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, 2024

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 October 24, 2024, the registrant had 100,846,294 shares of common stock, $0.0001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 OJEMDA™ (tovorafenib) and our product candidates, potential therapeutic benefits and economic value of OJEMDA and product candidates, our ability to market and sell OJEMDA while maintaining full compliance with applicable federal and state laws, rules and regulations, use of net proceeds from our public offerings, our ability to maintain and recognize the benefits of certain designations received by products and 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, changing interest rates, cybersecurity incidents, actual or perceived instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto 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.

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. "Day One" and all product and 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

PART I-FINANCIAL INFORMATION

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 422,765	$ 230,784
Short-term investments	135,618	135,563
Accounts receivable, net	8,695	—
Inventory	2,735	—
Prepaid expenses and other current assets	11,183	8,927
Total current assets	580,996	375,274
Property and equipment, net	904	208
Operating lease right-of-use asset	2,574	352
Intangible assets, net	16,216	—
Deposits and other long-term assets	117	214
Total assets	$ 600,807	$ 376,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,017	$ 2,576
Accrued expenses and other current liabilities	35,189	26,524
Current portion of deferred revenue	1,462	—
Current portion of operating lease liabilities	77	408
Total current liabilities	39,745	29,508
Long-term portion of deferred revenue	3,061	—
Long-term portion of operating lease liabilities	2,538	—
Total liabilities	45,344	29,508
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 100,810,357 and 87,227,132 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	10	9
Additional paid-in-capital	1,043,826	805,107
Accumulated other comprehensive (loss) income	(6)	9
Accumulated deficit	(488,367)	(458,585)
Total stockholders' equity	555,463	346,540
Total liabilities and stockholders' equity	$ 600,807	$ 376,048

See accompanying notes to the condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 20,070	$ —	$ 28,262	$ —
License revenue	73,691	—	73,691	—
Total revenues	93,761	—	101,953	—
Cost and operating expenses:				
Cost of product revenue	1,590	—	2,297	—
Research and development	33,563	33,163	165,879	93,173
Selling, general and administrative	28,972	18,275	85,715	53,374
Total cost and operating expenses	64,125	51,438	253,891	146,547
Income (loss) from operations	29,636	(51,438)	(151,938)	(146,547)
Non-operating income:				
Gain from sale of priority review voucher	—	—	108,000	—
Investment income, net	5,322	5,291	13,649	12,163
Other income (expense), net	1,197	(3)	1,177	(22)
Total non-operating income, net	6,519	5,288	122,826	12,141
Income (loss) before income taxes	36,155	(46,150)	(29,112)	(134,406)
Income tax benefit (expense)	882	—	(670)	—
Net income (loss)	37,037	(46,150)	(29,782)	(134,406)
Net income (loss) per share - basic	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)
Net income (loss) per share - diluted	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)
Weighted-average number of common shares used in net income (loss) per share - basic	96,623,123	85,952,501	90,164,895	77,682,237
Weighted-average number of common shares used in net income (loss) per share - diluted	96,937,759	85,952,501	90,164,895	77,682,237

See accompanying notes to the condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net income (loss)	$ 37,037	$ (46,150)	$ (29,782)	$ (134,406)
Other comprehensive income:				
Unrealized gain (loss) on available-for-sale securities	16	2	(15)	64
Total comprehensive income (loss)	$ 37,053	$ (46,148)	$ (29,797)	$ (134,342)

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed 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, 2023	87,227,132	$ 9	$ 805,107	$ 9	$ (458,585)	$ 346,540
Issuance of common stock upon exercise of stock options	4,862	—	48	—	—	48
Issuance of common stock upon release of restricted stock units	157,724	—	—	—	—	—
Unvested common stock forfeiture	(12,555)	—	—	—	—	—
Share-based compensation expenses	—	—	12,644	—	—	12,644
Unrealized loss on available-for-sale securities	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(62,412)	(62,412)
Balance at March 31, 2024	87,377,163	9	817,799	(5)	(520,997)	296,806
Issuance of common stock upon exercise of stock options	22,151	—	324	—	—	324
Issuance of common stock upon release of restricted stock units	211,635	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	94,827	—	973	—	—	973
Unvested common stock forfeiture	(12,860)	—	—	—	—	—
Share-based compensation expenses	—	—	13,052	—	—	13,052
Unrealized loss on available-for-sale securities	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(4,407)	(4,407)
Balance at June 30, 2024	87,692,916	9	832,148	(22)	(525,404)	306,731
Issuance of common stock upon exercise of stock options	67,540	—	977	—	—	977
Issuance of common stock upon release of restricted stock units	156,688	—	—	—	—	—
Issuance of common stock in connection with private placement, net of placement agent fees and offering costs	12,893,213	1	178,176	—	—	178,177
Issuance of prefunded warrants to purchase common stock in connection with private placement, net of issuance costs	—	—	20,941	—	—	20,941
Share-based compensation expenses	—	—	11,584	—	—	11,584
Unrealized gain on available-for-sale securities	—	—	—	16	—	16
Net income	—	—	—	—	37,037	37,037
Balance at September 30, 2024	100,810,357	$ 10	$ 1,043,826	$ (6)	$ (488,367)	$ 555,463

See accompanying notes to the condensed financial statements.

Day One Biopharmaceuticals, Inc.
Condensed 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	—	—	—	—	(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	—	—	—	—	(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	—	—	—	—	(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 financial statements.

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

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net income (loss)	$ (29,782)	$ (134,406)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development assets	55,000	3,000
Share-based compensation expense	37,228	28,530
Depreciation expense	54	23
Accretion of discounts on short-term investments, net	(3,566)	(8,502)
Amortization of intangible assets	884	—
Amortization of operating right-of-use asset	332	257
Gain from sale of priority review voucher	(108,000)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,695)	—
Inventory	(2,683)	—
Prepaid expenses and other current assets	(2,326)	(2,148)
Deposits and other long-term assets	97	236
Accounts payable	441	3,131
Accrued expenses and other current liabilities	8,665	4,697
Deferred revenue	4,523	—
Operating lease liability	(277)	(299)
Net cash used in operating activities	(48,105)	(105,481)
Cash flows from investing activities:		
Cash paid for purchase of short-term investments	(383,395)	(344,701)
Proceeds from maturity of short-term investments	307,482	445,915
Proceeds from sale of short-term investments	79,409	—
Cash paid for acquired intangible assets	(17,100)	—
Proceeds from sale of priority review voucher	108,000	—
Cash paid for acquired in-process research and development assets	(55,000)	(3,000)
Cash paid for purchase of property and equipment	(750)	(216)
Net cash provided by investing activities	38,646	97,998
Cash flows from financing activities:		
Proceeds from issuance of common stock in connection with private placement, net of placement agent fees and offering costs	178,177	—
Proceeds from issuance of prefunded warrants to purchase common stock in connection with private placement, net of issuance costs	20,941	—
Proceeds from issuance of common stock, net	—	161,409
Proceeds from issuance of common stock upon stock option exercises	1,349	1,338
Proceeds from issuance of common stock upon Employee Stock Purchase Plan purchase	973	653
Cash provided by financing activities	201,440	163,400
Net increase in cash and cash equivalents	191,981	155,917
Cash and cash equivalents, beginning of period	230,784	85,262
Cash and cash equivalents, end of period	$ 422,765	$ 241,179
Supplemental disclosure of cash flow information:		
Income taxes paid	883	—
Supplemental disclosures of noncash activities:		
Right-of-use asset obtained in exchange for new operating lease liabilities	2,554	—
Deferred offering costs not yet paid	66	—
Purchases of property and equipment included in accrued expenses and other current liabilities	—	41

See accompanying notes to the condensed financial statements.

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

1. Description of Business and Organization

Organization and Business

Day One Biopharmaceuticals, Inc., or the Company, is a commercial-stage biopharmaceutical company dedicated to developing and commercializing targeted cancer therapies for people of all ages with life-threatening diseases. The Company was founded in November 2018 and is headquartered in Brisbane, CA.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and Article 10 of Regulation S-X of the Securities and Exchange Commission, or SEC, and should be read in conjunction with the Company's consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024. The condensed financial statements presented in this Quarterly Report on Form 10-Q are unaudited; however, in the opinion of management, such financial statements reflect all adjustments, consisting solely of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in 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 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 financial statements, and the reported amounts of expenses during the reporting period. Estimates and assumptions made in the accompanying condensed financial statements include, but are not limited to, accruals for research and development expenses, variable consideration and other relevant inputs impacting the gross and net revenue recognition, the valuation of share-based awards, and the valuation of deferred tax assets. 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 developing and commercializing 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, short-term investments, and accounts receivable. 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 non-United States government or government backed issuer, which limits its exposure. The Company has not experienced any losses on its cash, cash equivalents and short-term investments.

For the three months ended September 30, 2024, three individual customers accounted for 100.0% of total net product revenue, with these individual customers representing 69.0%, 23.0%, and 8.0% of the Company's total net product revenue. For the nine months ended September 30, 2024, three individual customers accounted for 100.0% of total net product revenue, with these individual customers representing 66.6%, 27.0%, and 6.4% of the Company's total net product revenue. As of September 30, 2024, three customers accounted for 100.0% of the accounts receivable balance, with these individual customers representing 55.0%, 25.7%, and 19.3% of the accounts receivable balance. No other individual customers account for more than 10.0% of net product sales or accounts receivable. The Company monitors the financial condition of its customers so that it can

appropriately respond to changes in their creditworthiness. To date, the Company has not experienced any losses with respect to the collection of its accounts receivable.

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 commercial and 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.

Accounts Receivable, Net

Accounts receivable, net consists of trade receivables which are amounts due from the Company's specialty pharmacy and specialty distributor customers related to product sales. The Company records trade receivables net of discounts, chargebacks, and any allowances for potential credit losses. An allowance for credit losses is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period of time. For the three and nine months ended September 30, 2024, the Company did not record any expected credit losses related to outstanding accounts receivable.

Inventory

The Company began capitalizing inventory for OJEMDA upon approval by the U.S. Food and Drug Administration, or FDA, in April 2024. OJEMDA is approved for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma, or pLGG, harboring a BRAF fusion rearrangement, or BRAF V600 mutation. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

Inventory is comprised of raw materials, work-in-process and finished goods, and includes costs related to third-party contract manufacturing, packaging, freight-in and overhead. Inventory is stated at the lower of cost or net realizable value with cost based on the first-in-first-out method. Raw and intermediate materials that may be used for either research and development or commercial purposes where the intended use is not yet known are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is used or otherwise allocated for research and development, it is expensed as research and development in the period that determination is made.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenue. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product revenue in the statements of operations. There were no expenses recorded for excess inventory or other impairments during the three and nine months ended September 30, 2024.

Intangible Assets, Net

Upon FDA approval and commercial launch of OJEMDA in April 2024, the Company capitalized the $9.0 million milestone payment to Viracta Therapeutics, Inc. (f/k/a Sunesis Pharmaceuticals, Inc.), or Viracta, for a specified regulatory milestone as a finite-lived intangible asset. Upon the sale of the Priority Review Voucher, or PRV, in May 2024 to fully satisfy PRV-related obligations of the Company's license agreement with Viracta, dated December 16, 2019, as amended, the Company capitalized the $8.1 million payment to Viracta as a finite-lived intangible asset. The intangible assets will be amortized on a straight-line basis over each of the estimated useful life of the underlying intellectual property of 7.3 years. Amortization expense will be recorded as cost of product revenue.

Revenue Recognition

The Company recognizes net product and license revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606, which outlines a five-step process for recognizing revenue from contracts with customers: (i) identify

the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied.

Product Revenue, Net

The Company recognizes net product revenue from OJEMDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion rearrangement, or BRAF V600 mutation, which it began selling in May 2024 through contractual arrangements with its specialty pharmacy and specialty distributor customers.

The Company has determined that the delivery of OJEMDA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. Net product revenue is recognized at the transaction price when the customer obtains control of the Company's product, which occurs at a point in time upon delivery of the product to the customer.

The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with the Company's customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component.

Net product revenues from the sale of OJEMDA are recorded at the transaction price, which include adjustments for discounts and allowances, including estimated cash discounts, government chargebacks, government rebates, specialty distributor fees, copay assistance, and returns. These adjustments represent variable consideration under ASC 606 and are estimated using the expected value method or most likely amount method and are recorded when revenue is recognized on the sale of the product. These adjustments are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Adjustments for variable consideration are determined based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price, only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Cash Discounts — The Company estimates cash discounts based on contractual terms and expectations regarding future customer payment patterns. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Government Chargebacks — Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340B Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of chargebacks that customers have claimed, but for which the Company has not yet issued a credit and credits that the Company expects to issue for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Government Rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The

Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Specialty Distributor Fees — The Company pays fees to our specialty distributor customers for distribution services provided in connection with the sales of OJEMDA. These specialty distributor fees are based on a contractually determined fixed percentage of sales. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

Copay Assistance — The Company offers a co-pay assistance program, which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as accrued expenses and other current liabilities.

Product Returns — Consistent with industry practice, the Company's contracts with customers for OJEMDA generally provide for returns only if the product is damaged or defective upon delivery, if there is a shipment error, and for certain customers, if the product is within an eligible expiry window. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company believes the returns of OJEMDA will be minimal because our customers often carry limited inventory given the price of our products, and the limited number of patients. These reserves are established in the same period that the related revenue is recognized.

License Revenue

The Company generates license revenue from the Ipsen License Agreement, pursuant to which, the Company licensed to Ipsen Pharma SAS, or Ipsen, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services.

Under the terms of the Ipsen License Agreement, (i) Ipsen paid the Company an upfront license fee in the amount of $70.8 million and (ii) Ipsen Biopharmaceuticals, Inc., or the Investor, a fully-owned United States affiliate of Ipsen, purchased 2,341,495 shares of the Company's common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the volume weighted average price, or VWAP, of the Company's common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Company's public release of U.S. GAAP revenue for the quarter ended June 30, 2024 on July 30, 2024, or the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between the Company and the Investor dated July 23, 2024. The Company is also eligible to receive up to approximately $350.0 million in additional commercial launch and sales-based milestone payments, as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of tovorafenib, subject to customary adjustments specified in the Ipsen License Agreement.

The commercial launch milestones related to first commercial sale(s) in certain territories, sales-based milestones and royalties are recognized as revenue when the related sales occur as the license of intellectual property is deemed to be the predominant item to which the commercial launch milestones, sales-based milestones and royalties relate.

Upon execution of the Ipsen License Agreement, the transaction price was determined to be $78.2 million, representing the aggregate of the upfront license fee of $70.8 million and the premium paid by Ipsen on its equity investment in the Company of $7.4 million (the excess of the value of the shares of the Company issued to Ipsen), representing additional consideration from Ipsen for the rights under the Ipsen License Agreement.

The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue against each performance obligation as or when the performance obligations under the contract are satisfied.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. All other promised goods or services in the agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services where any additional consideration paid to the Company reflects their standalone selling prices do not provide the customer with a material right, and, therefore, are not considered performance obligations. If optional

future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as separate performance obligations.

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded within deferred revenue. Contract liabilities within deferred revenue are recognized as revenue after control of the goods or services is transferred to the customer and all revenue recognition criteria have been met.

Cost of Product Revenue

Our cost of product revenue includes the cost of inventory sold, amortization expense of intangible assets and third-party royalties payable on our net product revenue. Cost of product revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the effect of this update on its financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740) – Improvements to Income Tax Disclosures, which enhances the transparency and decision usefulness of income tax disclosures by requiring disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The ASU is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. The Company is currently evaluating the effect of this update on its financial statement disclosures.

3. Recurring Fair Value Measurements

The following table sets forth the Company's financial instruments as of September 30, 2024 and December 31, 2023, which are measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 249,276	$ —	$ —	$ 249,276
U.S. treasury securities	—	194,476	—	194,476
U.S. government agency securities	—	91,498	—	91,498
Total assets measured at fair value	$ 249,276	$ 285,974	$ —	$ 535,250

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 47,003	$ —	$ —	$ 47,003
U.S. treasury securities	—	246,208	—	246,208
U.S. government agency securities	—	63,202	—	63,202
Total assets measured at fair value	$ 47,003	$ 309,410	$ —	$ 356,413

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, 2024 and December 31, 2023.

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, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 249,276	$ —	$ —	$ 249,276
U.S. government agency securities	81,762	—	—	81,762
U.S. treasury securities	68,594	—	—	68,594
Total cash equivalents	399,632	—	—	399,632
Short-term investments				
U.S. government agency securities	9,733	4	(1)	9,736
U.S. treasury securities	125,890	27	(35)	125,882
Total short-term investments	$ 135,623	$ 31	$ (36)	$ 135,618

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 47,003	$ —	$ —	$ 47,003
U.S. government agency securities	63,202	—	—	63,202
U.S. treasury securities	110,645	—	—	110,645
Total cash equivalents	220,850	—	—	220,850
Short-term investments				
U.S. treasury securities	135,554	9	—	135,563
Total short-term investments	$ 135,554	$ 9	$ —	$ 135,563

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

	September 30, 2024	
	Amortized Cost	Fair Value
Mature in one year or less	$ 535,255	$ 535,250
Total	$ 535,255	$ 535,250

	December 31, 2023	
	Amortized Cost	Fair Value
Mature in one year or less	$ 356,404	$ 356,413
Total	$ 356,404	$ 356,413

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, 2024 and December 31, 2023, there were no securities that were in an unrealized loss position for more than 12 months. As of September 30, 2024, the unrealized losses, if any, on the Company's short-term investments 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. Realized gains and losses were immaterial for the three and nine months ended September 30, 2024. There were no realized gains and losses for the three and nine months ended September 30, 2023.

4. Balance Sheet Items

Prepaid Expenses and Other Current Assets

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

	September 30, 2024	December 31, 2023
Prepaid research and development expenses	$ 6,382	$ 5,657
Prepaid insurance	1,355	918
Other prepaid expenses and other assets	3,446	2,352
Total prepaid expenses and other current assets	$ 11,183	$ 8,927

Accrued Expenses and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Accrued research and development expenses	$ 16,299	$ 12,643
Accrued payroll related expenses	11,502	9,165
Accrued professional service expenses	2,893	3,675
Other	4,495	1,041
Total accrued expenses and other current liabilities	$ 35,189	$ 26,524

5. Significant Agreements

Takeda asset purchase agreement

On December 16, 2019, a subsidiary of the Company 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. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under the Takeda Asset Agreement. Pursuant to the Takeda Asset Agreement, the Company purchased certain technology rights and know-how related to TAK-580 (which is now OJEMDA™ (tovorafenib)) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. The Company 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 the Company its exclusive license agreement, or the Viracta License Agreement, with Viracta. Takeda also granted the Company 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 the Company 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.

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 the Company ceases 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 the Company's 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.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, the Company made an upfront payment of $1.0 million in cash and issued 9,857,143 shares of Series A redeemable convertible preferred stock in the Company's subsidiary 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 the Company's subsidiary. 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 the Company's subsidiary for 6,470,382 shares of the Company's common stock upon the effectiveness of the conversion, on May 26, 2021.

License agreement with Viracta

On December 16, 2019, a subsidiary of the Company amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under Viracta License Agreement. Under the Viracta License Agreement, the Company 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.

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. The Company 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.

The Company paid $2.0 million upfront in cash to Viracta, which was recorded as research and development expenses as the technology does not have an alternative future use.

On March 4, 2024, the Company entered into an amendment to the Viracta License Agreement. As part of the amendment, the Company made a one-time payment in March 2024 to Viracta of $5.0 million, which was recorded as research and development expenses during the nine months ended September 30, 2024, in exchange for reduced future payment obligations ranging from the mid-teens to the high single-digit percentage related to the future sale or use of the rare pediatric disease PRV received.

On April 23, 2024, the FDA approved OJEMDA (a tablet formulation and powder solution formulation of tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, the Company received a rare pediatric disease PRV from the FDA. The Company made a $9.0 million milestone payment to Viracta in May 2024 for the achievement of this milestone. The $9.0 million milestone was accounted for as a finite-lived intangible asset and will be amortized over the life of the underlying asset. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

On May 29, 2024, the Company sold its rare pediatric disease PRV for $108.0 million to an undisclosed buyer. As part of the transaction, $8.1 million of the total consideration received from the sale of the rare pediatric disease PRV was paid to Viracta to fully satisfy PRV-related obligations under the Viracta License Agreement. The gross proceeds of $108.0 million were recorded as a gain from sale of priority review voucher in the accompanying condensed statements of operations during the nine months ended September 30, 2024. As of September 30, 2024, the $8.1 million paid to satisfy PRV-related obligations was capitalized as a finite-lived intangible asset, which will be amortized on a straight-line basis over its estimated useful life. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

As of September 30, 2024, the Company could be required to make additional milestone payments of up to $40.0 million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication upon achievement of a specified milestone event being lower than milestones payable for the first indication. Commencing with the first commercial sale of OJEMDA in a country, the Company is obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products. 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.

License agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, a subsidiary of the Company entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Effective December 31, 2021, the subsidiary was merged with and into the Company, with the Company being the surviving corporation and assuming the subsidiary's obligations under the MRKDG License Agreement.

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.

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.

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. As of September 30, 2024, the Company could 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 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.

In November 2023, the Company discontinued its monotherapy substudy due to a limited duration of response in this rare patient population despite observing responses with a generally well tolerated therapy. In July 2024, the Company decided to close the program as the Company determined that the benefit/risk profile, as well as the market opportunity, did not justify the significant investment required to continue the trial despite observing some clinical responses.

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 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.

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. As of September 30, 2024, the Company could be required to make milestone payments of up to $309.0 million based upon achievement of specified development, regulatory, and commercial milestones for each licensed product, as well as tiered royalties ranging in the single-digit percentages 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.

License agreement with MabCare Therapeutics

On June 17, 2024, the Company entered into a license agreement, or the MabCare License Agreement, with MabCare Therapeutics, or MabCare, a pharmaceutical corporation located in Shanghai, China. Under the MabCare License Agreement, MabCare granted to the Company an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to develop, manufacture and commercialize DAY301 (formerly MTX-13), a novel Antibody Drug Conjugate, or ADC, targeting protein-tyrosine kinase 7, or PTK7. The Company will also receive clinical inventory supplies to use in its research and development activities. Under the MabCare License Agreement, the Company has obligations to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product in one indication in each of the United States, Japan, and three European countries.

The term of the MabCare License Agreement will expire in its entirety upon the expiration of the last to expire royalty term with respect to all licensed products in the Company's territory, unless terminated earlier. Following the expiration of the royalty term for a licensed product in a country, the license grant to the Company shall become non-exclusive, fully paid-up, royalty-free, perpetual, and irrevocable for such licensed product in such country. Upon the expiration of the term, the license granted to the Company shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety.

In consideration for the rights granted under the MabCare License Agreement, the Company made a $55.0 million upfront payment in July 2024. The upfront payment was recorded as research and development expenses, as the technology and supplies licensed do not have an alternative future use. As of September 30, 2024, the Company could be required to make additional payments of $1,152.0 million based upon the achievement of specified development, regulatory, and commercial success-based milestones plus low-to-mid single-digit royalties on net sales outside of Greater China. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

License agreement with Ipsen Pharma SAS

On July 23, 2024, the Company entered into the Ipsen License Agreement, pursuant to which, the Company licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services. Ipsen shall have the right to grant sublicenses to third-parties.

Under the terms of the Ipsen License Agreement, (i) Ipsen paid the Company an upfront license fee in the amount of $70.8 million and (ii) the Investor, a fully-owned United States affiliate of Ipsen, purchased 2,341,495 shares of the Company’s common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the VWAP of the Company’s common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and

including the date of the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between the Company and the Investor dated July 23, 2024.

As of September 30, 2024, the Company is also eligible to receive up to approximately $350.0 million in additional commercial launch and sales-based milestone payments, as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of tovorafenib, subject to customary adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of tovorafenib in the applicable country.

In addition, the Ipsen License Agreement provides that the Company will supply to Ipsen, and Ipsen will purchase from the Company, all required quantities of tovorafenib for all territories outside the United States in accordance with a supply agreement to be entered into by and between the Company and Ipsen, or the Ipsen Supply Agreement. The Company determined that the cost-plus rate to be charged for the supply of tovorafenib does not represent a material right. Ipsen has the right to request a manufacturing technology transfer of the then-current manufacturing process of tovorafenib under the Ipsen License Agreement, such consent shall not be unreasonably withheld, such that upon completion of the manufacturing technology transfer, Ipsen or a third-party would be solely responsible for the manufacture of tovorafenib for all territories outside the United States.

Following the two-year anniversary of July 23, 2024, the effective date of the Ipsen License Agreement, Ipsen may terminate the Ipsen License Agreement for convenience with six months' prior written notice or for certain other specified reasons. The Company may terminate the Ipsen License Agreement if Ipsen or any of its affiliates challenge the validity of any patents controlled by the Company that are licensed under the Ipsen License Agreement. Both Ipsen and the Company may terminate the Ipsen License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the Ipsen License Agreement or (ii) the other party's bankruptcy event.

The Company evaluated the Ipsen License Agreement under Accounting Standards Codification, or ASC, 606 and concluded that Ipsen represents a customer in the transaction. The Company identified two distinct performance obligations for licenses to intellectual property in the form of the exclusive license to commercialize tovorafenib outside the United States for both (i) relapsed or refractory and (ii) front-line pLGG; and three distinct research and development performance obligations related to tovorafenib for completion of (i) the pivotal Phase 2 relapsed or refractory pLGG trial, or FIREFLY-1, (ii) the pivotal Phase 3 front-line pLGG trial, or FIREFLY-2, and (iii) the European Union, or EU, companion diagnostic for pLGG. Both the FIREFLY-1 and FIREFLY-2 trials related to pLGG pertain to later-stage intellectual property and only involve validating the efficacy of tovorafenib with respect to each distinct designation and are not expected to significantly modify or customize the licensed intellectual property. The FIREFLY-1 and FIREFLY-2 trials, and EU companion diagnostic research and development services related to pLGG could be performed by a third-party. The Company determined that the promise of the manufacturing technology transfer is a customer option that does not represent a material right given the value of the services is not material and fulfillment of this promise is ancillary to the main transaction. Accordingly, the manufacturing technology transfer is not a performance obligation at the outset of the arrangement.

Upon execution of the Ipsen License Agreement, the transaction price was determined to be $78.2 million, representing the aggregate of the upfront license fee of $70.8 million and the premium paid by Ipsen on its equity investment in the Company of $7.4 million (the excess of the value of the shares of the Company issued to Ipsen), representing additional consideration from Ipsen for the rights under the Ipsen License Agreement. Commercial launch milestones related to first commercial sale(s) in certain territories, sales-based milestones and royalties on net sales upon commercialization by Ipsen were excluded from the transaction price and will be recognized when the related sales occur as they were determined to predominantly relate to the intellectual property and, therefore, have been excluded from the transaction price in accordance with the sales-based royalty exception.

The Company allocated the transaction price to the performance obligations based on their relative standalone selling price. The Company developed the estimated stand-alone selling price for each license using discounted cash flow models. In developing this estimate, the Company applied judgment in the determination of the assumptions relating to forecasted future revenues, the discount rate, and the probability of success. The stand-alone selling price for each of the research and development services was estimated based on the Company's forecasted costs to be incurred to fulfill the obligations plus a reasonable margin. The portion of the transaction price allocable to the relapsed or refractory and front-line pLGG licenses to intellectual property was determined to be $73.5 million and was recognized as license revenue at the point in time in which Ipsen had the right to use the license/know-how, which occurred during the third quarter of 2024. The portion of the transaction price allocable to the relapsed or refractory, front-line and companion diagnostic research and development services performance obligations was determined to be $4.7 million, which will be recognized over time as the services are delivered based on costs incurred relative to the total estimated cost to deliver the services. During the three and nine months ended September 30, 2024, $0.2 million of deferred revenue was recognized as license revenue related to the research and development services performance obligations with $1.4 million and $3.1 million of the undelivered services included in current and non-current deferred revenue, respectively.

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 balance sheet.

In June 2024, the Company entered into a lease agreement for approximately 19,000 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 approximately 7.4 years and commenced in August 2024. 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 $4.4 million. Upon execution of the agreement, the Company paid a security deposit of approximately $86,000 classified as deposits and other long-term assets on the condensed balance sheet.

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, 2024, the weighted-average remaining lease term and weighted-average discount rate were 7.0 years and 12.7%, 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 $0.2 million and $0.1 million for the three months ended September 30, 2024 and 2023, respectively, and was $0.4 million and $0.3 million for the nine months ended September 30, 2024 and 2023, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $0.4 million and $0.3 million for the nine months ended September 30, 2024 and 2023, respectively. Variable payments expensed during the three and nine months ended September 30, 2024 and 2023 were immaterial.

As of September 30, 2024, the future lease obligations were as follows (in thousands):

Year Ending December 31,		
2024 (Remaining)	$	147
2025		352
2026		435
2027		448
2028		461
Thereafter		2,613
Total future minimum lease payments		4,456
Less: imputed interest		(1,841)
Present value of operating lease liabilities		2,615
Less: current portion of operating lease liabilities		(77)
Operating lease liabilities	$	2,538

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, 2024 and December 31, 2023, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

The Company entered into license agreements, as disclosed in Note 5, with various parties under which it is obligated to make contingent and non-contingent payments.

Purchase Commitments

To support product needs for OJEMDA, the Company has entered into a manufacturing and supply agreement with Quotient Sciences - Philadelphia, LLC 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 $15.2 million, in aggregate, as of September 30, 2024. For the nine months ended September 30, 2024, the Company made purchases of $2.0 million 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, 2024 and December 31, 2023.

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, 2024, 100,810,357 shares of common stock were issued and outstanding.

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

	September 30, 2024
Common stock options issued and outstanding	11,926,321
Common stock available for future grants	3,799,351
Common stock available for ESPP	2,498,360
Restricted stock units issued and outstanding	1,887,246
Total	20,111,278

2024 Private Placement

In July 2024, the Company entered into a securities purchase agreement with certain institutional and accredited investors, or the Investors, pursuant to which the Company agreed to sell and issue to the Investors in a private placement, or the Private Placement, an aggregate of (i) 10,551,718 shares, or the Shares, of the Company's common stock, par value $0.0001 per share, or the Common Stock, at a purchase price of $14.50 per share and (ii) 1,517,241 pre-funded warrants, or the Pre-Funded Warrants, to purchase up to an aggregate of 1,517,241 shares of Common Stock, or the Warrant Shares, at a purchase price of $14.4999 per Pre-Funded Warrant. Each Pre-Funded Warrant has an exercise price of $0.0001 per Warrant Share.

The Pre-Funded Warrants are exercisable at any time after their original issuance at the option of each holder, in such holder's discretion, by (i) payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise or (ii) a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Pre-Funded Warrant. A holder will not be entitled to exercise any portion of any Pre-Funded Warrant if the holder's ownership of the Company's common stock would exceed 9.99% following such exercise.

In the event of certain fundamental transactions, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind of amounts of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the Pre-Funded Warrants.

The Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The Pre-Funded Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such Pre-Funded Warrants do not provide any guarantee of value or return. The Company valued the Pre-Funded Warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the Private Placement proportionately to the Common Stock and Pre-Funded Warrants.

The Private Placement closed on August 1, 2024 and the Company received net proceeds of $166.5 million, after deducting underwriting discounts, commissions, and offering costs, of which $145.6 million was allocated to the Common Stock and $20.9 million was allocated to the Pre-Funded Warrants. The net proceeds were recorded as a component of additional paid-in capital.

Investment agreement with Ipsen Biopharmaceuticals, Inc.

In July 2024, the Company entered into the Ipsen License Agreement, pursuant to which, the Company licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services. Under the terms of the Ipsen License Agreement, (i) Ipsen paid the Company an upfront license fee in the amount of $70.8 million and (ii) the Investor, a fully-owned United States affiliate of Ipsen, purchased 2,341,495 shares of the Company's common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the VWAP of the Company's common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between the Company and the Investor dated July 23, 2024. The Company valued the shares at issuance at $32.6 million, concluding that the Company's common stock price as traded on The Nasdaq Stock Market LLC on the close date of the transaction approximated fair value, which was recorded as a component of additional paid-in capital.

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

The Company has 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 $250.0 million under an at-the-market offering program, or the ATM. The Company has no obligation to sell any shares and could at any time suspend solicitations and offers under the ATM. No shares of the Company's common stock have been sold under the ATM as of September 30, 2024.

8. Share-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expense	$ 3,816	$ 3,312	$ 13,178	$ 10,102
Selling, general and administrative expense	7,738	6,294	24,050	18,428
Total share-based compensation expense	$ 11,554	$ 9,606	$ 37,228	$ 28,530

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.

2021 Equity Incentive Plan

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.

Stock Options

The following table provides a summary of stock option activity during the nine months ended September 30, 2024.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	10,211,758	$ 17.10		
Granted	2,830,362	$ 14.31		
Exercised	(94,553)	$ 14.26		$ 134
Forfeiture	(1,021,246)	$ 16.62		
Outstanding at September 30, 2024	11,926,321	$ 16.51	7.9	$ 2,367
Vested and expected to vest at September 30, 2024	11,926,321	$ 16.51	7.9	$ 2,367
Exercisable at September 30, 2024	6,722,507	$ 16.66	7.4	$ 1,224

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 intrinsic value of options exercised during the nine months ended September 30, 2024 and 2023 was less than $0.1 million and $0.6 million, respectively.

The total fair value of options that vested during the nine months ended September 30, 2024 and 2023 was $25.7 million and $19.8 million, respectively. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2024 and 2023 was $9.24 per share and $13.37 per share, respectively.

Unamortized share-based compensation for stock options as of September 30, 2024 was $53.3 million, which is expected to be recognized over a weighted-average period of 2.3 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,	
	2024	2023	2024	2023
Expected term (in years)	6.06 - 6.11	5.65 - 6.14	5.27 - 6.74	5.27 - 6.25
Expected volatility	68.46% - 68.72%	68.82% - 71.43%	68.27% - 70.57%	68.82% - 81.98%
Risk-free interest rate	3.43% - 4.40%	4.02% - 4.56%	3.43% - 4.47%	3.47% - 4.56%
Expected dividend yield	—	—	—	—

Restricted Stock Units

The following table provides a summary of restricted stock units activity during the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2023	1,031,545	$ 18.27
Granted	1,584,280	$ 14.38
Vested	(526,047)	$ 16.52
Forfeiture	(202,532)	$ 16.14
Unvested restricted stock units at September 30, 2024	1,887,246	$ 15.72

Unamortized share-based compensation for restricted stock units as of September 30, 2024 was $27.9 million, which is expected to be recognized over a weighted-average period of 2.8 years.

Restricted Stock Awards

The following table provides a summary of the unvested common stock awards activity during the nine months ended September 30, 2024.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested common stock as of December 31, 2023	747,679	$ 16.00
Vested	(556,424)	$ 16.00
Forfeiture	(25,415)	$ 16.00
Unvested common stock as of September 30, 2024	165,840	$ 16.00

Unamortized share-based compensation for restricted stock awards as of September 30, 2024 was $1.1 million, which is expected to be recognized over a weighted-average period of 0.5 years.

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. 331,014 shares have been issued under the ESPP as of September 30, 2024. The Company recognized compensation expense related to the ESPP of $0.2 million and $0.1 million for the three months ended September 30, 2024 and 2023, respectively, and $0.6 million and $0.6 million for the nine months ended September 30, 2024 and 2023, 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,	
	2024	2023
Expected term (in years)	0.5	0.5
Expected volatility	63.45%	63.57%
Risk-free interest rate	5.40%	5.24%
Expected dividend yield	—	—

9. Income Taxes

For the three months ended September 30, 2024, the Company recognized an income tax benefit of $0.9 million on pre-tax book income for the period, resulting in an effective tax rate of (2.4)%. For the nine months ended September 30, 2024, the Company recognized income tax expense of $0.7 million on a pre-tax book loss for the period, resulting in an effective tax rate of (2.3)%. The primary reconciling items between the federal statutory rate of 21.0% for the three and nine months ended

September 30, 2024 and the Company's overall effective tax rate of (2.4)% and (2.3)%, respectively, was the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of its net deferred tax assets. The Company did not record an income tax provision for the three and nine months ended September 30, 2023 as it generated tax losses during each of the periods.

A valuation allowance is established when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company continues to establish a valuation allowance against the full amount of its net deferred tax assets since it is more likely than not that benefits will not be realized, including those benefits created in the current year. This assessment is based on the Company's historical cumulative losses, which provide strong objective evidence that cannot be overcome with projections of income, as well as the fact the Company expects continuing losses in the future.

10. Net Income (Loss) Per Share

Basic and diluted net income (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,	
	2024	2023	2024	2023
Net income (loss) - basic and diluted	$ 37,037	$ (46,150)	$ (29,782)	$ (134,406)
Weighted average shares outstanding - basic	96,623,123	85,952,501	90,164,895	77,682,237
Effect of dilutive securities:				
Stock options	57,455	—	—	—
Restricted stock units	107,935	—	—	—
Restricted stock awards	149,246	—	—	—
Weighted average shares outstanding - diluted	96,937,759	85,952,501	90,164,895	77,682,237
Net income (loss) per share - basic	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)
Net income (loss) per share - diluted	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options	11,454,704	10,039,940	11,926,321	10,039,940
Unvested common shares	—	956,719	165,840	956,719
Restricted stock units	406,092	1,001,313	1,887,246	1,001,313
Shares committed under ESPP	88,832	69,578	88,832	69,578
Total	11,949,628	12,067,550	14,068,239	12,067,550

11. 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, 2024 and 2023, the Company made matching contributions of $0.4 million and $0.2 million, respectively. For the nine months ended September 30, 2024 and 2023, the Company made matching contributions of $1.4 million and $1.0 million, respectively.

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 financial statements and related notes, and other financial information appearing in our Annual Report on Form 10-K for the year ended December 31, 2023, 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 is a biopharmaceutical company 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.

Our lead product, tovorafenib, is an oral, brain-penetrant, highly selective type II rapidly accelerated fibrosarcoma, or RAF, kinase inhibitor. Tovorafenib 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 refractory 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 patients with pLGG. Pediatric low-grade glioma is the most common brain tumor diagnosed in children. While new targeted therapeutic options have recently become available for patients with pLGG, there is no consensual standard of care and a vast majority of patients with pLGG do not yet have access to approved therapies. Tovorafenib 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 for treatment of low-grade gliomas, or LGGs, harboring an activating RAF alteration in July 2021.

On April 23, 2024, we announced that the FDA approved OJEMDA™ (tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, we received a rare pediatric disease priority review voucher, or PRV, from the FDA. We have commenced the commercial launch of OJEMDA in the United States. OJEMDA is the only systemic therapy for pLGG that offers once-weekly dosing, with or without food, as a tablet or oral suspension.

The accelerated approval of OJEMDA is based on data from the Company's pivotal open-label Phase 2 trial, or FIREFLY-1, which enrolled a total of 137 relapsed or refractory BRAF-altered pLGG patients across two study arms. Arm 1, which accrued 77 patients, was used for the efficacy analyses. Arm 2 provided additional safety data from an incremental 60 patients and was initiated to enable access to OJEMDA once Arm 1 had fully accrued. Details of this trial were presented in November 2023 at the Society for Neuro-Oncology meeting through two oral plenary presentations and in parallel through a publication in Nature Medicine.

The approval of OJEMDA was based, in part, on the major efficacy outcome measure of overall response rate, or ORR, defined as the proportion of patients with complete response, partial response, or PR, or minor response, or MR, by independent review based on Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO LGG.

In Arm 1, data from the 76 RAPNO LGG evaluable patients include:

- A best ORR of 51% (95% CI: 40 - 63), which included 28 PRs and 11 MRs.
- The ORR for OJEMDA was 52% among the 64 patients with BRAF fusions or rearrangements and 50% for the 12 patients with a BRAF V600 mutation.
- The ORR was 49% among the 45 patients who had received a prior MAPK-targeted therapy, and 55% among the 31 patients who had not received a prior MAPK-targeted therapy.
- As of the June 5, 2023 data cutoff, the median duration of response by RAPNO LGG was 13.8 months (95% CI: 11.3, not estimable). In addition, 66% of patients remained on study and continue on treatment as of this date.
- The median time to response, following initiation of treatment, with OJEMDA was 5.3 months (range 1.6 months, 11.2 months).
- Based on RANO LGG criteria, the ORR was 53% [95% CI: (41, 64)].

The safety of OJEMDA was evaluated in 137 patients with relapsed or refractory pLGG, with the majority of adverse events being Grade 1 or Grade 2. The most common side effects were rash, hair color changes, tiredness, viral infection, vomiting, headache, fever, dry skin, constipation, nausea, acne and upper respiratory tract infection.

We initiated a pivotal Phase 3 trial, or FIREFLY-2, evaluating tovorafenib as a front-line therapy in patients ages 6 months to 25 years with pLGG in June 2022. The first patient was dosed in FIREFLY-2 in March 2023. To date, patients continue to enroll in the United States, Canada, Europe, Australia and Asia, with approximately 105 sites activated. In June 2024, we announced the following changes to our FIREFLY-2 trial: the primary endpoint of objective response rate will be assessed according to the RAPNO-LGG criteria, key secondary endpoints of progression free survival and duration of response will be assessed according to RAPNO-LGG criteria, new patients will be initiated on a starting dose of 380 mg/m^2/dose once weekly, and the addition of a once-monthly carboplatin regime as a fourth standard of care option for arm 2.

On July 23, 2024, we entered into the Ipsen License Agreement, pursuant to which, we licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services.

