the likelihood that tovorafenib (DAY101) will receive marketing authorization, and we may not receive Breakthrough Therapy Designation for other product candidates.

We have received Breakthrough Therapy Designation from FDA for the use of tovorafenib (DAY101) in patients with advanced pLGG. Although we have received this designation, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues relating to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical studies may delay the submission or review of an application for marketing authorization,, regardless of whether a product qualifies for Breakthrough Therapy Designation or access to any other expedited program. Access to an expedited program may also be withdrawn by FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any Breakthrough Therapy Designation or any of FDA's other expedited programs does not ensure that we will ultimately obtain marketing authorization for such product.

Receiving Breakthrough Therapy Designation for one product candidate does not increase the likelihood that we would receive Breakthrough Therapy Designation for other product candidates.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have obtained orphan drug designation in the United States and in the EU for use of tovorafenib (DAY101) in treating malignant glioma and glioma, respectively. We may seek orphan drug designation for tovorafenib (DAY101) in additional geographies or indications, or for pimasertib or any product candidates we develop in the future. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making available the drug for such disease or condition will be recovered from sales of the product in the United States.

Generally, if a product with a U.S. orphan drug designation subsequently receives the first marketing authorization for the drug for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes FDA from approving another marketing application for the same drug for the same indication for a period of seven years. Orphan drug exclusivity in the United States may be lost if FDA determines that the request for designation was materially defective or the drug in fact was ineligible for orphan-drug designation at the time the request for designation was submitted, or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The FDA may approve a subsequent application to market the same drug for the same indication during the exclusivity period in certain circumstances, such as if the subsequent product demonstrates clinical superiority (i.e., the subsequent product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. Orphan drug designation also entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

In the EU, if a medicinal product is granted marketing authorization as an orphan medicinal product, it benefits from a period of orphan market exclusivity during which the European Medicines Agency, or the EMA, or a national regulator may not accept a marketing authorization application for a similar medicinal product in the same orphan indication. The applicable period of orphan exclusivity is ten years in the EU, but this can be reduced to six years if a drug no longer meets the criteria for orphan drug designation. The EMA or a national regulator may accept an application and grant a marketing authorization for a similar medicinal product for the orphan indication during the exclusivity period if the similar product is safer, more effective or otherwise clinically superior to the orphan product.

We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States or other jurisdictions, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the other incentives associated with orphan drug designation.

Moreover, a recent Eleventh Circuit decision in Catalyst Pharmaceuticals, Inc. vs. FDA regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug's orphan designation has the potential to significantly broaden the scope of orphan drug exclusivity for such products. Specifically, the Eleventh Circuit held that orphan drug exclusivity precludes FDA from approving another marketing application for the same drug for the same orphan-designated disease or condition for a period of seven years. Although FDA has announced that it will not apply the Catalyst decision beyond the facts at issue in that case, Catalyst could serve as a precedent for future challenges to FDA's orphan drug-related decisions, and, accordingly, could fundamentally change how companies rely on, or seek to work around, orphan drug exclusivity in the United States. Legislation has also been introduced that may reverse the Catalyst decision, but such legislation is still in early stages and has not been passed.

We must comply with certain legal requirements and FDA policies, and may seek incentives under certain laws, relating to the development of drugs for pediatric patients, including the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act.

The Pediatric Research Equity Act, as amended, or PREA, requires that certain NDAs, Biologics License Applications, or BLAs, and NDA/BLA supplements contain assessment reports regarding the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations to support dosing and administration for each pediatric subpopulation for which the product has been assessed to be safe and effective. In addition, PREA requires a molecularly targeted pediatric cancer investigation for an original NDA or BLA for a new active ingredient if the product candidate is intended to treat an adult cancer and is directed at a molecular target that FDA determines to be substantially relevant to the growth or progression of a pediatric cancer, which may be different than the claimed adult cancer indication. PREA requires these pediatric studies be conducted using appropriate formulations for each age group that is studied, and an applicant must seek approval of any pediatric formulations that are used. FDA may grant deferrals of PREA requirements or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to a drug for an indication for which orphan designation has been granted, except that PREA will apply to an original NDA or BLA that is subject to the molecularly targeted pediatric cancer investigation requirement. Even if we are deemed exempt from PREA requirements for one application, other applications may be subject to PREA requirements.

Under the Best Pharmaceuticals for Children Act, or the BPCA, FDA can grant pediatric exclusivity to a sponsor that conducts pediatric studies requested by FDA in a document called a Written Request. We may seek pediatric exclusivity for one or more of our product candidates under the BPCA, although we may not be granted such exclusivity. Pediatric exclusivity, if granted, adds six months to the end of certain unexpired statutory exclusivity periods and may also extend unexpired patent terms, depending on whether the application is an NDA or BLA. Whether this six-month extension is granted depends on the voluntary completion of pediatric studies in accordance with and in response to a Written Request for such studies, the submission of the study reports to FDA within the timeframe required by the BPCA, and FDA's acceptance of the study reports. FDA has indicated a strong preference to issue Written Requests only for studies that are in addition to and/or different from pediatric studies required under PREA (if applicable).

In general, pediatric drug development is an area that recently has been, and may continue to be, subject to evolving statutory requirements and regulatory standards, so some uncertainty exists with respect to expectations for pediatric drug development generally.

We may seek a rare pediatric disease designation for one or more of our product candidates under FDA's Rare Pediatric Disease Priority Review Voucher program. Even if we were to obtain marketing authorization for a product with a rare pediatric disease designation, the Rare Pediatric Disease Priority Review Voucher program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher program.

Tovorafenib (DAY101) was granted rare pediatric designation by the FDA in May 2021 for tovorafenib (DAY101) in the treatment of LGGs harboring an activating RAF alteration that disproportionately affects children. We intend to submit the initial tovorafenib (DAY101) NDA as a rare pediatric designation marketing application which may or may not be designated as such by the FDA upon review.

Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the specified criteria. These vouchers are designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. Although the voucher can be sold or transferred to third parties, there is no guarantee that we will be able to receive such voucher or realize any value if we receive and were to sell the voucher.

For the purposes of this program, a rare pediatric disease is a (i) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (ii) rare disease or condition within the meaning of the Orphan Drug Act. The FDA may determine that an application for one or more of our product candidates does not meet the eligibility criteria for a priority review voucher upon approval.

Moreover, under the current statutory sunset provisions, FDA generally may not award rare pediatric disease priority review vouchers after September 30, 2024. However, if the sponsor has received rare pediatric disease designation for a drug no later than September 30, 2024, FDA may award a rare pediatric disease priority review voucher if the drug is approved by September 30, 2026.

If we or a business partner are unable to successfully develop, validate, obtain marketing authorization of and commercialize any companion diagnostic tests that are deemed necessary for the use of any of our product candidates, or experience significant delays in doing so, we may not be able to obtain marketing authorization for, or realize the full commercial potential of, one or more of our product candidates.

Diagnostic tests can be useful in identifying patients who are most likely to benefit from a particular therapeutic drug product, among other potential uses. If a regulatory authority determines that an in vitro diagnostic test is necessary for the safe and effective use of a corresponding therapeutic product, that test is referred to as a "companion diagnostic." Diagnostics that are not essential for the safe and effective use of a therapeutic product but that may aid in the benefit-risk decision-making about the use of the therapeutic product (such as to identify a subset of the indicated patient population for the therapeutic product that may respond particularly well) are typically referred to as "complementary diagnostics." In the future, we may evaluate opportunities to develop, either by ourselves or with collaborators, companion or complementary diagnostic tests for our product candidates for certain indications.

If a companion diagnostic is needed for a therapeutic product, the companion diagnostic is generally developed in conjunction with the clinical program for an associated therapeutic product. To date, FDA has required premarket approval of the vast majority of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a drug product, FDA generally requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before such product can be commercialized (except in limited circumstances). Where a companion diagnostic must be used to identify patients who are likely to benefit from the therapeutic product, the therapeutic product's labeling typically limits the use of the therapeutic product to only those patients who express the specific genetic alteration or other biomarker that the companion diagnostic was developed to detect. By contrast, complementary diagnostics are not typically referenced in the indications for the therapeutic product (i.e., the therapeutic product is not limited to use in biomarker positive patients) but the complementary diagnostic may be described in other areas of the therapeutic product labeling, such as when describing clinical study results for biomarker positive and negative patient subpopulations. While a complementary diagnostic is also typically developed in conjunction with the clinical program for an associated therapeutic product, FDA may not require that the complementary diagnostic be approved before or concurrent with approval of the therapeutic product.

Development of a companion or complementary diagnostic could include additional meetings with regulatory authorities, such as a pre-submission meeting and the requirement to comply with FDA's investigational device exemption regulations for clinical studies involving the diagnostic. In the case of an investigational diagnostic that is designated as "significant risk device," approval of an investigational device exemption application by an IRB and FDA is required before such diagnostic may be used in conjunction with the clinical trials for a corresponding product candidate.

To be successful in developing, validating, obtaining approval of and commercializing a companion or complementary diagnostic, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development, testing, validation and manufacture of companion diagnostic tests for our therapeutic product candidates that require companion diagnostic tests or would benefit from complementary diagnostics, the application for and receipt of any required marketing authorizations, and the commercial supply of these diagnostics. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing authorization, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing authorization. For any product candidate for which a companion diagnostic is necessary to select patients who may benefit from use of the product candidate, any failure to successfully develop a companion diagnostic may cause or contribute to delayed enrollment of our clinical trials, and may prevent us from initiating a pivotal trial. In addition, the commercial success of any of our product candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required marketing authorizations and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. There is no guarantee that physicians will adopt any particular companion diagnostic, be willing to understand how to use it, how to obtain reimbursement for it, how to explain it to patients, or dedicate staff to using it. Any failure to do so could materially harm our business, results of operations and financial condition.

Even if we obtain marketing authorization for our product candidates, the terms of approvals, ongoing regulation of our products or other post-approval restrictions may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing authorization of a product candidate, such as tovorafenib (DAY101), is granted, an approved product and the marketing authorization holder are subject to ongoing regulation by FDA and other regulators. Regulators may impose post-marketing requirements and elicit post-marketing commitments, which may be onerous and subject us to ongoing review and extensive regulation. For example, FDA may request or require post-marketing clinical studies, enhanced pharmacovigilance programs, additional reporting requirements, and other obligations at the time of approval or after approval. FDA also may impose a REMS under Section 505-1 of the FD&C Act in order to ensure that the benefits of our product candidates outweigh their risks. Additionally, either at the time or approval or after approval, FDA could invoke its authority under Section 505(o) of the FD&C Act and require costly post-marketing safety studies, including clinical trials, and/or epidemiologic surveillance to monitor the safety of our approved products in order to assess a known risk related to the product, assess signals of serious risks related to the product, or identify an unexpected serious risk when available data indicates the potential for a serious risk.

In addition, any product candidates for which we receive accelerated approval from FDA are required to undergo one or more clinical trials to confirm the clinical benefit of the product. If confirmatory studies fail to meet their efficacy endpoints, FDA may withdraw approval of the product pursuant to expedited withdrawal authorities. There is no assurance that any such product will successfully advance through its confirmatory clinical trial(s). Therefore, even if a product candidate receives accelerated approval from FDA, such approval may be withdrawn at a later date.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing authorization. Further, there are additional requirements regarding promotional communications if our products are approved through the accelerated approval pathway. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our CMOs could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs, including pre-approval inspections of any manufacturing facilities proposed to commercially manufacture our product candidates, the success of which would be required prior to a commercial product launch. Accordingly, assuming we obtain marketing authorization for one or more of our product candidates, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we are not able to comply with all of our post-approval regulatory requirements, we could have the marketing authorizations for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. In addition, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing authorization, including tovorafenib (DAY101), will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing authorization, such as tovorafenib (DAY101), along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the FD&C Act and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing authorizations;
- damage to relationships with any potential collaborators;
- unfavorable media coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Further, if any of these actions were to occur, we may have to discontinue the commercialization of our product candidates, including tovorafenib (DAY101), limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Our failure to obtain marketing authorization in foreign jurisdictions would prevent our product candidates from being marketed in those jurisdictions, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing authorizations and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing authorization process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing authorizations and may not receive necessary approvals to commercialize our products in any market.