Under the terms of the Ipsen License Agreement, (i) Ipsen paid us an upfront license fee in the amount of $70.8 million and (ii) Ipsen Biopharmaceuticals, Inc., or the Investor, a fully-owned Affiliate of Ipsen, purchased 2,341,495 shares of our common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the volume weighted average price, or VWAP, of our common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of our public release of U.S. GAAP revenue for the quarter ended June 30, 2024 on July 30, 2024, or the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between us and the Investor dated July 23, 2024.

We are also eligible to receive up to approximately $350.0 million in additional commercial launch and sales-based milestone payments, as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of tovorafenib, subject to customary adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of tovorafenib in the applicable country.

Our 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 as a monotherapy or in combination, which consists of two substudies. Substudy 1 is a Phase 2a trial of tovorafenib as a monotherapy in patients 12 years and older with relapsed, progressive, or refractory solid tumors harboring a RAF alteration (RAF fusion or amplification). Despite observing responses with a generally well tolerated therapy, a limited duration of response in this rare patient population was observed. We decided in November 2023 to discontinue this monotherapy substudy. Substudy 2 is a Phase 1b/2 combination trial of tovorafenib and pimasertib in patients 12 years and older with various MAPK-altered solid tumors. Despite observing some clinical responses, the benefit/risk profile, as well as the market opportunity, did not justify the significant investment required to continue the trial. Moreover, it is clear from competing efforts to combine other Type II RAF inhibitors with MEK inhibitors that the hoped-for therapeutic benefit of the combination was more limited than preclinical studies predicted. We decided in July 2024 to close the

program. Results from the substudies will be shared for presentation at a future medical meeting or in a publication after the final datasets becomes available.

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 most 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.

In June 2024, we entered into a license agreement, or the MabCare License Agreement, with MabCare Therapeutics, or MabCare, a pharmaceutical corporation located in Shanghai, China. Under the MabCare License Agreement, MabCare granted to us an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for the Company to develop, manufacture and commercialize DAY301 (formerly MTX-13 or CB-002). DAY301 is a novel Antibody Drug Conjugate, or ADC, targeting protein-tyrosine kinase 7, or PTK7. In pre-clinical studies, DAY301 showed antitumor activity in a wide range of solid tumors. DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers, including esophageal, ovarian, lung, and endometrial cancer, as well as pediatric cancers such as neuroblastoma, rhabdomyosarcoma and osteosarcoma. In April 2024, the FDA cleared the investigational new drug application for DAY301. We expect the first patient to be dosed in the Phase 1a portion of the Phase 1a/b study for DAY301 in the fourth quarter of 2024 or first quarter of 2025.

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 rights to develop tovorafenib, pimasertib, and VRK1 for all therapeutic areas worldwide and DAY301 for all therapeutic areas worldwide, excluding Greater China, subject to certain milestone and royalty payments. Further, we hold exclusive rights to commercialize tovorafenib in the United States subject to royalty payments. Pursuant to the Ipsen License Agreement, we licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside of the United States, in exchange for certain milestone and royalty payments.

The following table summarizes our product and product candidate pipeline.

Our Pipeline

Product Candidate	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3/ Registrational	Approved	Recent & Anticipated Milestones
Tovorafenib[3] Type II RAF Inhibitor OJEMDA brand name in U.S.[1] Ex-U.S. Rights: IPSEN Innovation for patient care	BRAF-altered relapsed pLGG	FIREFLY-1 (pivotal Phase 2)[2]				ojemda (tovorafenib)	**FDA approval** April 2024 **Ex-U.S. license agreement** July 2024
	Frontline RAF-altered pLGG	FIREFLY-2 (pivotal Phase 3)					**First patient dosed** March 2023
DAY301 PTK7 Targeted ADC	Adult and pediatric solid tumors						**U.S. IND cleared** April 2024 **First patient dosed expected** 4Q 2024 / 1Q 2025
VRK1 Program VRK1 Inhibitor	Adult and pediatric cancers						**In-licensed** August 2023

Significant Agreements

Takeda asset purchase agreement

On December 16, 2019, 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. Effective December 31, 2021, the subsidiary was merged with and into our company, with our company being the surviving corporation and assuming the subsidiary's obligations under the Takeda Asset Agreement. Pursuant to the Takeda Asset Agreement, we purchased certain technology rights and know-how related to TAK-580 (which is now OJEMDA) that provides a new approach for treating patients with primary brain tumors or brain metastases of solid tumors. We 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 us its exclusive license agreement, or the Viracta License Agreement, with Viracta. Takeda also granted us 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. We also granted Takeda a grant back license, as defined in the Takeda Asset Agreement, which is terminable either automatically or by us 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.

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.

In consideration for the sale and assignment of assets and the grant of the license under the Takeda Asset Agreement, we made an upfront payment of $1.0 million in cash and issued 9,857,143 shares of our Series A redeemable convertible preferred stock in our subsidiary 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 our subsidiary. 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 our subsidiary for 6,470,382 shares of our common stock upon the effectiveness of the conversion, on May 26, 2021.

License agreement with Viracta

On December 16, 2019, our subsidiary amended and restated the Viracta License Agreement that was assigned pursuant to the Takeda Asset Agreement. Effective December 31, 2021, our subsidiary was merged with and into our company, with our company being the surviving corporation and assuming our subsidiary's obligations under Viracta License Agreement. Under the Viracta License Agreement, we 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.

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 our obligation to pay royalties to Viracta with respect to such product in such country. We have 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.

We paid $2.0 million upfront in cash to Viracta, which was recorded as research and development expenses as the technology does not have an alternative future use.

On March 4, 2024, we entered into an amendment to the Viracta License Agreement. As part of the amendment, we made a one-time payment in March 2024 to Viracta of $5.0 million, which was recorded as research and development expenses during the nine months ended September 30, 2024, in exchange for reduced future payment obligations ranging from the mid-teens to the high single-digit percentage related to the future sale or use of the rare pediatric disease PRV received.

On April 23, 2024, the FDA approved OJEMDA (a tablet formulation and powder solution formulation of tovorafenib) for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. The indication was approved under accelerated approval based on response rate and duration of response. With the approval, we received a rare pediatric disease PRV from the FDA. We made a $9.0 million milestone payment to Viracta in May 2024 for the achievement of this milestone. The $9.0 million milestone was accounted for as a finite-lived intangible asset and will be amortized over the life of the underlying asset. Related amortization expense will be recorded as cost of product revenue in our statements of operations.

On May 29, 2024, we sold our rare pediatric disease PRV for $108.0 million to an undisclosed buyer. As part of the transaction, $8.1 million of the total consideration received from the sale of the rare pediatric disease PRV was paid to Viracta to fully satisfy PRV-related obligations under the Viracta License Agreement. The gross proceeds of $108.0 million were recorded as a gain from sale of priority review voucher in the accompanying condensed statements of operations during the nine months ended September 30, 2024. As of September 30, 2024, the $8.1 million paid to satisfy PRV-related obligations was capitalized as a finite-lived intangible asset, which will be amortized on a straight-line basis over its estimated useful life. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

As of September 30, 2024, we could be required to make additional milestone payments of up to $40.0 million upon achievement of specified development and regulatory milestones for each licensed product in two indications, with milestones payable for the second indication upon achievement of a specified milestone event being lower than milestones payable for the first indication. Commencing with the first commercial sale of OJEMDA in a country, we are obligated to pay tiered royalties ranging in the mid-single-digit percentages on net sales of licensed products. 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 us 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.

License agreement with Merck KGaA, Darmstadt, Germany

On February 10, 2021, our subsidiary entered into a license agreement, or the MRKDG License Agreement, with Merck KGaA, Darmstadt, Germany, a pharmaceutical corporation located in Darmstadt, Germany. Effective December 31, 2021, the subsidiary was merged with and into our company, with our company being the surviving corporation and assuming the subsidiary's obligations under the MRKDG License Agreement. 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.

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.

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. As of September 30, 2024, we could 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 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.

In November 2023, we discontinued our monotherapy substudy due to a limited duration of response in this rare patient population despite observing responses with a generally well tolerated therapy. In July 2024, we decided to close the program because we determined that the benefit/risk profile, as well as the market opportunity, did not justify the significant investment required to continue the trial despite observing some clinical responses.

Research collaboration and license agreement with Sprint Bioscience AB

On August 15, 2023, we entered into the Sprint License Agreement. 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 VRK1.

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. We have 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.

We 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. As of September 30, 2024, we could be required to make milestone payments of up to $309.0 million based upon achievement of specified development, regulatory, and commercial milestones for each licensed product, as well as tiered royalties ranging in the single-digit percentages 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.

License agreement with MabCare Therapeutics

On June 17, 2024, we entered into the MabCare License Agreement. Under the MabCare License Agreement, MabCare granted to us an exclusive worldwide license, excluding Greater China, with the right to grant sublicenses through multiple tiers, under specified patent rights and know-how for us to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7. We will also receive clinical inventory supplies to use in our research and development activities. Under the MabCare License Agreement, we have obligations to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product in one indication in each of the United States, Japan, and three European countries.

The term of the MabCare License Agreement will expire in its entirety upon the expiration of the last to expire royalty term with respect to all licensed products in our territory, unless terminated earlier. Following the expiration of the royalty term for a licensed product in a country, the license grant to us shall become non-exclusive, fully paid-up, royalty-free, perpetual, and irrevocable for such licensed product in such country. Upon the expiration of the term, the license granted to us shall become non-exclusive, transferable, sublicensable, fully paid, royalty free, perpetual, and irrevocable in its entirety.

In consideration for the rights granted under the MabCare License Agreement, we made an upfront payment of $55.0 million, which was recorded as research and development expenses, as the technology does not have an alternative future use. As of September 30, 2024, we could be required to make additional payments of $1,152.0 million based upon the achievement of specified development, regulatory, and commercial success-based milestones plus low-to-mid single-digit royalties on net sales outside of Greater China. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

License agreement with Ipsen Pharma SAS

On July 23, 2024, we entered into the Ipsen License Agreement, pursuant to which, we licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services. Ipsen shall have the right to grant sublicenses to third-parties.

Under the terms of the Ipsen License Agreement, (i) Ipsen paid us an upfront license fee in the amount of $70.8 million and (ii) the Investor, a fully-owned United States affiliate of Ipsen, purchased 2,341,495 shares of our common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the VWAP of our common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between us and the Investor dated July 23, 2024.

As of September 30, 2024, we are also eligible to receive up to approximately $350.0 million in additional commercial launch and sales-based milestone payments, as well as tiered, double-digit royalty payments starting at mid-teens percentage of annual net sales of tovorafenib, subject to customary adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of tovorafenib in the applicable country.

In addition, the Ipsen License Agreement provides that we will supply to Ipsen, and Ipsen will purchase from us, all required quantities of tovorafenib for all territories outside the United States in accordance with a supply agreement to be entered into by and between us and Ipsen, or the Ipsen Supply Agreement. We determined that the cost-plus rate charged for the supply of tovorafenib does not represent a material right. Ipsen has the right to request a manufacturing technology transfer of the then-current manufacturing process of tovorafenib under the Ipsen License Agreement, such consent shall not be unreasonably withheld, such that upon completion of the manufacturing technology transfer, Ipsen or a third-party would be solely responsible for the manufacture of tovorafenib for all territories outside the United States.

Following the two-year anniversary of July 23, 2024, the effective date of the Ipsen License Agreement, Ipsen may terminate the Ipsen License Agreement for convenience with six months' prior written notice or for certain other specified reasons. We may terminate the Ipsen License Agreement if Ipsen or any of its affiliates challenge the validity of any patents controlled by us that are licensed under the Ipsen License Agreement. Both we and Ipsen may terminate the Ipsen License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the Ipsen License Agreement or (ii) the other party's bankruptcy event.

Components of Results of Operations

Revenue

Product revenue, net

In April 2024, the FDA approved OJEMDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. We record product revenue net of estimated discounts, chargebacks, rebates, specialty distributor fees, copay assistance, and product returns.

License revenue

In July 2024, we entered into the Ipsen License Agreement, pursuant to which, we licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services. The transaction price of $73.5 million allocated to the licenses was recognized as revenue upon delivery of the licenses in the third quarter of 2024. The transaction price of $4.7 million allocated to the research and development services is being recognized over time as services are delivered.

Operating expenses

Cost of product revenue

Cost of product revenue includes the cost of inventory sold, amortization expense of intangible assets and third-party royalties payable on our net product revenue. Cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

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 product candidates.

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 business operational costs, such as rent, facilities and maintenance, travel and information technology, incurred related to research and development activities, but are not allocable to a specific product or product candidate.

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 OJEMDA, pimasertib, DAY301, and VRK1 programs. 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 for the foreseeable future as we continue to implement our business strategy; advance our product candidates 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.

Selling, general and administrative expenses

Selling, 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 selling, general and administrative personnel. Professional service expenses include legal fees; professional fees for accounting, marketing,

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 selling, general and administrative expenses will increase for the foreseeable future as we anticipate an increase in our personnel headcount to support the expansion of our corporate and commercial activities and 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.

Gain from sale of priority review voucher

Gain from the sale of priority review voucher represents the sale of our rare pediatric disease PRV, which was awarded to us in connection with the FDA's approval of OJEMDA.

Results of operations

Comparison of three months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (unaudited):

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
Revenue:				
Product revenue, net	$ 20,070	$ —	$ 20,070	*
License revenue	73,691	—	73,691	*
Total revenues	93,761	—	93,761	*
Cost and operating expenses:				
Cost of product revenue	1,590	—	1,590	*
Research and development	33,563	33,163	400	1.2 %
Selling, general and administrative	28,972	18,275	10,697	58.5 %
Total cost and operating expenses	64,125	51,438	12,687	24.7 %
Income (loss) from operations	29,636	(51,438)	81,074	(157.6)%
Non-operating income:				
Investment income, net	5,322	5,291	31	0.6 %
Other income (expense), net	1,197	(3)	1,200	*
Total non-operating income, net	6,519	5,288	1,231	23.3 %
Income (loss) before income taxes	36,155	(46,150)	82,305	(178.3)%
Income tax benefit	882	—	882	*
Net income (loss)	$ 37,037	$ (46,150)	$ 83,187	(180.3)%

* Amount and/or percentage not meaningful

Product revenue, net

For the three months ended September 30, 2024, we recorded net product revenue of $20.1 million from sales of OJEMDA in the United States.

License revenue

For the three months ended September 30, 2024, we recorded license revenue of $73.7 million from the transaction price related to the Ipsen License Agreement, of which $73.5 million related to the delivery of the licenses and $0.2 million the research and development services.

Cost of product revenue

For the three months ended September 30, 2024, we recorded cost of product revenue of $1.6 million related to sales of OJEMDA in the United States.

Research and development expenses

Research and development expenses increased $0.4 million, from $33.2 million for the three months ended September 30, 2023 to $33.6 million for the three months ended September 30, 2024. Third-party expenses increased by $1.5 million due primarily to an increase in clinical trial and manufacturing activities, personnel related expenses increased by $2.2 million driven by headcount growth, and other research and development costs decreased by $0.3 million. Additionally, during the three months ended September 30, 2024, there were no license agreement upfront payments made compared to the $3.0 million license agreement upfront payment made to Sprint during the three months ended September 30, 2023.

The following table summarizes our external and internal research and development expenses for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,	
	2024	2023
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 19,405	$ 17,929
Sprint license agreement upfront payment	—	3,000
Other research and development costs	1,907	2,256
Internal costs:		
Employee related expenses	12,251	9,978
Total research and development expenses	$ 33,563	$ 33,163

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib, pimasertib, DAY301, and VRK1 programs were $16.6 million, $0.7 million, $0.6 million, and $1.5 million, respectively, for three months ended September 30, 2024 compared to $16.3 million, $1.0 million, $0.0 million, and $0.6 million, respectively, for the three months ended September 30, 2023.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $10.7 million, from $18.3 million for the three months ended September 30, 2023 to $29.0 million for the three months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily due to an increase of $6.1 million in personnel related expenses driven by headcount growth, an increase of $3.1 million in professional services driven by commercial launch activities, and an increase of $1.5 million in other selling, general and administrative costs.

Income tax benefit

Income tax benefit for the three months ended September 30, 2024, was $0.9 million resulting in an effective tax rate of (2.4)% driven by the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of our net deferred tax assets. We did not record an income tax provision for the three months ended September 30, 2023 as it generated tax losses during the period.

Comparison of nine months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (unaudited):

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
Revenue:				
Product revenue, net	$ 28,262	$ —	$ 28,262	*
License revenue	73,691	—	73,691	*
Total revenues	101,953	—	101,953	*
Cost and operating expenses:				
Cost of product revenue	2,297	—	2,297	*
Research and development	165,879	93,173	72,706	78.0%
Selling, general and administrative	85,715	53,374	32,341	60.6%
Total cost and operating expenses	253,891	146,547	107,344	73.2%
Loss from operations	(151,938)	(146,547)	(5,391)	3.7%
Non-operating income (expense):				
Gain from sale of priority review voucher	108,000	—	108,000	*
Investment income, net	13,649	12,163	1,486	12.2%
Other income (expense), net	1,177	(22)	1,199	*
Total non-operating income, net	122,826	12,141	110,685	*
Loss before income taxes	(29,112)	(134,406)	105,294	(78.3)%
Income tax expense	(670)	—	(670)	*
Net Loss	$ (29,782)	$ (134,406)	$ 104,624	(77.8)%

* Amount and/or percentage not meaningful

Product revenue, net

For the nine months ended September 30, 2024, we recorded net product revenue of $28.3 million from sales of OJEMDA in the United States.

License revenue

For the nine months ended September 30, 2024, we recorded license revenue of $73.7 million from the transaction price related to the Ipsen License Agreement, of which $73.5 million related to the delivery of the licenses and $0.2 million the research and development services.

Cost of product revenue

For the nine months ended September 30, 2024, we recorded cost of product revenue of $2.3 million related to sales of OJEMDA in the United States. Prior to the FDA approval of OJEMDA, the majority of costs were expensed as research and development expense.

Research and development expenses

Research and development expenses increased $72.7 million, from $93.2 million for the nine months ended September 30, 2023 to $165.9 million for the nine months ended September 30, 2024. Third-party expenses increased by $8.1 million, due primarily to an increase in clinical trial, manufacturing, and other product development expenses, personnel related expenses increased by $6.7 million resulting from additional headcount and stock-based compensation, and other research and development expenses increased by $0.9 million. Milestone expense increased by $57.0 million due to a $55.0 million upfront fee related to the MabCare License Agreement and a $5.0 million amendment payment related to the Viracta License Agreement during the nine months ended September 30, 2024, which was offset by a $3.0 million upfront payment related to the Sprint License Agreement during the nine months ended September 30, 2023.

The following table summarizes our external and internal research and development expenses for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 61,497	$ 53,426
MabCare license agreement upfront payment	55,000	—
Viracta license agreement amendment payment	5,000	—
Sprint license agreement upfront payment	—	3,000
Other research and development costs	6,421	5,539
Internal costs:		
Employee related expenses	37,961	31,208
Total research and development expenses	$ 165,879	$ 93,173

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib, pimasertib, DAY301, and VRK1 programs were $52.7 million, $3.2 million, $0.6 million, and $5.0 million, respectively, for nine months ended September 30, 2024 compared to $50.0 million, $2.8 million, $0.0 million, and $0.6 million respectively, for the nine months ended September 30, 2023.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $32.3 million, from $53.4 million for the nine months ended September 30, 2023 to $85.7 million for the nine months ended September 30, 2024. The increase in selling, general and administrative expenses was primarily due to an increase of $18.0 million in personnel related expenses driven by headcount growth, an increase of $9.9 million in professional services driven by commercial launch activities, and an increase of $4.4 million in other selling, general and administrative costs.

Gain from sale of priority review voucher

Gain from sale of priority review voucher for the nine months ended September 30, 2024 was $108.0 million related to the sale of our rare pediatric disease PRV, which was awarded to us in connection with the FDA's approval of OJEMDA.

Income tax expense

Income tax expense for the nine months ended September 30, 2024, was $0.7 million resulting in an effective tax rate of (2.3)% driven by the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance

recorded against the full amount of our net deferred tax assets. The Company did not record an income tax provision for the nine months ended September 30, 2023 as it generated tax losses during the period.

Liquidity and Capital Resources

Sources of liquidity

In July 2024, we entered into a securities purchase agreement with certain institutional and accredited investors, or the Investors, pursuant to which we agreed to sell and issue to the Investors in a private placement, or the Private Placement, an aggregate of (i) 10,551,718 shares, or the Shares, of our common stock, par value $0.0001 per share, or the Common Stock, at a purchase price of $14.50 per share and (ii) 1,517,241 pre-funded warrants, or the Pre-Funded Warrants, to purchase up to an aggregate of 1,517,241 shares of Common Stock, or the Warrant Shares, at a purchase price of $14.4999 per Pre-Funded Warrant. Each Pre-Funded Warrant has an exercise price of $0.0001 per Warrant Share. The Pre-Funded Warrants are exercisable at any time after their original issuance and will not expire. The Private Placement closed on August 1, 2024 and we received net proceeds of $166.5 million, after deducting underwriting discounts, commissions, and offering costs, of which $145.6 million was allocated to the Common Stock and $20.9 million was allocated to the Pre-Funded Warrants. The net proceeds were recorded as a component of additional paid-in capital.

In July 2024, we entered into the Ipsen License Agreement, pursuant to which, we licensed to Ipsen, on an exclusive basis, the right to commercialize tovorafenib in all territories outside the United States and agreed to provide certain research and development and manufacturing services. Under the terms of the Ipsen License Agreement, (i) Ipsen paid us an upfront license fee in the amount of $70.8 million and (ii) the Investor, a fully-owned United States affiliate of Ipsen, purchased 2,341,495 shares of our Company's common stock in a private placement for $40.0 million, at a price per share representing a 17.0% premium to the VWAP of our Company's common stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Revenue Release, and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in an investment agreement by and between we and the Investor dated July 23, 2024. We valued the shares at issuance at $32.6 million, concluding that our Company's common stock price as traded on The Nasdaq Stock Market LLC on the close date of the transaction approximated fair value, which was recorded as a component of additional paid-in capital.

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.

We have 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 $250.0 million under an at-the-market offering program, or the ATM. No shares of our common stock have been sold under the ATM as of September 30, 2024.

As of September 30, 2024, we had an accumulated deficit of $488.4 million and $558.4 million in cash and cash equivalents and short-term investments. We believe our cash, cash equivalents and short-term investments will be sufficient to satisfy our capital requirements through at least twelve months after the date that this Quarterly Report is filed.

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures and selling, 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, 2024, we had fixed lease payment obligations of approximately $0.3 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, 2024, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

Under our license agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. The amount and timing of milestone obligations are unknown or uncertain as we

are unable to estimate the timing or likelihood of achieving the milestone events. Additionally, the amount of royalty payments are based upon future product sales, which we are unable to predict with certainty. These potential obligations are further described in Note 5 to the financial statements.

Cash flows

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$ (48,105)	$ (105,481)
Net cash provided by investing activities	38,646	97,998
Cash provided by financing activities	201,440	163,400
Net increase in cash and cash equivalents	$ 191,981	$ 155,917

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2024 was $48.1 million, consisting of our net loss of $29.8 million, non-cash charges of $18.1 million and net changes in operating assets and liabilities of $0.3 million. Non-cash charges are primarily related to a gain from the sale of our rare pediatric disease PRV of $108.0 million and accretion of discounts on short-term investments of $3.6 million, which was partially offset by acquired in-process research and development assets of $55.0 million and share-based compensation expense of $37.2 million. Net changes in operating assets and liabilities are primarily related to an increase in accrued expenses and other current liabilities of $8.7 million, deferred revenue of $5.3 million, and accounts payable of $0.4 million, which was partially offset by an increase in accounts receivable of $9.5 million, inventory of $2.7 million, prepaid expenses and other current assets of $2.3 million, and a decrease in operating lease liability of $0.3 million.

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

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2024 was $38.6 million related to the proceeds from the maturity of short-term investments of $307.5 million, proceeds from the sales of short-term investments of $79.4 million, and from the sale of our rare pediatric disease PRV of $108.0 million, partially offset by the purchase of short-term investments of $383.4 million, acquisition of in-process research and development assets of $55.0 million, acquisition of intangible assets of $17.1 million, and purchase of property and equipment of $0.8 million.

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.

Financing activities

Cash provided by financing activities for the nine months ended September 30, 2024 was $201.4 million related to net proceeds from the issuance of common stock in connection with private placement of $178.2 million and issuance of prefunded warrants to purchase common stock of $20.9 million, and upon stock option exercises and purchases made under our 2021 Employee Stock Purchase Plan of $2.3 million.

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.

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. As of September 30, 2024, we had $558.4 million in cash and cash equivalents and short-term investments. We believe our cash, cash equivalents and short-term investments will be sufficient to satisfy our capital requirements at least twelve months after the date that this Quarterly Report is filed.

If our cash, cash equivalents and short-term investments are not sufficient to meet capital needs until such time that we can generate substantial revenue, 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, stockholder ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect stockholder 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, potential instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto with respect to the federal budget, global regional conflicts, public health epidemics, 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 management's discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of condensed 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 consolidated financial statements and the reported amounts of expenses during the reporting period. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the Notes to our Condensed Financial Statements appearing within Item 2 of this Quarterly Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our condensed financial statements.

Accrued research and development expense

We record accrued liabilities for estimated costs of our clinical trials conducted by third-party service providers. We record the estimated costs of the clinical trials as research and development expense based upon the estimated amount of services provided but not yet invoiced. We accrue for these costs based on factors such as estimates of the work completed and in accordance with terms established with our third-party service providers under the service agreements.

We make payments in connection with the clinical trials under contracts with CROs who conduct and manage our clinical trials. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the activities to be performed for each patient, the number of active clinical sites and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time.

If we do not identify costs that have begun to be incurred or if we under- or over-estimate the level of services performed or the costs of these services, actual expenses could differ from our estimates. To date, we have not experienced any material differences between accrued costs and actual costs incurred. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

License revenue

We record license revenue related to the Ipsen License Agreement when Ipsen obtains control of the promised goods or services, in an amount that reflects the consideration we expect to receive in exchange for those goods or services.

To determine the amount of license revenue to recognize under the arrangement, we are required to make judgments related to identifying the performance obligations, estimating the amount of variable consideration to include in the transaction price, allocating the transaction price to each performance obligation and determining the period of time over which revenue should be recognized for each performance obligation. The significant estimates made in allocating the transaction price is the amount and timing of tovorafenib net product revenues in the long-range forecast. We base our estimates on the best information available at the time.

If we do not properly estimate the cash flows, actual revenues could differ from our estimates. To date, we have not experienced any material differences between estimated and actual cash flows. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information.

New Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There were no material changes to our market risks from those described in Part II Item 7A. Quantitative and qualitative disclosures about market risk of our 2023 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2024, management, with the participation of our Principal Executive Officer and Principal Financial 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 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 Officer concluded that, as of September 30, 2024, 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 three months ended September 30, 2024 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 2, and, to date, have not generated substantial revenue from the sales of our product, OJEMDA, 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, to date, have not generated substantial revenue from the sales of our product, OJEMDA. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.
- Our near-term revenues are highly dependent on the successful commercialization of OJEMDA, which received marketing approval in April 2024 from the FDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. To the extent that OJEMDA is not commercially successful, our business, financial condition and results of operations would be materially and adversely affected and the price of our common stock would 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 OJEMDA and our product candidates.
- We will require 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. OJEMDA and our product candidates may not have favorable results in later clinical trials, if any, or receive marketing authorization. If we fail to demonstrate the safety and effectiveness of OJEMDA or our product candidates, our reputation may be harmed and our business will suffer.
- We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial, 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 DAY301, VRK1 or any future product candidates, on a timely basis or at all.
- The manufacture of pharmaceutical products, including OJEMDA and our product candidates, including DAY301 and VRK1, 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 2 and, to date, have not generated substantial revenue from the sales of our product OJEMDA, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

We are a commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, have not generated substantial revenue from the sales of our product, OJEMDA. 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 OJEMDA and our product candidates and building our pipeline, organizing and staffing our company, business planning, building a commercial organization, establishing and maintaining our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates, raising capital and providing selling, 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 product, OJEMDA, initially for relapsed or refractory pediatric low-grade gliomas, or pLGGs. Further, pursuant to a License Agreement with MabCare Therapeutics, or MabCare, entered into in June 2024, or the MabCare License Agreement, we have exclusive rights to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7, worldwide, excluding Greater China. To date, we have financed our operations primarily through the sale and issuance of redeemable convertible preferred shares, convertible notes, the completion of our initial public offering, or 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 2, 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 biopharmaceutical companies in rapidly evolving fields and with recently approved therapies. 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, to date, have not generated substantial revenue from the sales of our product, OJEMDA. 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 substantial revenue from the sales of our product, OJEMDA, 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, 2024 and 2023, we reported a net loss of $29.8 million and $134.4 million, respectively. We had an accumulated deficit of $488.4 million as of September 30, 2024. We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we advance tovorafenib, DAY301 and VRK1 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 product and product candidates, including our ongoing pivotal Phase 2 FIREFLY-1 trial for OJEMDA, our ongoing pivotal Phase 3 FIREFLY-2 trial of tovorafenib as a potential front-line therapy in pLGG, our post-marketing commitments and requirements for OJEMDA, our Phase 1a/b trial of DAY301 targeting PTK7 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 U.S. Food and Drug Administration, or FDA, accepted our New Drug Applications, or NDAs, and granted priority review for OJEMDA as a monotherapy in relapsed or refractory pLGG. On April 23, 2024, the FDA approved the NDAs for OJEMDA for use in the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. We will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of OJEMDA, or our product candidates, including DAY301 and VRK1, if marketing authorization is received. 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.

Our near-term revenues are highly dependent on the successful commercialization of OJEMDA, which received marketing approval in April 2024 from the FDA for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. To the extent that OJEMDA is not commercially successful, our business, financial condition and results of operations would be materially and adversely affected and the price of our common stock would decline.

Our future success is highly dependent on our ability to timely complete successful clinical trials, obtain marketing authorization for, and then successfully commercialize, OJEMDA and our product candidates. OJEMDA is our only drug that has been approved for sale and it has only been approved for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Prior to OJEMDA, we have not, as an organization, launched or commercialized a product, and there is no guarantee that we will be able to do so successfully with OJEMDA. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential. We are focusing a significant portion of our activities and resources on OJEMDA, and we believe our near-term revenues are highly dependent on, and a meaningful portion of the value of our company relates to, our ability to successfully commercialize OJEMDA in the United States. If the launch or commercialization of OJEMDA is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

We are early in our development efforts and our product, tovorafenib, is currently in pivotal Phase 3 clinical trials. Our product candidates, DAY301 and VRK1, are in earlier stages of development and are not approved for sale in any jurisdiction. There can be no assurance that tovorafenib, DAY301, VRK1 or any future product candidates we develop, if any, will achieve success in their clinical trials or obtain marketing authorization.

The success of OJEMDA 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 pivotal Phase 3 FIREFLY-2 trial of tovorafenib as a front-line therapy for patients with pLGG;
- 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 OJEMDA and our product candidates to the satisfaction of the FDA and foreign regulatory agencies and attractiveness of OJEMDA and 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 for our product candidates such as DAY301 and VRK1, including potential restrictions or limitations on the conditions of use of our products;
- whether our patents will be sufficient to prevent generic competition for OJEMDA after our orphan drug exclusivity expires;
- 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 and successful commercialization of OJEMDA and our product candidates, including DAY301 and VRK1;
- obtaining and maintaining patent, trade secret and other intellectual property protection and statutory exclusivities for OJEMDA and 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 OJEMDA and 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 relevant 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, actual or perceived instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto and global regional conflicts, as well as any delays due to supply chain issues impacting the availability of certain standard-of-care chemotherapy drugs; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and if we cannot address any of them in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize OJEMDA and our product candidates, which would materially harm our business. It is also possible that not all of our product candidates, including DAY301 and VRK1, will obtain marketing authorization even if we expend substantial time and resources seeking such approval.

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

Our business depends entirely on the successful development and commercialization of OJEMDA and our product candidates. Our ability to generate future revenue at the levels or timing we expect and achieve profitability depends on several factors, including, but not limited to, our ability to:

- successfully market and sell OJEMDA while maintaining full compliance with applicable federal and state laws, rules and regulations;
- complete a successful pivotal Phase 3 FIREFLY-2 trial with tovorafenib that achieves a competitive, clinically meaningful and generally well-tolerated target product profile for the front-line treatment of pLGG;
- complete a successful Phase 1a/b trial of DAY301;
- initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain foreign marketing authorization for OJEMDA as a treatment for patients with pLGGs;
- initiate and complete additional, successful late-stage clinical trials that meet their clinical endpoints;
- obtain favorable results from our clinical trials and apply for and obtain marketing authorizations for DAY301 and VRK1 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 OJEMDA and 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;
- successfully commercialize OJEMDA, DAY301, VRK1 and any future product candidates we may develop, if approved, by building and maintaining 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, including for OJEMDA;
- demonstrate an acceptable safety profile of our product and our product candidates, including OJEMDA, DAY301 and VRK1, 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 OJEMDA and our product candidates, including DAY301 and VRK1, 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 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 OJEMDA and our product candidates, 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 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 in connection with our ongoing activities, particularly as we advance our product, OJEMDA, and product candidates, DAY301 and VRK1, 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, we expect to incur significant expenses related to the product manufacturing, marketing, sales and distribution of OJEMDA and, if we obtain marketing authorization, for our product candidates including DAY301 and VRK1. 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 additional funding in connection with our continuing operations.

We had $558.4 million in cash, cash equivalents and short-term investments as of September 30, 2024. Based on our cash, cash equivalents and short-term investments, as of September 30, 2024, we estimate that our current liquidity will be sufficient to satisfy

our capital requirements at least twelve months after the date that this Quarterly Report is filed. 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 OJEMDA and 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 OJEMDA, DAY301, VRK1 or any of our future pipeline products and 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 products and 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, including for OJEMDA;
- the revenue, if any, received from commercial sales of OJEMDA, DAY301, VRK1 or any of our future product candidates, if approved, or any other 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 to commercialize OJEMDA or 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 products and 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. We have 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 $250.0 million under an at-the-market offering program, or the ATM. No shares of our common stock have been sold under the ATM as of September 30, 2024. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the 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, actual or perceived instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, global regional conflicts, public health epidemics 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 OJEMDA and 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. OJEMDA and our product candidates may not have favorable results in later clinical trials, if any, and not all of our product candidates will receive marketing authorization. If we fail to demonstrate the safety and effectiveness of OJEMDA and our product candidates, our reputation may be harmed and our business will suffer.

The risk of failure for OJEMDA and our product candidates is high. It is impossible to predict when or if OJEMDA and our product candidates will prove effective or safe in humans or if our product candidates will receive marketing authorization. To obtain the requisite marketing authorizations to market and sell 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 OJEMDA and our product candidates. Products and 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 or 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.

OJEMDA has only been studied in a limited number of patients. Following commercial launch, OJEMDA will be available to a much larger number of patients, and we do not know whether the results of OJEMDA's use in such larger number of patients will be consistent with the results from our clinical studies.

OJEMDA has been administered only to a limited number of patients in clinical studies. While the FDA granted accelerated approval of OJEMDA based on the data included in the NDAs, we do not know whether the real world safety and effectiveness of the product will be consistent with the safety and effectiveness profile seen in the clinical studies. New data relating to OJEMDA, 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 OJEMDA from the market. If any of these actions were to occur, it could result in significant expense and delay and/or limit our ability to generate future sales revenues in line with our expectations.

We may rely on data from investigator-initiated studies, as we did for the Phase 1 clinical trial, 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 product, OJEMDA, which was run as an investigator-initiated, multi-center trial in patients with relapsed or 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 OJEMDA is a Day One-sponsored trial. 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 product candidates.

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 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 OJEMDA and 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 OJEMDA and our 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 successfully commercialize OJEMDA or our product candidates, including:

- the 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 causing clinical trial enrollment challenges or preventing or delaying 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, the 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, the 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 GCP regulations, that we are exposing participants to unacceptable health risks or if the 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 the FDA, which may require that additional U.S. data be generated.

Because some of our product candidates are 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 the FDA or comparable foreign regulatory authorities. The 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. The 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 the 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 OJEMDA 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;
- any invasive procedures that may be 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 and our Phase 1a/b trial for DAY301;
- 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, in March 2023, Novartis received approval for dabrafenib in combination with trametinib, which could in the future limit our ability to enroll patients in clinical trials for OJEMDA.

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. 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 overall response rate, or ORR, in alignment with the FDA, with ORR using Response Assessment for Pediatric Neuro-Oncology – Low-Grade Glioma, or RAPNO-LGG, as a secondary endpoint. Following discussions with the FDA and the March 2023 approval of dabrafenib, in combination with trametinib in BRAF V600E pLGG, we initially 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. Following further feedback from the FDA during review of the NDAs for OJEMDA, in June 2024 we updated the structure of the primary endpoint in our FIREFLY-2/LOGGIC trial to be assessed using the Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma, or RAPNO-LGG, criteria.

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 products or product candidates that we successfully develop and commercialize, including OJEMDA, 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 OJEMDA 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. A fifth MEK inhibitor – mirdametinib – is in development for patients with NF1 who have symptomatic, inoperable plexiform neurofibromas. An NDA for mirdametinib has been filed with the FDA and has received priority review with a PDUFA target action date of February 28, 2025. 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 approved by the FDA as a monotherapy for the treatment of patients with pLGG.

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 as well as in combination studies with mirdametinib and panitumumab. Fore Biotherapeutics (formerly NovellusDx) is developing the RAF dimer breaker plixorafenib (formerly FORE8394 or PLX-8394) in a Phase 2 trial in combination with cobicistat in patients with cancers harboring BRAF aalterations. Black Diamond Therapeutics have the next-generation BRAF inhibitor BDTX-4933 in Phase 1 clinical trials in adult solid tumors (KRAS-mutant NSCLC and solid tumors with RAF/RAS-mutations). 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 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. Naporafenib, in combination with trametinib, is being studied in a Phase 3 clinical trial in patients with NRAS-mutant melanoma. Nested Therapeutics has advanced NST-628, a pan-RAF/MEK “molecular glue” into a Phase 1 clinical trial.

With regard to the treatment of pLGG, some MEK inhibitors, some type I RAF inhibitors, and 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 OJEMDA if it is approved and enters the market.

Pursuant to the MabCare License Agreement, we have the exclusive right to develop, manufacture and commercialize DAY301, a novel ADC targeting PTK7, worldwide, excluding Greater China. We expect the first patient to be dosed in the Phase 1a portion of the Phase 1a/b study for DAY301 in the fourth quarter of 2024 or first quarter of 2025. There are a few ADCs targeting PTK7 in development. In February 2024, Profound Bio dosed its first patient in a Phase 1/2 Clinical Trial of PRO1107. Profound Bio was acquired by Genmab A/S in May of 2024 and the program was renamed to GEN1107. Eli Lilly and Company anticipates an IND submission in 2025 for LY4175408.

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 with a particular product or product candidate 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 OJEMDA or our 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 future revenue from the sale of the product candidates we may develop, if approved, could be adversely affected.

Safety risks or other side effects associated with OJEMDA, DAY301, VRK1 or any future products and 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 product, OJEMDA, and our product candidates. The most common side effects (adverse events) observed to date with OJEMDA 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 OJEMDA or 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 OJEMDA or 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 OJEMDA and 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 OJEMDA or 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 OJEMDA, DAY301, VRK1 or our other product candidates. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of OJEMDA and our product candidates will be harmed and our ability to generate product revenues from such product or 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 OJEMDA or 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 OJEMDA or 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.

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 or 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 products 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 products 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 products and product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. We have commenced the commercial launch of OJEMDA in the United States. There is no guarantee that OJEMDA or our product candidates will be approved for the front-line setting, 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 OJEMDA and our product candidates, are based on our beliefs and estimates. For example, pLGG is a rare disease, and 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 OJEMDA and 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 market research. These estimates may prove to be incorrect. Additionally, new studies or information may change the estimated incidence or prevalence of the cancers that we are targeting, which could affect our eligibility for orphan designation for certain indications. The potentially addressable patient population for OJEMDA and our product candidates may be limited or may not be amenable to treatment with OJEMDA and 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. Even if we obtain significant market share for our products, if the potential target populations are small, we may never achieve profitability without obtaining marketing authorization for additional indications, if at all.

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 additional 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 products and 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 OJEMDA and 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 OJEMDA and 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 successfully commercialize OJEMDA and our product candidates and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for RAF-driven cancers for our OJEMDA program, we may never successfully identify additional oncogenic alterations sensitive to OJEMDA 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.

OJEMDA and our product candidates, including DAY301 and VRK1, 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.

Our product, OJEMDA, and product candidates, including DAY301 and VRK1, if approved, 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. 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 and of any 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 REMS, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of OJEMDA and 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;
- 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 and marketing efforts and market access;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If 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. With respect to OJEMDA specifically, successful commercialization will depend on negotiations with, and coverage, reimbursement, selection and/or acquisition decisions by, third-party payors, which we cannot predict. These decisions in turn may depend on value assessments conducted by various entities (e.g., formulary committees, such as pharmacy and therapeutics committees, healthcare systems and pharmacies, among others) that consider various factors (including the price of OJEMDA)—the outcomes of which we cannot predict.