Our current and future relationships with customers and third-party payors may be subject to applicable anti-kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing authorization. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing authorization. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud 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, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value provided to teaching hospitals, as well as ownership and investment interests held by physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, as well as ownership and investment interests held by physicians and their immediate family members. Beginning January 1, 2021, manufacturers are required to collect information regarding payments and transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives for reporting in the following year. The reported information is made available on a public website; and

- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by state payors and non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. Certain state and local laws require the registration of pharmaceutical sales representatives. Certain state and non-U.S. laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, also govern the privacy and security of health information in some circumstances, thus complicating compliance efforts.

Efforts to ensure that our internal business processes and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing authorization of and commercialize our product candidates and decrease the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing authorization of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing authorization.

For example, in March 2010, the ACA was signed into law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- annual fees and taxes on manufacturers of certain branded prescription drugs;
- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report financial arrangements with physicians, as defined by such law, and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to repeal or replace certain aspects of the ACA, including measures taken during the former U.S. president's administration. The Trump administration released executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, since January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, eliminating the implementation of certain ACA-mandated fees and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In November 2020, the U.S. Supreme Court held oral arguments on the U.S. Court of Appeals for the Fifth Circuit's decision that held that the individual mandate is unconstitutional. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. In June 2021, the U.S. Supreme Court remanded the case with instructions to dismiss for lack of standing. However, the U.S. Supreme Court did not decide the ultimate issue of the validity of the individual mandate. Thus, there may be other efforts to challenge the individual mandate or to challenge, repeal or replace the ACA. It is unclear how the U.S. Supreme Court ruling, other such litigation and the healthcare reform measures of the current presidential administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, triggering the legislation's automatic reduction to several government programs. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the last presidential administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. The current presidential administration is also focused on drug pricing. For example, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow the U.S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA's negotiation program will apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics), among other negotiation selection criteria. One statutory exemption from the negotiation program is for a drug that has only a single orphan drug designation and is approved only for an indication or indications within the scope of such designation. The negotiated prices, which for the first round of selected drugs announced September 1, 2023 will become effective in 2026, will be capped at a statutorily-determined ceiling price. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These IRA provisions will take effect progressively starting in 2023, although the drug negotiation provisions of the IRA are currently the subject of legal challenges. In addition, the Secretary of the HHS recently proposed testing three new models for pricing efficiency, including one that develops payment methods for drugs approved under accelerated approval, in consultation with the FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data with the goal of reducing Medicare spending on drugs that have no confirmed clinical benefit. Further, at the state level, individual states have increasingly introduced and passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including: restricting price, reimbursement, discounts, product access, and marketing; imposing drug price and cost disclosure and transparency requirements; permitting importation from other countries; and encouraging bulk purchasing.

We expect that additional state and federal healthcare reform measures, including potentially significant additional changes to current drug pricing and reimbursement structures, will be adopted in the future, particularly if there is a change in presidential administration. Current and future reform measures may result in more rigorous coverage criteria and in additional downward pressure on the prices that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing authorizations of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing authorization, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, including Canada and certain member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing authorization for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, such as arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication or other countries. In addition, the withdrawal of the United Kingdom, or UK, from its membership in the EU, often referred to as "Brexit," could lead to further legal and regulatory uncertainty in the UK and may lead to the UK and EU adopting divergent laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the UK.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

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 Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business and their party agents from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third-party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are 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 transactions of the company, including 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.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. We are also subject to U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons. 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 product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. 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 harm our business.

We and our third-party contractors are subject to numerous foreign, federal, state and local 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 operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance. We could also be held liable for unexpected safety events that could happen in our business offices.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, 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. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing authorizations. 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.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We are developing our current product candidates, and may continue to develop future product candidates, in combination with other therapies, which would expose us to additional risks.

We are developing our current product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing authorization or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing authorization.

If the FDA or comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have never commercialized a product candidate as a company before and currently lack the comprehensive, fully staffed expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators and rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing authorization, we will have to develop our own sales, marketing, market access, commercial planning and supply organization or outsource these activities to a third-party. We are planning on finding collaborations to secure marketing authorizations and commercialize our products outside of the United States. We cannot assure that any collaboration(s) will result in short-term or long-term benefit to the company.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales, marketing, and market access personnel, developing and producing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, all communications and materials in the promotional domain, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

Risks Related to Our Reliance on Third Parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and potential preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain marketing authorization, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials of tovorafenib (DAY101) and pimasertib, and any preclinical studies and clinical trials of any future product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Since such third parties partially control the progress of these trials, they may also publish the data related to these trials prior to obtaining or without our approval for doing so. Specifically, we expect CROs, independent clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. For example, in addition to the Phase 1 clinical trial run by Dana Farber Cancer Institute in collaboration with PNOC, the Children's Oncology Group, a National Cancer Institute-supported clinical trials group and the world's largest organization devoted exclusively to childhood and adolescent cancer research, is developing a group-wide clinical trial of tovorafenib (DAY101) in relapsed Langerhans cell histiocytosis. However, these investigators, CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators, CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure or the failure of third parties on whom we rely to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing authorization process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. In addition, these third parties may be subject to supply chain or inflationary pressures that limit their ability to achieve anticipated timelines or result a greater cost to us. For example, we are aware of a shortage of non-human primates available for preclinical studies and although that is not expected to impact our current business if we begin new product development programs we could be subject to longer development times or difficulty completing necessary research. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