Any products and 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 products, including OJEMDA, and our product candidates, including DAY301 and VRK1, should it receive marketing authorization, will depend substantially, both in the United States and internationally, on the extent to which the costs of such products and 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 OJEMDA and 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 or 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. Public and private payor policies are expected to be critical to our ability to achieve broad payment coverage. Further, to the extent one or more of our products obtain coverage by one third-party payor, that does not assure that other payors will also provide coverage for the product. 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 generally challenging the prices for medical products, including by 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 pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, which may be costly. Nonetheless, our products and 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 products 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, 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 and commercialization of OJEMDA 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. The 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, 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 DAY301, VRK1 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 OJEMDA, DAY301 and VRK1, currently our only product and 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 the 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 the FDA of the NDA for that product.

The 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 the FDA as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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. The FDA approval process may also 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. On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. In connection with its approval of OJEMDA, the FDA may impose restrictions, post-marketing requirements or post-marketing commitments that may limit our ability to commercialize OJEMDA or any other product. If we fail to comply with FDA-mandated requirements or if the results of certain required post-marketing studies are negative, the FDA could withdraw approval, add warnings or narrow approved indications, which could affect the commercial success of our products.

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 advanced Project Optimus, 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, data integrity challenges or failure to demonstrate favorable safety or efficacy traits. 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 our product candidates, DAY301 and VRK1. While the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation, there is no assurance that we will receive similar approval for OJEMDA 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 seek to utilize any of the FDA's expedited programs, the 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.

The 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.

We may seek to avail ourselves of one or more of the FDA's expedited programs. For example, we may seek Fast Track designation for one or more of our product candidates.

The 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. The 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 the FDA would decide to grant it. The 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 in patients with advanced pLGG, and we may apply for breakthrough therapy designation for other product candidates or indications in the future. The FDA may designate a drug candidate as a potential breakthrough therapy if the drug candidate is intended, alone or in combination with one or more other drugs or drug candidates, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drug candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drug candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA. The FDA may withdraw breakthrough therapy designations if it determines that the criteria for the designation is no longer met.

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. The 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. The 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, the FDA may grant priority review to any application or supplement for a drug submitted with a priority review voucher. We cannot assure you that the 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 the FDA's Accelerated Approval Program, and subject to the conditions set forth in Section 506(c) of the FD&C Act and FDA regulations, the 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. The 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 ORR. The FDA may not agree with our conclusion that an endpoint we select is reasonably likely to predict clinical benefit, and thus the FDA may not agree that accelerated approval is appropriate based on that endpoint (even if the results on that endpoint are statistically significant), which could delay or preclude accelerated approval.

Products granted accelerated approval are subject to certain post-marketing requirements, which typically include a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product, which must be completed with due diligence. By the time of approval of the product, the 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. The 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. The 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 the FDA, the sponsor must submit all promotional materials at least 30 days prior to use.

The accelerated approval pathway has come under scrutiny within the FDA, by Congress and by other stakeholders. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the 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 the 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.

The 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:

- the failure to conduct any required post-approval study of a product candidate with due diligence, including with respect to conditions specified by the FDA;
- a study required to verify and describe the predicted clinical benefit of a product candidate fails to verify and describe such benefit;
- other evidence demonstrates that the product candidate is not shown to be safe or effective under the conditions of use; or
- the sponsor's dissemination of 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.

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 in treating malignant glioma and glioma, respectively. We may seek orphan drug designation for tovorafenib in additional geographies or indications, or for DAY301, VRK1 or any product candidates we may 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 candidate 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 the 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 the 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 a 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 the 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 the 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 the 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 has not yet 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 the 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. The 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, any of our other applications may be subject to PREA requirements.

Under the Best Pharmaceuticals for Children Act, or the BPCA, the FDA can grant pediatric exclusivity to a sponsor that conducts pediatric studies requested by the 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 the FDA within the timeframe required by the BPCA and the FDA's acceptance of the study reports. The 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 the 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.

OJEMDA was granted rare pediatric designation by the FDA in May 2021 for the treatment of LGGs harboring an activating RAF alteration that disproportionately affects children. We submitted the OJEMDA NDAs as a rare pediatric designation marketing application, and the FDA conditionally designated the marketing application as a "rare pediatric disease product application" pending the final determination at the time of approval or licensure on whether the application meets all of the eligibility criteria set forth in section 529(a)(4) of the FD&C Act. On April 23, 2024, the FDA approved the NDAs for the treatment of patients 6 months of age and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation, and in connection with the accelerated approval, Day One received a Priority Review Rare Pediatric Disease Voucher, or PRV.

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. On May 29, 2024, we entered into an asset purchase agreement, pursuant to which we agreed to sell our rare pediatric disease PRV to an undisclosed buyer for gross proceeds of $108.0 million. Following the sale, we are no longer eligible to take advantage of the incentives under the rare pediatric disease PRV, including priority review of a subsequent marketing application. 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 in the future for any of our current or future product candidates or that we will realize any value if we receive and were to sell any such 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, the 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, the 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 for 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, the 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, the 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, the 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 the 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 the 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 or 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.

For each product and product candidate for which marketing authorization is granted, including OJEMDA, 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 in line with our expectations.

For each product and product candidate for which marketing authorization is granted, including OJEMDA, an approved product and the marketing authorization holder are subject to ongoing regulation by the 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, the 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. The 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, the 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 the 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, the 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 the 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 for which we obtain marketing authorization, including OJEMDA, 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 for which we obtain marketing authorization, such as OJEMDA, 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, OJEMDA, and product candidates, 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 and/or limit our ability to generate sales revenues.

Our failure to obtain marketing authorization in foreign jurisdictions would prevent OJEMDA and 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. Further, FDA approval of OJEMDA does not guarantee approval in jurisdictions outside of the United States. 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. Since 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 do 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.

Existing, 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 products 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 Trump 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 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 August 29, 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 future revenue in line with our expectations, attain profitability or commercialize OJEMDA and our product candidates.

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.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

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

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.

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 U.S. Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could 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 our current or future product candidates, including DAY301 and VRK1, 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 limited experience as a commercial company and the sales, marketing, and distribution of OJEMDA or any future approved products may be unsuccessful or less successful than anticipated.

We recently began commercializing our first product, OJEMDA, in the United States. As a company, we had no prior experience commercializing a product. The success of our commercialization efforts for OJEMDA and any future approved products is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities.

For example, we have completed hiring in areas to support commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could delay or negatively affect the success of our commercialization efforts and our business. For example, the commercialization of OJEMDA may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses.

Alternatively, we may license certain rights with respect to our products or product candidates to collaborators and rely on the assistance and guidance of those collaborators. We may also seek 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. 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 products and product candidates, we may not generate substantial revenues, if any, from them or be able to reach or sustain profitability.

Given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of OJEMDA or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

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, DAY301, VRK1 and any preclinical studies and clinical trials of any future products and 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 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 products and 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 products and product candidates 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 OJEMDA or 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 OJEMDA, DAY301, VRK1 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 OJEMDA and our product candidates including DAY301 and VRK1, 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 OJEMDA and our product candidates for clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture of our product candidates. In addition, we expect to contract with analytical laboratories for release and stability testing of OJEMDA and our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of OJEMDA or 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 the 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, may impact our ability to procure sufficient supplies for the development of OJEMDA and 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 OJEMDA and 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. Legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, including those affiliated with the manufacture of our API, Wuxi STA, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation.

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 OJEMDA and a packaging agreement with Sharp Corporation, or Sharp, for the packaging and serialization of OJEMDA. Supply chain issues, such as those related to certain packaging material, may negatively impact our ability to package and deliver OJEMDA and our 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 the 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;
- 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.

OJEMDA and 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 commercialization of OJEMDA, we will need to take steps to increase the scale of production of OJEMDA and our product candidates. Other than for our product OJEMDA, we have not yet scaled up the manufacturing process for any of our product candidates 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. 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 OJEMDA or 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. 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 OJEMDA or our product candidates 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, actual or perceived instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, natural disasters, fire, regional geopolitical conflicts, acts of terrorism, pandemics, 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 OJEMDA and 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 OJEMDA and our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of OJEMDA and our product candidates.

We may seek third-party collaborators for the development and commercialization of OJEMDA and 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 OJEMDA and 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 OJEMDA and 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 OJEMDA and 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 OJEMDA or 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 OJEMDA or our 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. The 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 OJEMDA or our 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 products or product candidates;
- collaboration agreements may not lead to development or commercialization of OJEMDA or our 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.

The loss of any large customer, or any cancellation or delay of a significant purchase by a large customer, could reduce our net sales and harm our operating results.

We have received a substantial portion of our revenue from a limited number of customers. For example, for the nine months ended September 30, 2024, three individual customers accounted for 100.0% of our total net product revenue, with these individual customers representing 66.6%, 27.0%, and 6.4% of total net product revenue. As of September 30, 2024, three customers accounted for 100.0% of the accounts receivable balance, with these individual customers representing 55.0%, 25.7%, and 19.3% of the accounts receivable balance.

We cannot provide any assurances that we will retain our current customers or groups of customers, that they will maintain their current or forecasted demand for our products, or that we will be able to attract and retain additional customers in the future. If for any reason we were to lose our ability to sell to a specific group or class of customers, we could experience a significant reduction in revenue or loss of market share, which would adversely impact our operating results.

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, and 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, quality, 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 OJEMDA or 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 174 full-time employees as of September 30, 2024. 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, 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 OJEMDA, DAY301, VRK1 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 DAY301, VRK1 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 OJEMDA, DAY301, VRK1, 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 future 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 future 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., cGMP) 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 the 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 the 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 OJEMDA, DAY301, VRK1 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 OJEMDA, DAY301, VRK1 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 or 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 scopes 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. The My Health Data Act became effective on March 31, 2024 and there may be substantial regulatory action and litigation associated with the My Health Data Act.

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 which, 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. Effective July 10, 2023, the new EU-U.S. Data Privacy Framework, or the DPF, has been recognized as adequate under EU law to allow transfers of personal data from the EU to certified companies in the United States. However, the DPF is subject to further legal challenges which could cause the legal requirements for personal data transfers from the EU to the United States to become uncertain once again. While the DPF does not apply to the UK, on October 12, 2023, the UK government adopted an adequacy decision concluding that the United States ensures an adequate level of protection transferred from the UK to the United States under the UK Extension to the EU-U.S. Data Privacy Framework, or the UK DPF. We anticipate a similar adequacy decision from the Swiss government, or Swiss DPF. Both the UK DPF and the Swiss DPF could also be contested or otherwise affected by any challenges to the EU-U.S. DPF. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. In the EU and other markets, potential new rules and restrictions on the flow of data across borders could increase the cost and complexity of doing business in those regions.

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.

Further, on July 26, 2023, the SEC adopted new cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board's role in overseeing cybersecurity risks, management's role and expertise in assessing and managing cybersecurity risks and processes for assessing, identifying and managing cybersecurity risks) in annual reports on Form 10-K. These new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents by Form 8-K, within four business days of determining an incident is material.

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

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain regulators, investors, employees, users and other stakeholders concerning corporate responsibility, specifically related to ESG matters both in the United States and internationally. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies.

Further, ESG initiatives, goals or commitments could be difficult to achieve or costly to implement. If our competitors' corporate social responsibility performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. Moreover, California recently adopted two new climate-related bills, which require companies doing business in California that meet certain revenue thresholds to publicly disclose certain greenhouse gas emissions data and climate-related financial risk reports, and compliance with such requirements could require significant effort and resources. Additionally, in March 2024, the SEC enacted comprehensive climate change disclosure rules, although the SEC has since issued an order to stay the rules pending the completion of judicial review of multiple petitions challenging the rules. Our business may face increased scrutiny related to these activities and our related disclosures, including from the investment community, and our failure to achieve progress or manage the dynamic public sentiment and legal landscape in these areas on a timely basis, or at all, could adversely affect our reputation, business, and financial performance.

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 OJEMDA or 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., Merck KGaA, Darmstadt, Germany, MabCare, and Ipsen, 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 (such as DAY301 and VRK1) 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 OJEMDA and 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 OJEMDA and 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 20 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 OJEMDA and 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 OJEMDA or our 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 OJEMDA or our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize OJEMDA or 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 OJEMDA and 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 products or 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 OJEMDA and 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 OJEMDA or 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, 2024, others may hold proprietary rights that could prevent OJEMDA or our product candidates from being marketed. It is possible that a third-party may assert a claim of patent infringement directed at OJEMDA or our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to OJEMDA or 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 OJEMDA or 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 OJEMDA, 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 OJEMDA or 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 OJEMDA and 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., Merck KGaA, Darmstadt, Germany, MabCare, and Ipsen 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, MabCare, and Ipsen 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 OJEMDA and 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 OJEMDA or our current product candidates;
- lose patent or trade secret protection for OJEMDA or our current product candidates;
- experience significant delays in the development or commercialization of OJEMDA or 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 OJEMDA and our product candidates.

If we breach any of the agreements under which we license the use, development and commercialization rights to OJEMDA and 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.

OJEMDA and 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.). OJEMDA and 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. Further, pursuant to the MabCare License Agreement, we have the exclusive right to develop, manufacture and commercialize DAY301 worldwide, excluding Greater China.

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 OJEMDA and 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 successfully commercialize OJEMDA and 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., Merck KGaA, Darmstadt, Germany, MabCare, and Ipsen 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 OJEMDA or 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 from their regular responsibilities. 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 OJEMDA and 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 post-grant review, *inter partes* review 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 OJEMDA and 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 involves 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 with respect to our patents or third-party patents. In addition, the U.S. 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. 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.

Additionally, starting from June 1, 2023, European applications 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 the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

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 and product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing authorization of our product and 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 may 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 successfully commercializing OJEMDA and 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 OJEMDA and 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 OJEMDA and 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 OJEMDA and our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to OJEMDA and 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 OJEMDA and 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 OJEMDA and 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, among others, Viracta Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Merck KGaA, Darmstadt, Germany, MabCare, and Ipsen. 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 OJEMDA and 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.

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.

Certain geo-political actions in the United States or other countries may increase the uncertainties and costs related to the prosecution or maintenance of our patent applications, or those of our 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.

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 a product candidate we develop receives marketing authorization, the timing and terms of such approval and market acceptance and demand for such product;
- 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 products, if any, 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, actual or perceived instability in the global banking system, changes in the U.S. presidential administration, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, global regional conflicts and public health epidemics;
- 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 and other calamities;
- general economic, industry and market conditions, including inflation, actual or perceived instability in the global banking system and uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, changes in the U.S. presidential administration, 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, as well as 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 100,810,357 shares of our outstanding common stock as of September 30, 2024 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 vesting of outstanding restricted stock unit awards, 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, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 40.6% 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.

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 amended and 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 of 1933, as amended, or 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 amended and restated bylaws 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 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, we 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 and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting in our annual reports on Form 10-K. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm's evaluations of our internal control over financial reporting, 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, including any failure to implement required new or improved controls, or difficulties encountered in their implementation, could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we or our independent registered public accounting firm 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 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 have been concerns with respect to the stability of 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.

Further, our business and operations may be impacted by the political instability and military hostilities in multiple geographies including Ukraine, the Middle East and the tensions between China and Taiwan. 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 results of operations. However, if the conflict continues to worsen or intensify, any business interruptions or spillover effects could adversely affect our business and operations.

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.

		Incorporated by Reference				
Exhibit Number	Description	Form	File No.	Filing Date	Exhibit	Filed/Furnished Herewith
10.1†^	Exclusive License Agreement by and between Day One Biopharmaceuticals, Inc. and Ipsen Pharma SAS dated July 23, 2024.					X
10.2†^	Form of Securities Purchase Agreement	8-K	001-40431	July 30, 2024	10.1	
10.3	Form of Pre-Funded Warrant	8-K	001-40431	July 30, 2024	4.1	
10.4	Form of Registration Rights Agreement	8-K	001-40431	July 30, 2024	10.2	
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 With Embedded Linkbase Documents.					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.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

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: October 30, 2024

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: October 30, 2024

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 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE LICENSE AGREEMENT

BY AND BETWEEN

DAY ONE BIOPHARMACEUTICALS, INC.

AND

IPSEN PHARMA SAS

JULY 23, 2024

37942/00605/FW/20045121.1

EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** ("**Agreement**") is entered into as of July 23, 2024 (the "**Effective Date**"), by and between Day One Biopharmaceuticals, Inc., a Delaware corporation located at 2000 Sierra Point Parkway, Suite 501, Brisbane, CA 94005 ("**Day One**") and Ipsen Pharma SAS, a French corporation located at 65 Quai Georges Gorse, 92100 Boulogne- Billancourt, France ("**Licensee**"). Day One and Licensee may be referred to in this Agreement individually as a "**Party**" or collectively as the "**Parties**."

BACKGROUND

WHEREAS, Day One is a biopharmaceutical company that owns or controls certain intellectual property relating to tovorafenib, an oral, small molecule type II RAF inhibitor, which Day One is currently developing and commercializing in the United States under the brand name "OJEMDA" for pediatric low-grade glioma (pLGG);

WHEREAS, Licensee is a global pharmaceutical company with expertise in developing and commercializing pharmaceutical products;

WHEREAS, Licensee desires to obtain from Day One an exclusive license to develop and commercialize Licensed Products (as defined herein) in the Licensee Territory (as defined herein), and Day One is willing to grant such a license to Licensee in accordance with the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged by both Parties, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, and any cognates or correlatives thereof, whether used in the singular or plural, shall have the meanings specified.

1.1 "**Accounting Standards**" means IFRS (as defined below) consistently applied by the applicable Party or other entity in maintaining its books and records, or with respect to Day One, the then United States of America generally accepted accounting principles ("**U.S. GAAP**"). Each accounting term used herein that is not specifically defined herein should be determined in accordance with IFRS accounting principles, as consistently applicable at the time where these amounts are calculated, or with respect to Day One, the U.S. GAAP.

1.2 "**Acquirer**" means a Third Party that acquires a Party through a Change of Control, together with any Affiliates of such Third Party existing immediately prior to the consummation of the Acquisition. For clarity, an "**Acquirer**" of a Party shall exclude the Party and all of its Affiliates existing immediately prior to the consummation of the Acquisition.

1.3 "**Additional Studies for the Initial Field**" has the meaning set forth in Section 4.2.2.

1.4 "**Affiliate**" means, with respect to an entity, any entity directly or indirectly controlled by, controlling, or under common control with such entity, regardless of whether such entity is or becomes an

Affiliate on or after the Effective Date, but only for so long as such control exists. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of fifty percent (50%) or more (or the maximum ownership interest permitted by Applicable Law giving control) of the voting securities or other ownership or general partnership interest (whether directly or indirectly) or other comparable equity interests in an entity.

1.5 "Alliance Manager" has the meaning set forth in Section 3.7.

1.6 "**AMF"** has the meaning set forth in Section 7.5.2.

1.7 "**ANDA**" has the meaning set forth in Section 8.4.2(e).

1.8 "**Applicable Law**" means all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing) and any other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party's activities in connection with this Agreement including, GCP, GLP and GMP).

1.9 "**Arising Know-How**" means any and all Know-How, including Clinical Data, generated, developed, conceived, reduced to practice or otherwise made during the Term by or on behalf of a Party either solely or jointly, its Affiliates or respective (sub)licensees (or any Third Party acting on their behalf) in the performance of activities or exercise of rights under this Agreement.

1.10 "**Audited Party**" has the meaning set forth in Section 6.11.

1.11 "**Auditing Party"** has the meaning set forth in Section 6.11.

1.12 "**Business Day**" means a day other than any Saturday, Sunday or other day on which banking institutions in San Francisco, CA, USA and Paris, France are authorized or required by Applicable Law to remain closed.

1.13 "**Calendar Quarter**" means any of the three (3) consecutive calendar month periods beginning on January 1, April 1, July 1 or October 1 of any Calendar Year, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first full Calendar Quarter thereafter, and the last Calendar Quarter shall end on the last day of the Term.

1.14 "**Calendar Year**" means any of the twelve (12) consecutive calendar month periods beginning on January 1 and ending on December 31, except that the first Calendar Year shall commence on the Effective Date and end on the first December 31 to occur after the Effective Date, and the last Calendar Year shall end on the last day of the Term.

1.15 "**CDA**" has the meaning set forth in Section 7.4.

1.16 "**CDx Agreement**" has the meaning set forth in Section 5.5.

1.17 "**CE Marking Approval**" means, with respect to the [*] CDx, completion of all conformity assessment procedures required under the Directive 98/79/EC of the European Parliament and of the Council of October 27, 1988 on in vitro diagnostic medical devices, as amended from time to time, and as implemented in the EU member states ("**IVD Directive**") or Regulation (EU) 2017/746 of the

European Parliament and of the Council of April 5, 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 210/227/EU ("**IVD Regulation**"), as applicable, including obtaining any necessary certifications by the relevant Governmental Authority of the conformity of an in vitro diagnostic medical device with the requirements of the IVD Directive or IVD Regulation, as applicable, and applicable harmonized standards necessary for the manufacturer of such device to affix a CE mark and place such device on the market in the EU.

1.18"**Change of Control**" means, with respect to a Person (an "**Acquired Person**"), the occurrence of any of the following events from and after the Effective Date: (a) any Person or group of Persons becomes the beneficial owner (directly or indirectly) of fifty percent (50%) or more of the voting shares of such Acquired Person who did not own fifty percent (50%) or more of the voting shares of such Acquired Person immediately prior to the occurrence of the event; (b) such Acquired Person consolidates with or merges into or with another Person pursuant to a transaction in which fifty percent (50%) or more of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting shares of such Acquired Person immediately preceding such consolidation or merger; or (c) such Acquired Person sells or transfers to another Person all or substantially all of its assets. With regard to the foregoing clause (a) or (b), a Change of Control will be deemed to occur if a Third Party has the power, directly or indirectly, to direct or cause the direction of the management of a Party, regardless of whether such Third Party holds beneficial ownership of more than fifty percent (50%) of the voting shares. Notwithstanding the foregoing, (i) a transaction or series of transactions effected for the primary purpose of financing the operations of such Person including the issuance or sale of securities for financing purposes less than a controlling share; (ii) internal reorganization of such Person; or (iii) changing the form or jurisdiction of organization of such Person, will not be deemed a "Change in Control" for purposes of this Agreement.

1.19"**Clinical Data**" means any and all data generated in a Clinical Trial for the Licensed Product conducted by or on behalf of a Party or any of its Affiliates or (sub)licensees in any Indication in accordance with this Agreement, including all clinical trial reports for such Clinical Trial.

1.20"**Clinical Trial**" means a clinical study involving the administration of a pharmaceutical or biological product to a human.

1.21"**Closing Date**" has the meaning set forth in the Investment Agreement annexed at **Schedule 6.2**.

1.22"**CMC**" means chemistry, manufacturing and controls.

1.23"**CMC Subcommittee**" has the meaning set forth in Section 3.8.

1.24"**CMO**" means a Third Party contract manufacturing organization or Third Party contract development and manufacturing organization.

1.25"**Combination Product**" means a pharmaceutical product that [*]

1.26"**Combination Therapy**" means a therapy comprising [*].

1.27"**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended by Licensee or Day One in connection with an obligation hereunder, those efforts and resources [*].

1.28"**Committee**" has the meaning set forth in Section 3.3.1.

1.29"**Common Stock**" has the meaning set forth in Section 6.2.

1.30"**Competing Product**" means [*].

1.31"**Competitive Infringement**" has the meaning set forth in Section 8.4.1.

1.32"**Confidential Information**" has the meaning set forth in Section 7.1.

1.33"**Control**" means, subject to Section 2.1.6, with respect to any Know-How, Regulatory Materials, Patent Rights or other rights, the possession by a Party or any of its Affiliates of the legal authority or right (whether by ownership, license or otherwise, other than by operation of the licenses and other grants in this Agreement) to grant to the other Party a license, sublicense, right to use or right to access such Know-How, Regulatory Material, Patent Right or other right without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such license, sublicense, right to use or right to access. Notwithstanding the foregoing, in the event a Party or its Affiliate undergoes a Change of Control transaction, then [*].

1.34"**CRO**" means a Third Party contract research organization.

1.35"**Corporate Name**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of a Party that are associated with such Party's business name or corporate identity.

1.36"**Cover**" means (a) with respect to a claim of an issued Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof), or (b) with respect to a claim of a pending Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would, if such claim were to issue in its current form, infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof).

1.37"**Data Protection Laws**" has the meaning set forth in Section 9.3.1.

1.38"**Day One Arising Know-How**" means all Arising Know-How generated, developed, conceived, reduced to practice or otherwise made by Day One or its Affiliates or Sublicensees (or any Third Party acting on their behalf).

1.39"**Day One Arising Patents**" means all Patent Rights that claim Day One Arising Know-How.

1.40"**Day One CMO**" has the meaning set forth in Section 5.6.1.

1.41"**Day One CMO Agreement**" has the meaning set forth in Section 5.6.1.

1.42[*]

1.43[*]

1.44"**Day One Indemnitee**" has the meaning set forth in Section 10.1.

1.45[*]

1.46"**Day One Know-How**" means all Know-How Controlled by Day One or any of its Affiliates as of the Effective Date or during the Term that is necessary to develop, manufacture or commercialize the Licensed Product in the Field. For clarity, Day One Know-How shall include Day One Arising Know How.

1.47"**Day One Marks**" has the meaning set forth in Section 8.7.1 and as listed in **Schedule 8.7.1**.

1.48"**Day One Patents**" means all Patent Rights Controlled by Day One or any of its Affiliates as of the Effective Date or during the Term that are necessary to develop, manufacture or commercialize the Licensed Product in the Field. The Day One Patents existing as of the Effective Date are listed on **Schedule 1.48** hereto. For clarity, Day One Patents shall include Day One Arising Patents.

1.49"**Day One Retained Rights**" has the meaning set forth in Section 2.1.4.

1.50"**Day One Technology**" means the Day One Know-How, Day-One Patents and Day One's and its Affiliates' interests in any Joint Arising Know-How and Joint Arising Patents.

1.51"**Day One Territory**" means the United States.

1.52"**Dispute**" has the meaning set forth in Section 12.5.1.

1.53"**Distributor**" means any Third Party that purchases Licensed Product from Licensee, its Affiliates or Sublicensees for distribution and sale in a particular country or region in the Licensee Territory and [*].

1.54"**Divestiture**" or "**Divest**" means[*].

1.55"**DPA**" has the meaning set forth in Section 2.8.

1.56"Drug Master File" means any (a) drug master files filed with the FDA with respect to the Licensed Product, (b) active substance master file ("**ASMF**") filed with the EMA, and (c) equivalent filing in other countries in the Licensee Territory.

1.57"**Early Access Program**" means the administration of the Licensed Product, prior to the receipt of Regulatory Approval, to named patients to provide access between availability of positive risk/benefit data and commercial availability. Early Access Programs include expanded access programs to patients outside of a Clinical Trial or after completion of a Clinical Trial for patients who do not meet the Clinical Trial enrollment criteria such as the "*Expanded Access to the Oral Pan-RAF Inhibitor DAY101 in Pediatric Patients With RAF-Altered, Relapsed or Refractory Low-Grade Glioma*" (NCT05760586), named patient programs/named patient supply ("**NPP(s)**"), temporary authorization for use, and compassionate use programs. For clarity, an Early Access Program may continue to be temporarily performed in a country following the receipt of Regulatory Approval, and costs may continue to be incurred in accordance with the performance of such Early Access Program after Regulatory Approval.

1.58"**Electronic Delivery**" has the meaning set forth in Section 12.13.

1.59"**EMA**" means the European Medicines Agency or any successor entity thereto.

1.60"**Enforcement Action**" has the meaning set forth in Section 8.4.2.

1.61"**EU5**" means each of France, Germany, Italy, Spain and the United Kingdom.

1.62"**European Union**" or "**EU**" means the European Union.

1.63"**Executive Officers**" means a member of senior executive management of a Party who is designated by such Party to resolve Disputes or any other issue referred to them under this Agreement and that has decision-making authority on behalf of the applicable Party.

1.64"Existing Early Access Programs" has the meaning set forth in Section 4.2.8.

1.65"Existing Early Access Handover Date" has the meaning set forth in Section 4.2.8.

1.66"Existing Early Access Program Revenues" has the meaning set forth in Section 4.2.8.

1.67"**Existing In-License Agreement(s)**" means the: [*].

1.68"**Excluded Sales**" has the meaning set forth in Section 1.123.

1.69[*]

1.70"**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.71"**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as may be amended from time to time.

1.72"[*] CDx" has the meaning set forth in Section 5.5.

1.73"[*] CDx Milestone Event" has the meaning set forth in Section 6.4.

1.74"[*] CDx Milestone Payment" has the meaning set forth in Section 6.4.

1.75"**Field**" means all Indications for the diagnosis or treatment for all diseases and conditions, including, without limitation, (i) first line pLGG and (ii) relapsed or refractory treatment of pLGG in patients six (6) months and older in the U.S. (or equivalent Indication in the Licensee Territory) (clause (i) and (ii), the "**Initial Field**"). The foregoing definition of the Field shall be [*].

1.76"**FIREFLY-1 Study**" means the Clinical Trial currently being conducted by Day One for the Licensed Product in pediatric and young adult patients with RAF-altered, relapsed or progressive low-grade glioma and advanced solid tumors (NCT04775485).

1.77"**FIREFLY-2 Study**" means the Clinical Trial currently being conducted by Day One for the Licensed Product in first line pLGG and having the protocol entitled "DAY101 vs. Standard of Care Chemotherapy in Pediatric Patients With Low-Grade Glioma Requiring First- Line Systemic Therapy" (NCT05566795).

1.78"**First Commercial Sale**" means, with respect to a Licensed Product and country, the first sale of such Licensed Product by or on behalf of Licensee, its Affiliates or Sublicensees to a Third Party for distribution, use or consumption in such country after Regulatory Approval (including, solely for the purposes of applicable Launch Milestone Events, any required Pricing and Reimbursement Approvals) has been obtained for such Licensed Product in such country, but excluding any Excluded Sales (as defined below).

1.79"**Force Majeure**" has the meaning set forth in Section 12.6.

1.80"**FTE**" means the equivalent of a full-time individual's work in a Calendar Year (consisting of a total of [*] per Calendar Year. Any person who devotes more or less than [*] per Calendar Year on the applicable activities under this Agreement shall be treated as an FTE on a *pro-rata* basis, based upon the actual number of hours worked by such person on such activities, divided by [*]. FTEs will be pro-rated on a daily basis if necessary. For avoidance of doubt, the hours spent by Day One temporary workers and contractors on applicable activities may be treated as FTE on a *pro-rata* basis. FTE shall be determined in accordance with a standard software system, as reasonably acceptable to Licensee which includes tracking of individuals' full-time hours using standard practices and normal systems and methodologies. Over-time work will not be counted with any multiplier toward the number of hours that are used to calculate the FTE contribution. No hours shall be allocated for time spent by an individual on projects that are not directed to performing the activities under this Agreement. For example, if an individual spent 25 hours of their time on the applicable work under this Agreement and 75 hours of their time on projects outside of the Agreement, then the Party would record such time for such individual as [*] of an FTE for purposes of this Agreement.

1.81"**FTE Rate**" means an initial rate of (a) with respect to Day One's personnel, [*] per FTE per Calendar Year which rate shall apply through January 1st, 2025. Thereafter, the FTE Rate shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics ("**CPI**"), (changes based on the change in the CPI from the most recent applicable index available as of the Effective Date to the most recent applicable index available as of the date of the calculation of such revised FTE Rate).

1.82"**Future Clinical Trial**" has the meaning set forth in Section 4.2.7.

1.83"**GCP**" means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the FFDCA and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.

1.84"**Generic Product**" means, with respect to the Licensed Product and a country, any pharmaceutical product other than the Licensed Product that is (a) approved by way of an expedited or abbreviated regulatory mechanism by the relevant Regulatory Authority in such country based on bioequivalence or interchangeability with the Licensed Product in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of the Licensed Product as a substitutable generic for such Product, and (b) is sold in such country by a Third Party that is not a Sublicensee of Licensee or any of its Affiliates and that did not purchase such product in a chain of distribution that included Licensee or any of its Affiliates or Sublicensees. For clarity, Generic Product also include "**Hybrid Product**" which means any pharmaceutical product, other than the Licensed Product, but containing the same active ingredient that has been approved for sales by a Regulatory Authority for the same indication and sold in the Licensee Territory, independently of Licensee, its Affiliates and its Sublicensees, for which a bio-equivalence cannot be shown or which differs from the Licensed Product in indication, strength, pharmaceutical form or route of administration and whose approval depends partly on the safety and efficacy data for the Licensed Product and partly on new data from clinical trials.

1.85"Global Development Plan" means a written global development plan relating to any global Clinical Trials conducted by Day One in the Licensee Territory and the Day One Territory and any Future Clinical Trials. The initial version of the Global Development Plan is attached herein as **Exhibit B**.

1.86"**GLP**" means the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the FFDCA and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good laboratory practice as are required by any Regulatory Authority in such country.

1.87"**GMP**" means the applicable then-current standards for manufacturing activities for pharmaceuticals or biologicals, as set forth in (a) the FFDCA and any regulations or guidance documents promulgated thereunder, as amended from time to time in the United States, (b) any similar standards of good manufacturing practice as are required by any Regulatory Authority such as "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products", or International Council for Harmonization GMP Guidelines, including ICH Q7, and (c) all Applicable Laws promulgated by any Governmental Authority of the other jurisdiction of the Licensee Territory such as Japan or Brazil having jurisdiction over the manufacture of any Licensed Compound or Licensed Product, as applicable as each may be amended from time to time.

1.88"**Governmental Authority**" means any federal, state, national, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.89"**ICC**" has the meaning set forth in Section 12.5.2(b).

1.90"**IFRS**" means International Financial Reporting Standards adopted by the European Union as issued by the International Accounting Standards Board and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.

1.91"**IND**" means an investigational new drug application, clinical trial authorization application or similar application or submission (including any supplements of any of the foregoing) filed with or submitted to a Regulatory Authority for approval to conduct Clinical Trials of a pharmaceutical product. Specifically for an IND submitted to the FDA, pursuant to U.S. 21 C.F.R. Part 312. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application ("**CTA**") in the EU).

1.92"**Indemnified Party**" has the meaning set forth in Section 10.3.1.

1.93"**Indemnifying Party**" has the meaning set forth in Section 10.3.1.

1.94"**Indication**" means any separate and distinct disease or medical condition in humans. For purposes of this Agreement[*].

1.95"**Initial Assistance Period"** has the meaning set forth in Section 4.1.

1.96"**Initial Field**" has the meaning set forth in Section 1.75.

1.97"**Investment Agreement**" has the meaning set forth in Section 6.2.

1.98"**Joint Arising Know-How**" means all Arising Know-How generated, developed, conceived, reduced to practice or otherwise made jointly by (a) Licensee, its Affiliates or Sublicensees (or

any Third Party acting on their behalf), and (b) Day One or its Affiliates or Sublicensees (or any Third Party acting on their behalf).

1.99"**Joint Arising Patents**" means all Patent Rights that Cover Joint Arising Know-How.

1.100"**JSC**" has the meaning set forth in Section 3.1.

1.101"**Know-How**" means any proprietary or confidential scientific or technical information, inventions, discoveries, results and data, in any tangible or intangible form, including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know- how, trade secrets, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and non- clinical and clinical test data, Clinical Data, physical and analytical data, regulatory data, safety data, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process, CMC information and development information, results and data. "Know- How" excludes physical substances.

1.102"**Launch Milestone Event**" has the meaning set forth in Section 6.3.

1.103"**Launch Milestone Payment**" has the meaning set forth in Section 6.3.

1.104"**License**" has the meaning set forth in Section 2.1.

1.105"**Licensed Compound**" means the small molecule known as "tovorafenib", as described in more detail in **Exhibit A** hereto.

1.106"**Licensed Product**" means any pharmaceutical preparation, in any presentation, dosage strength, route of administration and formulation, that contains the Licensed Compound as a sole active ingredient, including the pharmaceutical preparation being developed and commercialized by Day One as of the Effective Date in the Initial Field in the U.S. for patients 6 months and older under the brand name "OJEMDA" (tovorafenib), as described in more detail in **Exhibit A** hereto. The foregoing definition of the Licensed Product shall be [*].

1.107"**Licensed Product Promotional Materials**" means advertising, marketing or promotional materials for the Licensed Product that are generated by or on behalf of a Party, its Affiliates or (sub)licensees in connection with commercializing the Licensed Product.

1.108"**Licensee Arising Know-How**" means all Arising Know-How generated, developed, conceived, reduced to practice or otherwise made solely by Licensee, its Affiliates or Sublicensees (or any Third Party acting on their behalf).

1.109"**Licensee Arising Patents**" means all Patent Rights that Cover Licensee Arising Know-How.

1.110"**Licensee Indemnitee**" has the meaning set forth in Section 10.2.

1.111"**Licensee Technology**" means the Licensee Arising Know-How, Licensee Arising Patents and Licensee's and its Affiliates' interest in any Joint Arising Know-How and Joint Arising Patents.

1.112"**Licensee Territory**" means worldwide, excluding the Day One Territory.

1.113"**Licensee Territory Commercialization Plan**" has the meaning set forth in Section 5.2.

1.114"**Licensee Territory Development Plan**" has the meaning set forth in Section 4.2.3.

1.115[*]

1.116"**Licensee Territory-Specific Clinical Trial**" means, with respect to a particular dosage strength, route of administration, formulation, presentation or Indication of a Licensed Product, in each case that [*] a Clinical Trial of the Licensed Product for such dosage strength, route of administration, formulation, presentation or Indication in a country or jurisdiction of the Licensee Territory conducted to obtain or maintain Regulatory Approval of such Licensed Product for the exclusive benefit of such country or jurisdiction of the Licensee Territory, such as a bridging/clinical study, a post-marketing commitment study or a post-marketing surveillance study; *provided that* [*].

1.117"**Losses**" has the meaning set forth in Section 10.1.

1.118"**Major Market**" means [*].

1.119"**Manufacturing Technology Transfer Plan**" has the meaning set forth in Section 5.6.2.

1.120"**Manufacturing Technology Transfer Budget**" has the meaning set forth in Section 5.6.2.

1.121"**Manufacturing Technology Transfer**" has the meaning set forth in Section5.6.2.

1.122"**Marketing Authorization Application**" or "**MAA**" means a Marketing Authorization Application filed with the EMA under the centralized or decentralized EMA filing procedure to gain approval to market a pharmaceutical product in the EU, or any equivalent application or request for authorization filed in support of approval to market a pharmaceutical product in any country, in each case including any amendments and supplements thereto.

1.123[*]

1.124"**New Early Access Programs**" has the meaning set forth in Section 4.2.8(b).

1.125[*]

1.126"**NPP(s)**" has the meaning set forth in Section 1.57.

1.127"**ODD Status**" mean a designation under Section 526 of the Federal Food, Drug, and Cosmetic Act as amended by section 2 of the Orphan Drug Act (sections 525-528 (21 U.S.C. 360aa-360dd)) or any grant of a corresponding designation by a corresponding Regulatory Authority in the Licensee Territory.

1.128"**Out-of-Pocket Expenses**" means all costs and expenses actually paid by a Party or its Affiliate to any Third Party, without mark-up and including Third Party contract costs required to perform the relevant activity(ies), other than to internal employees or consultants of such Party or its Affiliates.

1.129"**Patent Right(s)**" means all patents and patent applications (including any certificates of invention, supplementary protection certificates and applications therefor, applications for certificates of

invention and priority rights) in any country or other jurisdiction, including all international applications, provisional applications, substitutions, continuations, continuations-in-part, continued prosecution applications, including requests for continued examination, divisional applications and renewals, and all letters, patents or certificates of invention granted thereon, and all reissues, reexaminations, term extensions, term adjustments, term restorations, renewals, substitutions, confirmations, registrations, revalidations, revisions and additions of or to any of the foregoing, in each case, in any country or other jurisdiction.

1.130"**Person**" means any individual, corporation, company, partnership, association, joint-stock company, trust, unincorporated organization or governmental or political subdivision thereof.

1.131"**Personal Data**" has the meaning set forth in Section 9.3.1.

1.132"**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.4.

1.133"**Pricing and Reimbursement Approval**" means any approval, agreement, determination or decision establishing prices that (a) can be charged to consumers for a pharmaceutical product in a country where Governmental Authorities approve or determine such pricing for pharmaceutical products, or (b) will be reimbursed by Governmental Authorities for a pharmaceutical product in a country where Governmental Authorities approve or determine such reimbursement pricing pharmaceutical products.

1.134"**Proposal**" has the meaning set forth in Section 4.2.7.

1.135"Prosecution and Maintenance" means, with regard to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right, as well as re-examinations, reissues and appeals with respect to such Patent Right, together with the initiation or defense of interferences, oppositions, *inter partes* review, derivations, re-examinations, post-grant proceedings and other similar proceedings (or other defense proceedings with respect to such Patent Right, but excluding the defense of challenges to such Patent Right as a counterclaim in an infringement proceeding) with respect to the particular Patent Right, and any appeals therefrom, and actions to obtain patent term extensions and supplementary protection certificates with respect to such Patent Right and the like. For clarification, "Prosecution and Maintenance" does not include any other enforcement actions taken with respect to a Patent Right.

1.136"**Publication**" has the meaning set forth in Section 7.6.1.