In addition, with respect to investigator-sponsored trials that may be conducted, we would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-sponsored clinical trials could have a material adverse effect on our efforts to obtain marketing authorization for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If 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, we will not be able to obtain, or may be delayed in obtaining, marketing authorizations for tovorafenib (DAY101), pimasertib or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

The manufacture of pharmaceutical products, including our product candidates, such as tovorafenib (DAY101), is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

We do not have any manufacturing facilities, and we currently contract with certain third-party manufacturers in China. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if any of our product candidates obtain marketing authorization. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts and cause FDA to withdraw certain designations, including orphan drug designation. For example, we cannot be sure to what extent the supply chain issues caused by geopolitical uncertainty and public health epidemics, such as the COVID-19 pandemic, may impact our ability to procure sufficient supplies for the development of our product candidates and what, if any, impact that may have on our facilities and operations in the region, including but not limited to a decrease or disruption of production, increased costs of production or other interruptions in our supply chain. In addition, any disruption in production or inability of our manufacturers, specifically in China, to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. Any of these matters could materially adversely affect our business, financial condition and results of operations. In addition, disruptions in logistics routes and transportation capabilities could disrupt our supply chain. And, if we experience unexpected spikes in demand over time, we risk running out of our necessary supplies.

We entered into a manufacturing and supply agreement with Quotient for drug manufacturing of tovorafenib (DAY101) and a packaging agreement with Sharp Corporation, or Sharp, for the packaging and serialization of tovorafenib (DAY101). Supply chain issues, such as those related to certain packaging material, may negatively impact our ability to package and deliver product candidates if not managed effectively. Moreover, if any of our existing or future contract manufacturers or suppliers fail to perform satisfactorily, it could delay development or regulatory approval of our drug candidates or commercialization of our drugs, which could negatively impact our results of operations and business.

We may be unable to enter into additional agreements with third-party manufacturers or suppliers or do so on favorable terms. Our anticipated reliance on a limited number of third party-manufacturers or suppliers exposes us to the following risks:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing, and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter, or other enforcement action by FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates. We have not yet scaled up the manufacturing process for any of our product candidates apart from tovorafenib (DAY101) and may need to scale further to support future supply needs for any of our product candidates. Third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up or commercial activities. For example, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing authorization. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs for clinical testing cannot perform as agreed, we may be required to replace such CMOs. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics such as the COVID-19 pandemic. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing authorization on a timely and competitive basis.

We rely on a limited number of suppliers for raw materials and any disruptions arising from our sole suppliers could result in delays in our clinical trials or otherwise adversely affect our business and results of operations.

We rely on a limited number of suppliers, some of whom are our sole source for certain materials, and some of whom are based in foreign jurisdictions. Our small number of suppliers involves a number of additional risks, including risks related to supplier capacity constraints, component availability, price increases, timely delivery, component quality, failure of a key supplier to remain in business and adjust to market conditions, including inflation and changes in interest rates, turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget, natural disasters, fire, acts of terrorism, pandemics, including the COVID-19 pandemic, or other catastrophic events. Further, in the case of materials for which we have a sole supplier, even if we are able to replace any raw materials or other materials with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the materials that we use to manufacture our product candidates are complex materials, which may be more difficult to substitute. Therefore, any disruptions arising from our sole suppliers could result in delays and additional regulatory submissions, which may adversely affect our business and results of operations.

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

We may seek third-party collaborators for the development and commercialization of some of our product candidates on a select basis. We have not entered into any collaborations to date. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may reassign manufacturing responsibilities to themselves or a new CMO, which would require that any new manufacturing facility also comply with cGMPs. FDA or another regulator could decide to conduct an inspection of any new manufacturing facility and a material noncompliance could delay the launch of commercial manufacturing at such facility.
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, marketing authorization and commercialization described herein would also apply to the activities of any such future collaborators.

Risks Related to Employee Matters and Our Operations

Our future success depends on our ability to retain our executive officers and key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific, medical and commercial personnel. We are highly dependent on the development and management expertise of Jeremy Bender, Ph.D., M.B.A., our Chief Executive Officer, Samuel Blackman, M.D., Ph.D., our Head of Research and Development, as well as the other members of our management team, other key employees and advisors. We currently do not maintain key person insurance on these individuals. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing, commercial and management skills and experience.

We largely conduct our operations in the greater San Francisco Bay Area, a region that is home to other pharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. In addition, as our business changes, key personnel may not want to work for a larger, commercial enterprise. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our product candidates and to grow our business and operations as currently contemplated. We have adopted a greater level of flexibility in our recruiting practices to attract and hire candidates outside of the San Francisco Bay Area, which is intended to increase retention but could have a negative impact on employee engagement, resulting in greater employee turnover.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

We had 133 full-time employees as of September 30, 2023. We expect significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs and, if any of our product candidates receives marketing authorization, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of tovorafenib (DAY101), pimasertib, or any future product candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing authorization of tovorafenib (DAY101), pimasertib, or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize tovorafenib (DAY101), pimasertib, our other pipeline product candidates or any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees and third-parties that we rely on, including, clinical trial investigators, CROs, CMOs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing (e.g., GMP) and clinical practice (e.g., GCP) standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. In particular, research, sales, marketing, and business arrangements in our industry are subject to a wide variety of laws and regulations that are intended to prevent fraud, misconduct, kickbacks, and other abusive practices. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Further, with respect to third parties, third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control resources that any such third party will devote to our preclinical studies or our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting drug development activities, which could affect their performance on our behalf. Our reliance on third parties for drug development activities means that we will have less direct control over the conduct, timing and completion of studies and the management of data generated from such studies. Nonetheless, we remain responsible for ensuring that our studies and trials are conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards. In other words, our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the investigational plan and relevant protocols and that any such trial complies with GCP standards. If we or any of our CROs or any clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in those trials may be deemed unreliable. This may cause FDA or other comparable foreign regulatory authorities to require us to perform additional clinical trials before approving our marketing applications. If any of the third parties we rely on violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or other laws, actions may be instituted against us.

If any actions based on our conduct, our employees' conduct, or third-party conduct 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, Medicaid and other federal healthcare programs, injunctions, private actions brought by individual whistleblowers in the name of the government, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Additionally, there are risks that the third parties we rely on could become disqualified, debarred, suspended or otherwise penalized by FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to engage a substitute and may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

If our security measures are compromised, or our information technology systems or those of our CROs, CMOs, vendors, contractors, consultants, or other third-party partners fail or suffer security breaches, cyber-attacks, loss or leakage of data or other disruptions, this could result in a material disruption of our development programs, compromise sensitive information related to our business or other personal information or prevent us from accessing critical information, potentially exposing us to liability, harm our reputation, or otherwise adversely affecting our business.

In the ordinary course of business, we may collect, process, store, and transmit proprietary, confidential, and sensitive information (including but not limited to intellectual property, trade secrets, proprietary business information, personal information, and protected health information, or PHI). It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We depend on information technology and telecommunications systems for significant elements of our operations and we have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit, and modify our controls over our critical information. This risk extends to the third parties with whom we work, as we rely on a number of third parties to operate our critical business systems and process confidential, proprietary, and sensitive information.

Despite the implementation of security measures, given the size, complexity, and increasing amounts of proprietary, sensitive, and confidential information maintained by our internal information technology systems and those of our CROs, CMOs, vendors, contractors, consultants, and other third-party partners are potentially vulnerable to breakdown, service interruptions, system malfunction, accidents by our personnel or third-party partners, natural disasters, terrorism, global pandemics, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel or those of our CROs, CMOs, vendors, contractors, consultants, business partners and/or other third-party partners, or from cyber-attacks by malicious third parties (including through viruses, worms, malicious code, malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our CROs, CMOs, vendors, contractors, consultants, and other third-party partners, or lead to data leakage.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, viruses, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The increase of “work from home” in recent years has generally increased the attack surface available for exploitation, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the increase of remote work to their advantage. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our CROs, CMOs, vendors, contractors, consultants, and other third-party partners, or inappropriate disclosure of confidential, sensitive, or proprietary information, we could incur liability and reputational damage and the further development and commercialization of tovorafenib (DAY101), pimasertib, or any future product candidates could be delayed. Any breach, loss or compromise of proprietary, sensitive, or confidential information may also subject us to civil fines and penalties, including under HIPAA, and other relevant state and federal privacy laws in the United States. For example, the California Consumer Privacy Act of 2018, or the CCPA, as amended by the California Privacy Rights Act, or the CPRA, imposes a private right of action for security breaches that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences.

The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our CROs, CMOs, vendors, contractors, consultants, and other third-party partners become subject to disruptions or security breaches, 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.

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our CROs, CMOs, vendors, contractors, consultants, and other third-party partners, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, CMOs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for tovorafenib (DAY101), pimasertib, or any other product candidates could result in delays in our marketing authorization efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CMOs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or personnel, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We are required to comply with laws, rules and regulations that require us to maintain the security of personal information. We may have contractual and other legal obligations to notify relevant stakeholders of security breaches. Failure to prevent or mitigate cyber-attacks could result in the unauthorized access to sensitive, confidential, or proprietary information. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with CROs, CMOs, vendors, contractors, consultants, and other third-party partners may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause our customers to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by the actual or perceived security breach.

The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these issues may not be successful, and these issues could result in interruptions, delays, negative publicity, loss of customer trust, diminished use of our products as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses. Any security breach may result in regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition.

Litigation resulting from security breaches may adversely affect our business. Unauthorized access to our systems, networks, or physical facilities could result in litigation with our customers or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management’s time and attention, increase our costs of doing business, or adversely affect our reputation.

We may not have adequate insurance coverage for security incidents or breaches, including fines, judgments, settlements, penalties, costs, attorney fees and other impacts that arise out of incidents or breaches. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or results in changes to insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. Our risks are likely to increase as we continue to expand, grow our customer base, and process, store, and transmit increasingly large amounts of proprietary and sensitive data.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations related to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and third parties who we work with are or may become subject to numerous domestic and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security), the scope of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. The actual or perceived failure by us or related third parties to comply with such obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

In the United States, numerous federal and state laws and regulations, including federal health information privacy and security laws, federal and state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain protected health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Washington state recently passed the My Health My Data Act, which is focused on the collection of consumer health data. The My Health My Data Act has a broader scope than HIPAA and includes a private right of action. There may be substantial regulatory action and litigation associated with this Act once it becomes effective.