1.137"**Regulatory Approval**" means, (a) with respect to a given pharmaceutical product and a given country or other jurisdiction, all approvals, licenses, registrations, or authorizations of the applicable Regulatory Authority necessary to sell or offer for sale such pharmaceutical product in such country or other jurisdiction, such as MAA approval and, if required prior to the initiation of selling or offering to sell such pharmaceutical product in such country or jurisdiction, Pricing and Reimbursement Approval or (b) with respect to an *in vitro* diagnostic product and a given country or other jurisdiction, all approvals, licenses, registrations, or authorizations of the applicable Regulatory Authority necessary to sell or offer for sale such *in vitro* diagnostic product in such country or jurisdiction, including without limitation, any required certificate of conformity from a notified body and the manufacturer's formal declaration of conformity that the *in vitro* diagnostic product complies with requirements from CE marking (or UKCA marking as applicable).

1.138"**Regulatory Authority**" means any applicable Governmental Authority with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a pharmaceutical product, including any Governmental Authority having the authority to grant Regulatory Approval or Pricing Approval.

1.139"**Regulatory Exclusivity"** means, with respect to a given pharmaceutical product and a given country, a period of exclusivity (other than exclusivity due to Patent Rights) granted or afforded under Applicable Law or by a Regulatory Authority in such country or other jurisdiction that prevents the Regulatory Approval or marketing of any Generic Product of such product in such country, such as new chemical entity, orphan drug or pediatric exclusivity granted or afforded pursuant to the FFDCA or any corresponding foreign law or regulations; *provided however* that all Regulatory Exclusivity with respect to a Licensed Product in any country in the Licensee Territory will be deemed expired whenever a first Generic Product is approved in such country.

1.140"**Regulatory Materials**" means any and all regulatory submissions, registrations, applications, authorizations and approvals made to or with any Regulatory Authority for the development (including the conduct of Clinical Trials), manufacture, or commercialization of a pharmaceutical product or an *in vitro* diagnostic product, as applicable, together with all related correspondence made to or received from any Regulatory Authority in connection therewith, including any Regulatory Approval such as INDs, NDAs, MAAs, CTAs, Pricing and Reimbursement Approvals and drug master files and any equivalents of any of the foregoing.

1.141"**Regulatory Meeting**" has the meaning set forth in Section 4.6.2.

1.142[*]

1.143"**Remedial Action**" has the meaning set forth in Section 4.5.

1.144[*]

1.145"**Review Period**" has the meaning set forth in Section 7.6.2.

1.146"**ROFN**" has the meaning set forth in Section 2.4.

1.147"**ROFN Exercise Notice**" has the meaning set forth in Section 2.4.

1.148"**ROFN Exercise Period**" has the meaning set forth in Section 2.4.

1.149"**ROFN Negotiation Period**" has the meaning set forth in Section 2.4.

1.150"**ROFN Offer Notice**" has the meaning set forth in Section 2.4.

1.151"**Royalty Term**" means, on a Licensed Product-by-Licensed Product and country- by-country basis, the period beginning on the First Commercial Sale of such Licensed Product in such country until the latest of: (a) the expiration of the last Valid Claim within the Day One Patents that Covers such Licensed Product as it is sold in such country, (b) ten (10) years after the First Commercial Sale of such Licensed Product in such country, and (c) termination or expiration of all Regulatory Exclusivities for such Licensed Product in such country.

1.152"**Sales Milestone Event**" has the meaning set forth in Section 6.4.

1.153"**Sales Milestone Payment**" has the meaning set forth in Section 6.4.

1.154"**Securities Regulations**" has the meaning set forth in Section 7.5.2.

1.155"**Securities Regulator**" has the meaning set forth in Section 7.5.2.

1.156"**Segregate**" means, with respect to a Competing Product, [*].

1.157"Semi-Finished Product" has the meaning set forth in Section 5.6.1.

1.158"**Subcontractor**" has the meaning set forth in Section 2.1.3.

1.159"**Sublicensee**" means a Third Party that is granted a sublicense to any of the rights granted to Licensee under the License with respect to the Licensed Products in the Licensee Territory, *provided* that "Sublicensee" shall exclude Distributor(s).

1.160"**Supply Agreement**" has the meaning set forth in Section 5.6.1.

1.161"**Supply Contact**" has the meaning set forth in Section 3.8.

1.162"[*].

1.163 "**Technology Transfer**" has the meaning set forth in Section 4.1.

1.164"**Term**" has the meaning set forth in Section 11.1.

1.165"**Third Party**" means any Person, other than a Party or an Affiliate of a Party.

1.166"**Third Party Claim**" has the meaning set forth in Section 10.1.

1.167"[*].

1.168"**Third Party Infringement Claim**" has the meaning set forth in Section.

1.169"**Third Party Payments**" has the meaning set forth in Section 6.6.2(b).

1.170"**Transaction**" has the meaning set forth in Section 2.4.

1.171"**Transfer Price**" has the meaning set forth in **Schedule 5.6**.

1.172"**Transition Services**" has the meaning set forth in Section 4.1.2.

1.173"**Transition Service Agreement**" has the meaning set forth in Section 4.1.2.

1.174"**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.175"**Upfront Fee**" has the meaning set forth in Section 6.1.

1.176"**USD**" or "**Dollars**" means United States dollars.

1.177"**Valid Claim**" means (a) a claim of any issued and unexpired patent whose validity, enforceability or patentability has not, in the county of issuance, been rendered invalid by any of the following: (i) irretrievable lapse, abandonment, revocation, cancellation, dedication to the public or disclaimer; or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, Governmental Authority, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim of a pending patent application, *provided that* if such claim does

not issue as a valid and enforceable claim [*], such claim shall cease to be a Valid Claim for the purposes of the Agreement unless and until it is actually issued (from and after which time such claim once issued would be deemed a Valid Claim) and has not been abandoned or finally disallowed without the possibility of appeal.

1.178 "**VAT**" has the meaning set forth in Section 6.12.2.

1.179 [*]

1.180 [*]

1.181 "**Wholesaler**" means any Third Party that purchases bulk quantities of Licensed Product directly from Licensee, its Affiliates or Sublicensees for resale in smaller quantities to multiple customers in a particular country or region in the Licensee Territory and [*].

1.182 "**Withholding Taxes**" has the meaning set forth in Section 6.12.1.

ARTICLE 2
LICENSE

2.1 License Grant to Licensee.

2.1.1 License Grant. Subject to the terms and conditions of this Agreement, during the Term, Day One, on behalf of itself and its Affiliates, hereby grants to Licensee an exclusive (even as to Day One and its Affiliates, subject to Section 2.1.4), transferable (solely in accordance with Section 12.1), sublicensable (solely in accordance with Section 2.1.2), royalty- bearing license under the Day One Technology to make, have made, use, import, offer for sale, sell and otherwise clinically develop and perform related regulatory activities, manufacture and commercialize the Licensed Products in the Field in the Licensee Territory (the "**License**"). For clarity, the License [*]

2.1.2 Right to Sublicense. Licensee shall have the right to grant sublicenses of the License through multiple tiers to Third Parties:

(a) to an Affiliate of Licensee [*];

(b) to any Sublicensee or Distributor [*];

(c) [*].

All Sublicensees and Distributors shall be subject to a written agreement [*]. Licensee shall remain responsible and liable to Day One for the performance of all Sublicensees and Distributors to the same extent as if such activities were conducted by Licensee. [*]. Licensee shall remain responsible and liable to Day One for the performance of all Sublicensees and Distributors in compliance with the terms and conditions of this Agreement to the same extent as if such activities were conducted by Licensee.

2.1.3 Right to Subcontract. Licensee may subcontract the performance of any of its obligations under this Agreement to one or more Third Party subcontractors without Day One's prior consent (each such Third Party a "**Subcontractor**"). All Subcontractors, including Wholesalers, shall be subject to a written agreement [*]. Licensee shall remain responsible and liable to Day One for the performance of all Subcontractors with the terms and conditions of this Agreement to the same extent as if such activities were conducted by Licensee.

2.1.4 Day One Retained Rights. Day One (on behalf of itself and its Affiliates) retains the rights to practice the Day One Technology (a) to perform its obligations or exercise its rights under this Agreement, including with respect to manufacturing the Licensed Compound or Licensed Product and to conduct the FIREFLY-2 Study and FIREFLY-1 Study and Future Clinical Trials for the Licensed Product in both the Day One Territory and Licensee Territory under the Global Development Plan, and (b) outside the scope of the License (the "**Day One Retained Rights**").

2.1.5 Existing In-Licenses.

[*]

2.1.6 Third Party License.

[*]

2.2 License Grant to Day One.

2.2.1 Subject to the terms and conditions of this Agreement, during the Term, Licensee, on behalf of itself and its Affiliates, hereby grants to Day One:

(a) an exclusive (even as to Licensee and its Affiliates, subject to Section 2.2.3), transferable (solely in accordance with Section 12.1), sublicenseable through multiple tiers, royalty-free license under the Licensee Technology to (a) develop, make, have made, use, import, offer for sale, sell, and commercialize the Licensed Products in the Field in the Day One Territory or (b) otherwise exercise the Day One Retained Rights;

(b) a co-exclusive (with Licensee and its Affiliates), royalty-free, fully paid-up, transferable (solely in accordance with Section 12.1), sublicenseable through multiple tiers, license under the Licensee Technology to develop the Licensed Products in the Licensee Territory under the Global Development Plan; and

(c) an exclusive (even as to Licensee and its Affiliates), royalty-free, fully paid-up, transferable (solely in accordance with Section 12.1), sublicenseable through multiple tiers, license under the Licensee Technology to make and have made the Licensed Compound and Licensed Products anywhere in the world.

2.2.2 Right to Sublicense. Day One shall have the right to grant sublicenses of the above license through multiple tiers for the rights granted in Section 2.2.1(a) to Third Parties:

(a) to an Affiliate of Day One [*];

(b) to any Third Party sublicensee [*].

2.2.3 Licensee Retained Rights. Notwithstanding the exclusive nature of the license granted to Day One in Section 2.2, Licensee retains the rights to practice the Licensee Technology outside the scope of the license granted in Section 2.2.

2.3 No Implied Licenses. Except as expressly set forth in this Agreement, neither Party nor its Affiliates, by virtue of this Agreement, shall acquire any license, right or other interest, whether by implication or otherwise, in or to any Know-How, Patent Rights, Regulatory Materials or other intellectual property rights owned or controlled by the other Party or its Affiliates.

2.4 ROFN. [*].

2.5 Combination Therapy; License.

2.5.1 [*].

2.5.2 [*].

2.6 Exclusivity; Change of Control.

2.6.1 Exclusivity – Non Compete.

(a) Licensee shall not (and shall cause its Affiliates and Sublicensees not to): (i) directly or indirectly commercialize any Competing Product, or (ii) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly commercialize any Competing Product, in each case ((i) and (ii)) in any country in the Licensee Territory [*].

(b) Day One shall not (and shall cause its Affiliates not to) directly or indirectly commercialize any Competing Product in any country in the Licensee Territory [*].

2.6.2 Exception for Change of Control. Notwithstanding Section 2.6.1, if:

(a) Licensee or its Affiliate or Sublicensee acquires the rights to commercialize any Competing Product anywhere in the Licensee Territory [*] in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction) then [*];

(b) Licensee or its Affiliate or its Sublicensee undergoes a Change of Control and the Acquirer (or its Affiliates) is at the time of the closing of such Change of Control commercializing a Competing Product anywhere in the Licensee Territory [*], then [*];

(c) Day One or its Affiliate acquires the rights to commercialize any Competing Product anywhere in the Licensee Territory [*] in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction) then [*]; or

(d) Day One or its Affiliate undergoes a Change of Control and the Acquirer (or its Affiliates) is at the time of the closing of such Change of Control or thereafter commercializing a Competing Product anywhere in the Licensee Territory [*], then [*].

2.7 No Diversion. Each Party hereby covenants that it shall not, and shall ensure, to the extent permitted by Applicable Law, that its Affiliates and its and their distributors and (sub)licensees do not, knowingly promote, market, distribute for sale, import for sale, sell or have sold the Licensed Products in the other Party's territory. With respect to any country in the other Party's territory, a Party shall not, and shall ensure that its Affiliates and its and their distributors and (sub)licensees do not: (a) knowingly engage in any advertising or promotional activities relating to any Licensed Product that are directed primarily to customers or other purchaser or users of the Licensed Product located in such countries in the other Party's territory, (b) actively solicit orders for any Licensed Product from any prospective purchaser located in such countries in the other Party's territory, or (c) knowingly sell or distribute any Licensed Product to any person in such Party's territory who intends to sell (or has in the past sold in violation of this clause (c)) the Licensed Product in such countries in the other Party's territory. If either Party receives any commercial

order for the Licensed Product from a prospective purchaser reasonably believed to be located in a country in the other Party's territory for use in the other Party's territory, such Party shall [*]. Each Party shall not deliver (or tender) for sale (or cause to be delivered (or tendered) for sale) any Licensed Product into a country in the other Party's territory. For clarity, [*].

2.8 Data Protection. In their capacity as independent data controllers, the Parties agree to comply with the terms of **Schedule 9.3.1** to cover the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates as contemplated by this Agreement. In the event the Parties determine that there is a need to enter into an additional data protection agreement to cover the processing of Personal Data in connection with specific services to be performed by Day One under this Agreement, the Parties will promptly negotiate and enter into such data protection agreement prior to or concurrently to the provision of such services.

ARTICLE 3
GOVERNANCE

3.1 Joint Steering Committee.

3.1.1 Formation. Within [*], the Parties shall establish a Joint Steering Committee (the "**JSC**") to serve as a forum to discuss and oversee the development, manufacture and commercialization of Licensed Products under this Agreement. The JSC shall be composed of [*], and each Party shall notify the other Party of its initial JSC representatives within [*]. Each Party may change its JSC representatives from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party's JSC representatives shall be employees of such Party with appropriate experience and authority within such Party's organization.

3.1.2 Responsibilities. During the Term, the JSC shall carry out the following specific responsibilities:

(a) [*]

(b) [*]

(c) [*];

(d) [*]

(e) [*]

(f) [*]

(g) [*]

(h) [*]

(i) [*]

(j) [*]

(k) [*]

(l) perform such other functions as expressly set forth in this Agreement.

3.2 Joint Commercialization Committee.

3.2.1 Formation. [*], the Parties shall establish a Joint Commercialization Committee (the "**JCC**") to serve as a forum to discuss and oversee the commercialization of Licensed Products under this Agreement. The JCC shall be composed of [*], [*]. Each Party may change its JCC representatives from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party's JCC representatives shall be employees of such Party with appropriate experience and authority within such Party's organization.

3.2.2 Responsibilities. During the Term, the JCC shall carry out the following specific responsibilities:

(a) [*]

(b) [*]

(c) [*]; and

(d) perform such other functions as expressly set forth in this Agreement or as the JSC may request from time to time.

3.3 Composition and Meetings.

3.3.1 Additional Committees. From time to time, the JSC may establish and delegate duties to the JCC or additional committees (each a "**Committee**") on an "as-needed" basis to oversee particular projects or activities, which delegations shall be reflected in the minutes of the meetings of the JSC. Such Committees may be established on an *ad hoc* basis for purposes of a specific project, for the life of the Licensed Product or on such other basis, and shall be constituted and shall operate as JSC may determine, *provided that* each Committee shall be subject to the oversight, and shall report to, the JSC. In no event shall the authority of any Committee exceed that of the JSC.

3.3.2 Composition. A reasonable number of representatives of each Party who are not committee members may attend meetings of the JSC, JCC or a Committee; *provided, however*, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall [*].

3.3.3 Meetings. The JSC and JCC (once established) will hold a meeting [*]. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. [*] will distribute to the JSC or JCC members the agenda items for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept of all JSC and JCC meetings. Meeting minutes will be prepared by [*]. Minutes will be deemed approved [*].

3.4 Decision-Making. All decisions on matters that require JSC approval, [*].

3.5 Discontinuation. The JSC or JCC will disband and shall have no further authority hereunder upon [*].

3.6 Limitations on Authority. The JSC and JCC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to (a) modify or amend the terms and conditions of this Agreement, (b) waive either Party's compliance with, or

determine that either Party has or has not fulfilled, the terms and conditions of this Agreement, or (c) determine any issue in a manner that would conflict with, expand, or reduce the express terms and conditions of this Agreement.

3.7 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Alliance Manager will ensure communication to the JSC of all relevant matters raised by the JCC or Committees. Each Alliance Manager shall be permitted to attend meetings of the JSC, JCC and other Committees as appropriate as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC, JCC and its Committees. [*]

3.8 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of Licensed Compound and Licensed Product within this Agreement ("**Supply Contacts**") and under the direction of the JSC. Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of Licensed Compound and Licensed Product under this Agreement. Both Party's Supply Contact shall, collectively, be a Committee under the delegation of the JSC to oversee manufacturing and supply of the Licensed Compound and Licensed Product ("**CMC Subcommittee**"). A reasonable number of representatives of each Party who are not Committee members may attend CMC Subcommittee meetings. Each Party shall bear its own costs of its Supply Contact and participation of any additional representatives.

ARTICLE 4
DEVELOPMENT AND REGULATORY

4.1 Technology Transfer; Transition Services; and *Ad-hoc* Services.

4.1.1 Technology Transfer. [*]. Day One will, and will cause its Affiliates and will use reasonable efforts to cause its Third Party contractors involved in development (including regulatory activities) related to Licensed Compound or Licensed Product, to make available or otherwise disclose to Licensee, at no additional cost to Licensee: (i) copies of all documents, materials and data which are part of the existing Day One Know-How (including existing Clinical Data and a copy of the final, audited study reports from the ongoing carcinogenicity study and dissolution study for the Licensed Product once available) for the Licensed Product as listed on **Schedule 4.1.1** and (ii) copies of all required Regulatory Materials in Day One's possession and Control as of the Effective Date related to the Licensed Compound or Licensed Product listed on **Schedule 4.1.1** (the "**Technology Transfer**"). The Parties shall cooperate and agree upon formats and procedures to facilitate the orderly and efficient Technology Transfer and Day One may effect such transfer by [*]. Day One will support the Technology Transfer (e.g., maintain the data room) for a period of [*] and during such time will answer the reasonable questions of Ipsen in connection with ensuring all documents, materials, data, and required Regulatory Materials relevant to the Technology Transfer have been properly transferred All such Day One Know-How will be provided [*]. For clarity, the Technology Transfer will not include [*]. In the event Day One has not made available to Licensee any items due under this Section 4.1.1 within the aforementioned time period, Day One shall [*].

4.1.2 Transition Services. Without limiting the foregoing, Day One will: (a) provide Licensee and its designees reasonable assistance with respect to the transition of the development (including regulatory matters) of the Licensed Product in the Licensee Territory to Licensee; and (b) provide Licensee and its designees with reasonable access by teleconference or in-person meetings (as mutually agreed upon) to Day One's personnel and personnel of Day One's Affiliates (and will use reasonable efforts to provide access to Third Party contractors involved in development (including regulatory activities) related to such Licensed Compound or Licensed Product) to assist with the transition and answer reasonable questions related to such Licensed Compound or Licensed Product (the "**Transition Services**"); *provided, however*, that Licensee shall be responsible for the planning and conduct of all Licensee Territory-Specific Clinical Trials and for the preparation and submission of all MAAs and related Regulatory Materials for the Licensed Product in the Licensee Territory, and such activities shall not be Transition Services. The Transition Services will be provided for [*]. The Parties shall work together to negotiate and execute [*] a transition services agreement to cover the provision of the Transition Services by Day One to Licensee (the "**Transition Service Agreement**").

4.1.3 *Ad-hoc* Services. In the event that, in addition to the Technology Transfer and the Transition Services described in Sections 4.1.1 and 4.1.2, Licensee reasonably determines that it would require specific services from Day One in connection with the activities to be performed by Licensee under this Agreement (such as but not limited to [*]), the Parties shall negotiate in good faith (but shall not be obligated to enter into) a specific services agreement(s) in connection with the provision of such services by Day One to Licensee, which agreement shall provide that [*]. Without limiting the generality of the foregoing, the Parties will negotiate a service agreement for Day One to provide specific services in connection with [*].

4.2 Clinical Trials.

4.2.1 Generally. Except for Licensee's right to conduct Licensee Territory- Specific Clinical Trials, as between the Parties, Day One shall be responsible for the conduct of all global Clinical Trials for the Licensed Product worldwide for any Indication, formulation, dosage strength or route of administration. Subject to the terms and conditions of this Agreement, the Parties will share the Clinical Data resulting from the Parties' respective development of the Licensed Product worldwide (*i.e.*, Day One's conduct of the global Clinical Trials and Licensee's conduct of Licensee Territory-Specific Clinical Trials), to facilitate the development of the Licensed Compound and Licensed Products throughout the Licensee Territory and the Day One Territory.