The state of California recently enacted the CCPA, which creates new individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. The CCPA, in effect since January 1, 2020, and most recently amended by the CPRA, is now in effect as of January 1, 2023 and enforced as of July 1, 2023, subject to the regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency, or the CPPA. The CCPA gives California residents expanded privacy rights, including the right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed, including by California residents' employers. The CCPA and CPRA provide for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability. The CCPA has prompted several proposals for new federal and state-level privacy legislation, such as in Nevada, New Hampshire, Ohio, New York, Washington, Illinois and Nebraska, as well as in Virginia, which passed the Virginia Consumer Data Protection Act, or VCDPA (effective as of January 1, 2023), and Colorado, which enacted the Colorado Privacy Act, or CoPA (effective as of July 1, 2023). The VCDPA, CoPA and other such proposed legislation, if enacted, could increase our potential liability and compliance costs, and adversely affect our business.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may apply to personal information (including health-related data) obtained from individuals in the European Economic Area, or the EEA, and Switzerland. The GDPR, and its implementing legislation across the EU, imposes strict obligations on businesses, including requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators, requiring limitations on data processing, establishing a legal basis for processing personal information, notification of data processing obligations, notification of security incidents to appropriate data protection authorities or data subjects, protecting the security and confidentiality of the personal information, and establishing means for data subjects to exercise rights in relation to their personal information. The GDPR subjects noncompliant companies to fines of up to the greater of 20 million Euros or 4% of their global annual revenues, potential bans on processing of personal information (including clinical trials), and private litigation. To the extent applicable, the GDPR will increase our responsibility and liability in relation to personal information that we process, and we may be required to put in place additional mechanisms and expend additional time and resources to ensure compliance with the EU data protection rules. Additionally, the UK implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK-specific derogations, for how GDPR is applied in the UK. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies. In addition, supervisory authorities in the EEA, Switzerland, and the UK have enforced data protection legislation inconsistently, which may result in us having to spend additional resources in order to comply with rules and guidance applicable only in certain, local jurisdictions.

Further, European data protection laws generally prohibit the transfer of personal information to countries outside of the EEA, UK, and Switzerland, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal information from the EEA, UK, and Switzerland to the United States and other countries, they are or may become subject to legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal information of Europeans outside of Europe and adversely impact our business. For example, in July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, which enabled the transfer of personal information from EU to the U.S. for companies that had self-certified to the Privacy Shield on the grounds that the EU-U.S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the CJEU did not invalidate the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to uncertainty regarding the use of such mechanisms for data transfers to the United States, and the CJEU made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The European Data Protection Board, or EDPB, issued additional guidance regarding the CJEU's decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross-border data transfers. In June 2021, the European Commission adopted new Standard Contractual Clauses under the GDPR for transfers of personal data outside the EU to countries that the European Commission has not deemed to provide an adequate level of protection for such personal data. If we elect to rely on the new Standard Contractual Clauses for personal data transfers out of the EU, and in light of the EDPB recommendations, we may be required to expend significant resources to meet the obligations the new Standard Contractual Clauses impose; for example, we may be required to conduct transfer impact assessments for such cross-border data transfers and implement additional security measures. We will also have to spend resources to ensure that these new Standard Contractual Clauses continue to be incorporated into all contracts governing data processing and cross-border transfer. In addition, it is anticipated that the UK will finalize its new model clauses governing cross-border data transfers, and therefore we will have to spend additional time and resources seeking to comply with the UK's unique requirements in this area. Due to potential legal challenges, there is uncertainty regarding whether the new EU Standard Contractual Clauses will remain a valid mechanism for transfers of personal information out of the EEA. The use of Standard Contractual Clauses for the transfer of personal information specifically to the United States also remains under review by a number of European data protection supervisory authorities. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. To comply with these requirements and as supervisory authorities continue to issue further guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of Europe, we could suffer additional costs, complaints, or regulatory investigations or fines, and if we are otherwise unable to transfer personal information between and among countries and regions in which we operate, it could affect the manner in which we provide our products and services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK-specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. With respect to transfers of personal data from the EU to the United Kingdom, on June 28, 2021 the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure.

Other countries, including China, Brazil, Australia and Japan, for example, have adopted certain legal requirements for local storage and processing of data and cross-border transfers of personal information, any and all of which could increase the cost and complexity of conducting preclinical testing and clinical trials or delivering our future products, if any, and operating our business. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices.

We are or may become subject to the terms of external and internal privacy and security policies, representations, certifications, publications related to privacy and security.

Compliance with domestic and foreign privacy, data security, and data protection laws, regulations, and contractual and other obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. The actual or perceived failure to comply with domestic and foreign privacy, data privacy, and data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators 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 privacy, data security, and data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

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

Our current operations are primarily located in the San Francisco Bay Area. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather conditions, medical epidemic or pandemic, power shortage, telecommunication failure or other natural or man-made accident or incident that results in our being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, 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 research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Cuts and Jobs Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use our net operating loss carryforwards and certain other tax attributes 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. Unused losses incurred in taxable years beginning on or prior to December 31, 2017, will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. 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 and the fact that there may be additional ownership changes in the future. As a result, our net operating loss carryforwards generated in taxable years beginning on or before December 31, 2017, may expire prior to being used, and the deductibility of our net operating loss carryforwards generated in taxable years beginning after December 31, 2017 may be limited, and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. 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 net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

We have engaged, and will continue to engage, in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We have engaged in strategic transactions, for instance with affiliates of Takeda Pharmaceutical Company Limited, Viracta Therapeutics, Inc. and Merck KGaA, Darmstadt, Germany, and from time to time, we may consider further strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;

- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under our patents (owned, co-owned or licensed) is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current product candidates and future products, as well as our core technologies, including our manufacturing know-how. We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of cancer drug development. Additionally, we intend to rely on regulatory protection afforded through rare drug designations, data exclusivity and market exclusivity as well as patent term extensions, where available.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our own or licensed patent applications will mature into issued patents, and cannot provide any assurances that any such patents, if issued, will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Additionally, patents can be enforced only in those jurisdictions in which the patent has issued. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after its first nonprovisional U.S. filing. The natural expiration of a patent outside of the United States varies in accordance with provisions of applicable local law, but is generally 20 years from the earliest local filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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.

Moreover, our exclusive licenses may be subject to field restrictions and retained rights, which may adversely impact our competitive position. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Significant Agreements.” Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates, including generic versions of such products. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties outside our licensed field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

Other parties have developed technologies that may be related or competitive to our own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in 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 the inventors of our patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Further, we cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Further, 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.

In addition, the patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, the scope of the claims initially submitted for examination may be significantly narrowed by the time they issue, if at all. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that we will be able to pursue or obtain additional patent protection based on our research and development efforts, or that any such patents or other intellectual property we generate will provide any competitive advantage. Moreover, we do not have the right to control the preparation, filing and prosecution of patent applications, or to control the maintenance of the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be filed, prosecuted or maintained in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain competitive advantage, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Third parties, including competitors, may challenge the inventorship, scope, validity, or enforceability thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If issued, our patents may be challenged in patent offices in the United States and abroad, or in court. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, challenging the validity of one or more claims of our patents, once issued. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our patent applications. We may become involved in opposition, reexamination, *inter partes* review, post-grant review, derivation, interference, or similar proceedings in the United States or abroad challenging the claims of our patents, once issued. Furthermore, patents may be challenged in court, once issued. Competitors may claim that they invented the inventions claimed in such patents or patent applications prior to the inventors of our patents, or may have filed patent applications before the inventors of our patents did. A competitor may also claim that we are infringing its patents and that we therefore cannot practice our technology as claimed under our patent applications and patents, if issued. As a result, one or more claims of our patents may be narrowed or invalidated. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, even if we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention if the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Certain regulatory exclusivities may be available, however, the scope of such regulatory exclusivities is subject to change and may not provide us with adequate and continuing protection sufficient to exclude others from commercializing products similar to our product candidates.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, and *inter partes* review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could jeopardize patent term adjustment or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable, our patent rights, or allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. 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 the patents that we 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 own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we 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 in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, *inter partes* review proceedings and post grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

There may also be patent applications that, if issued as patents, could be asserted against us. 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. patent applications that will not be filed outside the United States can remain confidential until patents issue. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates and their uses or manufacturing processes. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. Further, we may incorrectly determine that our product candidates and their uses and manufacturing processes are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent 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, which may negatively impact our ability to develop and market our product candidates. Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our product candidates and the relevant uses and processes.

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. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology 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. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of September 30, 2023, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third-party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our current and/or future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, 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.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Some of our current product candidates and research programs are licensed from third parties. If these license agreements are terminated or interpreted to narrow our rights, our ability to advance our current product candidates or develop new product candidates based on these technologies will be materially adversely affected.

We now depend on, at least in part, Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc. and Merck KGaA, Darmstadt, Germany, and will continue to depend on Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc. and Merck KGaA, Darmstadt, Germany and on licenses and sublicenses from other third parties, as well as potentially on other strategic relationships with third parties, for the research, development, manufacturing and commercialization of our current product candidates. If any of our licenses or relationships or any in-licenses on which our licenses are based are terminated or breached, we may:

- lose our rights to develop and market our current product candidates;
- lose patent or trade secret protection for our current product candidates;
- experience significant delays in the development or commercialization of our current product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

Additionally, even if not terminated or breached, our intellectual property licenses or sublicenses may be subject to disagreements over contract interpretation which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations.

If we experience any of the foregoing, it could have a materially adverse effect on our business and could force us to cease operations which could cause you to lose all of your investment.

If we breach our license agreements, it could have a material adverse effect on our commercialization efforts for our product candidates.

If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Or if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Our current lead product candidates are protected by, among other intellectual property rights, patents and patent applications we co-own and exclusively in-license from Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.). Our current lead product candidates and pipeline and our anticipated near-term pipeline may include technologies, licensed from other third parties, including, for example, Merck KGaA, Darmstadt, Germany.

Under the license agreements, we are subject to various obligations, including diligence obligations such as development and commercialization obligations, as well as potential royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensors may have the right to terminate the applicable license in whole or in part. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could harm our business, prospects, financial condition and results of operations.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

In addition, the agreements under which we license intellectual property or technology from third parties, including our licenses with Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Dana Farber Cancer Institute, Millennium Pharmaceuticals, Inc. and Merck KGaA, Darmstadt, Germany, are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek marketing authorization of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

While we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

Other companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from third parties to further develop or commercialize our existing or future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our existing or future product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our existing or future product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The in-licensing and acquisition of these technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business, financial condition and prospects could suffer.

We may be involved in lawsuits to protect or enforce our own patents or our licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our own issued patents or our licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our collaborators were to initiate legal proceedings against a third-party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review proceedings, post grant review proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating costs and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

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

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our product development, in-license needed technology, or enter into development partnerships that would help us bring our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and/or those of our licensors and the enforcement or defense of our issued patents and/or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third-party was first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and/or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, 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. The Federal Circuit recently issued a decision that involves the interaction of patent term adjustment, or PTA, terminal disclaimers, and obviousness-type double patenting. This decision creates uncertainty to the patent terms of certain U.S. patents that share the same priority claim where one expires later than another due to accrued PTA. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We and/or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. In addition, we cannot assure you that all inventors have been or will be identified by us and/or by our collaborators despite diligent effort. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. 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 and/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 have a material adverse effect on our business. 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.

Our licensors may have relied on third-party consultants or collaborators such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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 have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

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 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 product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing authorization of our product candidates, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon marketing authorization of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration 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 revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent 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 or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors 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. 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and 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 the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals 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 rules applicable to the particular jurisdiction. However, there are situations in which noncompliance 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. If such an event were to occur, it could have a material adverse effect on our business.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors 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 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 secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

We rely in part on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into or may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. 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, 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.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, 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.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Currently, our intellectual property protection includes patents and patent applications that we have in-licensed from Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, and Merck KGaA, Darmstadt, Germany. Our exclusive and non-exclusive licenses may be subject to certain retained rights, which may adversely impact our competitive position. We do not control the prosecution and maintenance of several of the licensed patent portfolios; thus, we cannot assure you that the licensed patent families will be prepared, filed, prosecuted, or maintained in a manner consistent with the best interests of our business. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Significant Agreements.” Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of our own issued patents or pending patent applications may have been generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our existing or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

No earlier than June 1, 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC.

This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

Geo-political actions in the United States 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.

For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Additionally, we are closely monitoring the unfolding events of the armed conflict in Israel which began in October 2023. While this conflict is still evolving, to date, the conflict has not had an adverse impact on our business and results of operations. However, should these conflicts worsen or intensify, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Risks Related to Our Common Stock

An active and liquid trading market for our common stock may never be sustained. As a result, you may not be able to resell your shares of common stock at or above the purchase price.

An active trading market for our common stock may never be sustained. The market value of our common stock may decrease from the purchase price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the purchase price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares.

Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the current or future development of our programs;
- timing and status of enrollment for our clinical trials;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any product candidate we may develop receive marketing authorization, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing authorization and intend to commercialize on our own or jointly with future collaborators;
- regulatory developments affecting current or future product candidates or those of our competitors;
- the amount of expense or gain associated with the change in value of the success payments and contingent consideration;
- changes in general market and economic conditions, such as due to rising interest rates, inflation, recent turmoil in the global banking system, government shutdowns, uncertainty with respect to the federal budget, global regional conflicts and public health epidemics, such as the COVID-19 pandemic;
- business development activities, such as additional program in-licensing, which could result in up-front payments or increased development expenses; and
- cybersecurity incidents.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our common stock is likely to be highly volatile, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, you may not be able to sell your shares of common stock at or above the price paid. The market price for our common stock may be influenced by many factors, including the other risks described in this “Risk Factors” section and the following:

- results of preclinical studies or clinical trials by us or those of our competitors or by existing or future collaborators or licensing partners;
- the timing and enrollment status of our clinical trials;
- changes in the development status of our product candidates, including variations in the level of expense related to the development of our programs or funding support by us or by existing or future collaborators or licensing partners;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our business;

- the success of competitive products or technologies;
- introductions and announcements of new product candidates by us, our future collaboration partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or product candidates;
- announced or completed significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- developments or disputes concerning our intellectual property and proprietary rights;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock;
- the impact of interest rate increases on the overall stock market and the market for biopharmaceutical company stocks;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of shares of our common stock by us, insiders or our stockholders;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- natural disasters, terrorist acts, acts of war and other calamities;
- general economic, industry and market conditions, including rising interest rates, inflation and the recent turmoil in the global banking system, government shutdowns and uncertainty with respect to the federal budget, many of which are beyond our control;
- other events or factors, including those resulting from global pandemics, such as the COVID-19 pandemic, or war, incidents of terrorism or responses to these events, including global regional conflicts; and
- cybersecurity incidents.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, increase in inflation and changes in interest rates, and disruptions to the supply chain, that have been often unrelated or disproportionate to the operating performance of the issuer. Furthermore, the trading price of our common stock may be adversely affected by third parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

The holders of an aggregate of 87,042,933 shares of our outstanding common stock as of September 30, 2023 will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also have registered shares of common stock that we may issue under our equity incentive plans. These shares are freely tradeable in the public market upon issuance.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

Based on the beneficial ownership of our common stock as of September 30, 2023, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 42% of our voting stock. The voting power of this group may increase to the extent they convert shares of non-voting common stock they hold into common stock. As a result, these stockholders, if acting together, will continue to 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 a change of control of our company, even if such 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 our company or our assets and might affect the prevailing market price of our common stock.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will 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 (i) not being required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously.

We could be an emerging growth company for up to five fiscal years following the completion of the IPO; *provided*, *however*, certain 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 equals or exceeds $700 million, if we have total annual gross revenue of $1.235 billion or more, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time.

Even after we no longer qualify as an emerging growth company, we may 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. 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our 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 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 the same exemptions from certain disclosure requirements, 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 and the option to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K. 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.

As of December 31, 2023, we will no longer qualify as an emerging growth company or a smaller reporting company and be able to take advantage of the exemptions from various reporting requirements beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2023 to be filed in 2024.

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

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. 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 classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

The exclusive forum provision in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits against us and our directors, officers, and other employees.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our company, our common stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts, or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and future clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

General Risk Factors

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

As a public company, and particularly after we are no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our products once commercialized. Moreover, these rules and regulations are often 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.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When we are no longer an “emerging growth company” and become an “accelerated filer” or a “large accelerated filer,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Global Select Market, or Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed 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. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

The market price of our common stock may be volatile. 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 these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007-2008 caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID-19 pandemic caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and inflation, as well as the possibility of a recession or further economic downturn. Moreover, there has been recent turmoil in the global banking system. For example, on March 10, 2023, Silicon Valley Bank, or SVB, one of our banking partners, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. While we only had a minimal amount of our cash directly at SVB and, since that date, the FDIC has stated that all depositors of SVB will be made whole, there is no guarantee that the federal government would guarantee all depositors as they did with SVB depositors in the event of further bank closures and continued instability in the global banking system may adversely impact our business and financial condition. Likewise, the capital and credit markets may be adversely affected by global regional conflicts, and the possibility of wider or additional global conflicts, global sanctions imposed in response thereto or an energy crisis. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index below.

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Filing Date	Exhibit	
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.					X
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.					X
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.					X
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.					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

DAY ONE BIOPHARMACEUTICALS, INC.

Date: November 6, 2023

By: /s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., M.B.A.
Chief Executive Officer and President
Principal Executive Officer

Date: November 6, 2023

By: /s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.
Chief Operating Officer and Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeremy Bender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Day One Biopharmaceuticals, 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 6, 2023

/s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., MBA
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles N. York II, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Day One Biopharmaceuticals, 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 6, 2023

/s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer and Principal 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

I, Jeremy Bender, Chief Executive Officer of Day One Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 6, 2023

/s/ Jeremy Bender, Ph.D., M.B.A.
Jeremy Bender, Ph.D., MBA
Chief Executive Officer and President
(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

I, Charles N. York II, Chief Financial Officer of Day One Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 6, 2023

/s/ Charles N. York II, M.B.A.
Charles N. York II, M.B.A.

Chief Operating Officer and Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)