4.2.2 FIREFLY-2 Study and FIREFLY-1 Study. The Parties acknowledge and agree that (a) as of the Effective Date, Day One is conducting the FIREFLY-2 Study and the FIREFLY-1 Study in both the Licensee Territory and Day One Territory as such studies are set forth in the initial Global Development Plan attached to this Agreement as **Exhibit B**, and (b) Day One shall use Commercially Reasonable Efforts to [*]. In the event of any material changes to the timelines or design of the FIREFLY-2 and FIREFLY-1 Studies, such changes shall [*]. Day One shall provide updates to the JSC on the progress of the FIREFLY- 2 and FIREFLY-1 Studies including any material changes thereto. For the avoidance of doubt, Day One is and shall continue to be the sponsor of the FIREFLY-2 and FIREFLY-1 Studies under the Global Development Plan (as may be amended), and shall be responsible for communicating with Regulatory Authorities both in the Day One Territory and the Licensee Territory in connection with the conduct of such Clinical Trials, and shall own all Regulatory Materials for the conduct of such Clinical Trials. If upon the determination by the JSC, any pre-clinical or Clinical Trials not included in the Global Development Plan for the Licensed Product (in the form existing as of the Effective Date) in the Initial Field [*].

4.2.3 Licensee Territory-Specific Clinical Trials. Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible at its cost and expense for all development and regulatory activities that are exclusively for the benefit of the countries of the Licensee Territory with respect to [*]. All development of the Licensed Product by or on behalf of Licensee (or its Affiliates or Sublicensees) in the Licensee Territory shall be conducted in accordance with a written development plan approved by the JSC (such plan, as updated and amended from time to time, the "**Licensee Territory Development Plan**"). Licensee shall provide an initial Licensee Territory Development Plan [*]. The Licensee Territory Development Plan shall include (i) all Licensee Territory-Specific Clinical Trials planned or being conducted by or on behalf of Licensee (or its Affiliates or Sublicensees) in the Licensee Territory, and anticipated timelines therefor, (ii) an anticipated timeline for submitting an MAA and for obtaining Regulatory Approval for the Licensed Product in each Major Market. [*], Licensee shall submit an updated Licensee Territory Development Plan to the JSC for review and approval. For clarity, (a) Licensee shall be solely responsible for developing the Licensee Territory Development Plan and conducting all Licensee Territory-Specific Clinical Trials, at Licensee's cost and expense, and (b) Licensee shall not itself, and shall not authorize or enable an Affiliate or Sublicensee to, conduct any development or regulatory activities for a dosage strength, route of administration, formulation, presentation or Indication that is not a [*]. Notwithstanding the foregoing "for clarity" clause, in the event that a Regulatory Authority in a country or jurisdiction of the Licensee Territory requires a change in the dosage, route of administration, formulation or presentation of a Licensed Product that is not a [*].

4.2.4 Licensee Diligence. Licensee shall use Commercially Reasonable Efforts to [*].

4.2.5 Records; Audits.

(a) Inspection of Records by Day One. Licensee shall, and shall require its Affiliates, Sublicensees and Subcontractors to, maintain complete, current, and accurate records with respect to all activities conducted in connection with this Agreement (including all activities conducted under the Licensee Territory Development Plan), and all results, data, developments and other Know-How made in conducting such activities. Such records shall accurately reflect all such work done and results achieved in sufficient detail to verify compliance with its obligations under this Agreement and shall be in good scientific manner appropriate for applicable patent and regulatory purposes. Licensee shall, and shall require its Affiliates, Sublicensees and Subcontractors to, maintain such records until [*]. Day One shall have the right[*] to inspect and copy all such records of Licensee, its Affiliates and Sublicensees to ensure compliance with this Agreement.

(b) Audit by Day One. Day One or its representatives may, for actual cause or based upon a reasonable belief of non-compliance with the Licensee Territory Development Plan, this Agreement or Applicable Law, perform audits of Clinical Trial sites, or other facilities used, by Licensee, its Affiliates or Sublicensees or its or their vendors to conduct the Licensee Territory Development Plan, and any related documentation. [*], Day One will provide the Licensee with a written summary of its findings in English, including any deficiencies or other areas of remediation that Day One reasonably identifies during such audit, and the Parties shall promptly meet to discuss such findings and proposed remedial actions. Without limiting any other remedies of Day One, if the Parties agree on a proposed remedial action, then Licensee will [*]. In the event any Regulatory Authority within the Day One Territory notifies Day One that it needs to conduct inspections of Clinical Trial sites, or other facilities used, by Licensee, its Affiliates or Sublicensees or its or their vendors to conduct development or manufacturing activities hereunder, Day One shall promptly notify Licensee of any such request for inspection from a Regulatory Authority, and in such case Licensee shall allow such Regulatory Authority, and a representative of Day One to the extent applicable (and to the extent allowed under Licensee's agreement with its CRO or site), to inspect such facilities. In the event Day One's representative cannot participate in the inspection, Licensee will provide Day One with information on the results of the inspection.

(c) Audit Confidentiality. Each Party shall treat all information that it receives under this Section 4.2.5 in accordance with the confidentiality provisions of Article 7 of this Agreement, and shall cause its representatives conducting such audit to [*].

(d) Inspection of Records and Audit by Licensee. [*] to the extent required for Licensee to comply with its obligations and responsibilities as MAA holder in the Licensee Territory for the Licensed Product, including any of its responsibilities for submission of Regulatory Materials including MAAs to any Regulatory Authority in the Licensee Territory, upon Licensee's request [*], Day One shall allow Licensee[*] to audit and inspect during [*], (i) all records maintained and Controlled by Day One relating to the conduct by Day One of Clinical Trials, including, to the extent Controlled by Day One, those generated by the CROs conducting such Clinical Trials on behalf of Day One and the investigational sites ([*]), and (ii) Day One's facilities, and each of Day One's clinical sites or CRO facilities in which the Licensed Compound or the Licensed Product is developed ([*]) to assess compliance with GCP, good pharmacovigilance practices standards and Applicable Law.

(e) Inspections for Development Activities By Regulatory Authority. In the event any Regulatory Authority within the Licensee Territory notifies Licensee, in its capacity of MAA holder or applicant in the Licensee Territory, that it needs to conduct GCP inspections of Day One's Clinical Data, then Licensee shall [*] notify Day One and Day One shall cooperate in good faith with Licensee to provide to such Regulatory Authority the relevant documentation (*e.g.,* raw data) which have not been already transferred to Licensee in accordance with this Agreement and to provide reasonable support by relevant experts to answer any requests from Regulatory Authorities during such inspection within agreed timelines depending on such Regulatory Authority's requests; *provided that* Licensee shall [*]. In addition, if required by any Regulatory Authority in the Day One Territory or Licensee Territory, the Parties shall negotiate in good faith and enter into a clinical quality agreement to allocate the Parties roles and responsibilities with respect to clinical data. In the event any Regulatory Authority within the Licensee Territory notifies Licensee that, it needs to conduct inspections of Day One's Clinical Trial sites, Licensee shall [*] notify Day One of any such request for inspection from a Regulatory Authority, and in such case Day One shall allow such Regulatory Authority, and a representative of Licensee to the extent applicable ([*]), to inspect such facilities as requested by the Regulatory Authority. In the event Licensee's representative cannot participate in the inspection, Day One will [*].

4.2.6 Clinical Data. As between the Parties, all Clinical Data generated by or on behalf of Day One, its Affiliates or (sub)licensees under this Agreement will be owned by Day One and subject to Licensee's rights to use such data as set forth in this Agreement in accordance with Section 2.1. As between the Parties, all Clinical Data generated by or on behalf of Licensee, its Affiliates or Sublicensees will be owned by Licensee and be subject to Day One's rights to use such data as set forth in this Agreement in accordance with Section 2.2.1. The Parties, via the JSC, shall develop a process for the exchange of Clinical Data generated under this Agreement. Without limiting the foregoing and in addition to its adverse event and safety data reporting obligations pursuant to Section 4.4 (Adverse Events Reporting), each Party shall, upon the other Party's reasonable request, provide the other Party with copies of all Clinical Data that are generated by or on behalf of such Party or any of its Affiliates or (sub)licensees.

4.2.7 Future Clinical Trials. Except for the Licensee Territory-Specific Clinical Trials, which shall be the sole responsibility of Licensee, Day One shall have the sole right, but not the obligation, at its cost and expense to conduct additional Clinical Trials for the Licensed Product (for clarity, other than the ongoing FIREFLY-2 Study and the FIREFLY-1 Study) in the Field (*i.e.,* new Indications beyond the Initial Field or a new dosage, route of administration, formulation or presentation of the Licensed Product) in both the Day One Territory and Licensee Territory (each a "**Future Clinical Trial**"). For the avoidance of doubt, changes or updates to, or activities related to, the FIREFLY-2 Study or the FIREFLY-1 Study shall not be considered a Future Clinical Trial. With respect to any Future Clinical Trial, Day One or its

designee shall (a) be the sponsor of such Future Clinical Trial, (b) be solely responsible for communicating with Regulatory Authorities both in the Day One Territory and the Licensee Territory in connection with the conduct of such Clinical Trial, and (c) shall own all Regulatory Materials for the conduct of such Clinical Trial. In the event Day One proposes to conduct a Future Clinical Trial, Day One shall [*] ("**Proposal**"). Day One shall keep Licensee reasonably informed of the status of any Future Clinical Trial via the JSC. [*] the JSC or delegated Committee shall meet to review and discuss the Proposal and to permit Licensee an opportunity to ask questions and request additional information from Day One related to the Proposal, including whether such Proposal [*]. All Clinical Data generated by or on behalf of Day One, its Affiliates or (sub)licensees in the conduct of a Future Clinical Trial for the Licensed Product and Controlled by Day One shall be subject to Section 4.2.6 and the license grant to Licensee in Section 2.1. In the event that Licensee has a suggestion for a Future Clinical Trial (*e.g.,* for a new Indication) for the benefit of the Day One Territory or the Licensee Territory, then [*]. Day One shall not conduct any Future Clinical Trial under the Global Development Plan in a manner that [*].

4.2.8 Early Access Programs.

(a) Day One shall be responsible, at its sole cost and expense and for its benefit, for operationally managing and conducting the Early Access Programs for the Licensed Product: [*] ("**Existing Early Access Programs**") [*].

(b) Licensee shall be responsible[*] for any other Early Access Programs for the Licensed Product in the Licensee Territory after the Effective Date that are not Existing Early Access Programs ("**New Early Access Programs**") and shall [*].

4.3 Right of Access and Reference. Licensee hereby grants to Day One and its Affiliates a right of reference to all Regulatory Materials submitted by Licensee or its Affiliates in the Licensee Territory for the Licensed Products for the purpose of Day One, its Affiliates or (sub)licensees obtaining or maintaining Regulatory Approvals of products owned or controlled by Day One or its Affiliates. Day One hereby grants to Licensee and its Affiliates a right of reference to all Regulatory Materials submitted by such Day One or its Affiliates relating solely to any Licensed Product for the purpose of Licensee, its Affiliates or Sublicensees obtaining or maintaining Regulatory Approvals of the Licensed Products in the Field in the Licensee Territory. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this section, including providing a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of access and reference to enable the other Party's access and reference rights including, to the extent applicable, an informed consent letter under Article 10c of Directive 2001/83/EC as amended. For the purposes of this Section, "right of reference" shall mean the "right of reference or use" as defined in 21 C.F.R. §314.3(b) and any equivalent regulation outside the US, including Article 10c of Directive 2001/83/EC, as each may be amended from time to time.

4.4 Adverse Events Reporting. [*], the Parties shall negotiate and enter into a pharmacovigilance agreement for exchanging adverse event and other safety information relating to the Licensed Product worldwide (the "**Pharmacovigilance Agreement**"). In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, [*]. The Pharmacovigilance Agreement shall provide for an adverse event database for the Licensed Product in the Field in the Licensee Territory to be maintained [*], and a global safety database for the Licensed Product to be maintained [*]. The Pharmacovigilance Agreement shall (a) ensure that adverse events and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Law, including any local regulatory requirements, and (b) stipulate that Day One shall [*].

4.5 Remedial Actions. Each Party will notify the other Party in writing [*] if it obtains information (including notice by a Regulatory Authority) indicating that any Licensed Product may be subject to any recall, corrective or similar regulatory action by virtue of Applicable Law (each a "**Remedial Action**"). Subject to the terms and conditions of the Supply Agreement, each Party shall have the right to determine to conduct a Remedial Action in its respective territory, *provided that* [*].

4.6 Regulatory Responsibility.

4.6.1 Regulatory Materials.

(a) Transfer of Regulatory Materials. Day One shall, in each case as may be required to enable Licensee to submit and file Marketing Authorization Applications and obtain Regulatory Approvals for Licensed Products in the Licensee Territory and upon Licensee's reasonable request and to the extent not already provided to or in the possession of Licensee or its Affiliates:

[*]

4.6.2 Regulatory Communications with Regulatory Authorities. [*], each Party shall provide the other Party with a list and schedule of any material in-person meetings or material teleconferences with the Regulatory Authorities (or related advisory committees) in its respective territory [*], as applicable (each, a "**Regulatory Meeting**"). With respect to Regulatory Meetings with Regulatory Authorities in connection with any Licensed Product [*] then in each case (a) and (b) to the extent permitted by Applicable Law and by the applicable Regulatory Authorities, each Party shall have the right to participate (including attending in person as applicable) in all such meetings, provided that such participation shall be [*].

4.6.3 Day One Territory. Subject to the terms and conditions of this Agreement, including Sections 4.6.1 and 4.6.2, Day One shall have the sole authority and discretion to prepare, file, prosecute and maintain all Regulatory Materials (including any Pricing and Reimbursement Approvals), and to communicate and otherwise interact with all Regulatory Authorities, with respect to the Licensed Compound and Licensed Products in the Day One Territory, and shall own all Regulatory Materials, Regulatory Approvals, and Pricing Approvals for the Licensed Compound and Licensed Products in Day One Territory.

4.6.4 Regulatory Interactions with [*] for the [*] CDx. Day One shall use Commercially Reasonable Efforts in support of [*]. To the extent permitted under the CDx Agreement, Day One shall promptly inform Ipsen of the [*].

ARTICLE 5
COMMERCIALIZATION AND MANUFACTURING

5.1 Responsibility. Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible, at its sole cost and expense, for commercializing the Licensed Products in the Field in the Licensee Territory in accordance with this Agreement, including booking all sales of the Licensed Products in the Licensee Territory. Day One shall be responsible, at its sole cost and expense, for commercializing the Licensed Products in the Day One Territory, including the booking of all sales of the Licensed Products in the Day One Territory.

5.2 Medical Affairs and Licensed Product Promotional Materials.

5.2.1 The Parties intend to coordinate, via the JSC, medical affairs activities for the Licensed Products in the Day One Territory and Licensee Territory and in the delivery of key messages to be communicated at internationally recognized oncology conferences.

5.2.2 Upon mutual agreement, the Parties may coordinate on the preparation, content and exchange of Licensed Product Promotional Materials. Without limiting the foregoing, each Party shall be responsible for its Licensed Product Promotional Materials for its territory which shall be in compliance with all Applicable Laws, including local regulations and requirements.

5.3 Licensee Commercialization Plan. [*], Licensee shall submit [*] a written plan setting forth in reasonably detail Licensee's plans for commercializing the Licensed Products in the Licensee Territory (such plan, as updated from time to time, the "**Licensee Territory Commercialization Plan**"). The Licensee Territory Commercialization Plan shall include: [*] Licensee shall submit [*]. The current Licensee Territory Commercialization Plan, and progress thereunder, may be discussed at meetings of the JSC.

5.4 Licensee Diligence. After receipt of Regulatory Approval for a Licensed Product in a particular country in the Licensee Territory, Licensee shall use Commercially Reasonable Efforts to [*].

5.5 Manufacturing and Commercialization with CDx Partner.

5.5.1 Day One Territory & EU. [*].

5.5.2 Other countries of the Licensee Territory. [*].

5.6 Manufacturing and Supply.

5.6.1 Supply Agreement. [*] the Parties will negotiate in good faith and enter into a written agreement for Day One (whether itself or using one or more third party contractors (each a "**Day One CMO**")) to supply the Licensed Product (in the form manufactured by Day One as of the Effective Date) in the form [*] (collectively, the "**Semi-Finished Product**") to Licensee in a quality that complies with GMP requirements and in quantities necessary for Licensee to conduct the development and Licensee Territory-Specific Clinical Trials and commercialization activities for sale in the Licensee Territory in accordance with this Agreement (such supply agreement and related quality agreement the "**Supply Agreement**"). The Supply Agreement shall be consistent with the terms set forth on **Schedule 5.6**, and shall provide specific terms and obligations concerning, among other things, [*]. In addition, the quality agreement negotiated in good faith and entered into between the Parties together with the Supply Agreement shall be consistent with [*]. All Licensed Product supplied by or on behalf of Day One to Licensee under this Section 5.6.1 shall have passed the quality assurance and control release and batch release testing as set forth in the Supply Agreement and any relevant quality agreement. The Licensed Product shall be at a price [*].

5.6.2 Manufacturing Technology Transfer. [*], the Parties shall promptly prepare a plan and budget for Day One to transfer to Licensee or its designee the then-current manufacturing process for the Licensed Product(s) (such plan and budget the "**Manufacturing Technology Transfer Plan**" and "**Manufacturing Technology Transfer Budget**", respectively, and such transfer the "**Manufacturing Technology Transfer**"). The Parties will conduct the Manufacturing Technology Transfer in accordance with the Manufacturing Technology Transfer Plan and Manufacturing Technology Transfer Budget, at [*] cost. Following completion of the Manufacturing Technology Transfer, Licensee shall be solely responsible, at its sole cost and expense, for manufacturing and supplying quantities of the Licensed Products to Licensee, its Affiliates and Sublicensees in the Licensee Territory to conduct activities in

accordance with this Agreement. Licensee, its Affiliates or Sublicensees shall not use any Third Party to manufacture the Licensed Compound or Licensed Products [*], and Day One shall have the right to audit any facilities involved in the manufacture of the Licensed Compound or Licensed Products by Licensee, its Affiliates or Sublicensees, [*]). Upon Day One's reasonable request, Licensee shall provide Day One with copies of or access to all [*].

5.6.3 Audits & Inspections for Manufacturing Activities By Licensee. [*] with respect to any Licensed Product supplied by Day One to Licensee pursuant to the Supply Agreement, subject to the terms and conditions of the Supply Agreement and to the extent required for Licensee to comply with its obligations and responsibilities as MAA holder in the Licensee Territory for such Licensed Product, including any of its responsibilities for submission of MAAs and CMC variations to a Regulatory Authority in the Licensee Territory for such Licensed Product, upon [*], Day One shall allow Licensee, to conduct (a) [*] an audit and inspection of Day One's manufacturing site for the Licensed Product (if Day One is manufacturing itself) or (b) [*]) an audit of the manufacturing site of each of Day One CMO in which the Licensed Compound and the Licensed Product is manufactured (including for purposes of Clinical Trials conducted by Day One) to permit Licensee as MAA holder to verify Day One and such Day One CMO's compliance with GCP, GVP (i.e., good pharmacovigilance practice) and GMP standards and Applicable Law, [*] to assess compliance with GCP and GMP standards and Applicable Law.

5.6.4 Inspections for Manufacturing Activities By Regulatory Authority. With respect to any Licensed Product supplied by Day One to Licensee pursuant to the Supply Agreement, in the event any Regulatory Authority within the Licensee Territory notifies Licensee that it needs to conduct inspections of manufacturing sites for such Licensed Product in the Day One Territory, Licensee shall [*] notify Day One of any such request for inspection from such Regulatory Authority. Subject to the terms and conditions of the Supply Agreement, Day One shall allow such Regulatory Authority within the Licensee Territory, and a representative of Licensee to the extent [*] to inspect the facilities where such Licensed Product is manufactured, including, subject to [*]. In the event Licensee's representative cannot participate in the inspection, Day One will provide Licensee with [*].

ARTICLE 6
PAYMENTS

6.1 Upfront Fee. As partial consideration for the license and other rights granted by Day One to Licensee herein, Licensee shall pay to Day One a one-time, non-refundable, non- creditable upfront fee of [*] (such fee, the "**Upfront Fee**").

6.2 Equity. As partial consideration for the rights and licenses granted by Day One to Licensee herein, Licensee shall ensure that Ipsen Biopharmaceuticals, Inc. (USA), a fully-owned Affiliate of Licensee, pays Day One forty million U.S. Dollars (US$40,000,000) on the Closing Date to acquire newly issued shares of Day One's common stock, par value $0.0001 per share (the "**Common Stock**") at a price per share equal to a dollar amount that represents a premium of seventeen percent (17%) to the volume weighted average price, as reported by Bloomberg, of the Common Stock as traded on The Nasdaq Stock Market LLC for the ten (10) consecutive trading days prior to and including the date of the Company's public release of U.S. GAAP revenue for the quarter ended June 30, 2024 (the "**Revenue Release**") and the ten (10) consecutive trading days following the Revenue Release in accordance with the terms set forth in a certain investment agreement, substantially in the form attached hereto as **Schedule 6.2** (the "**Investment Agreement**").

6.3 Launch Milestones. As further partial consideration for Day One's grant of the License to Licensee, upon the first achievement by Licensee, its Affiliate or Sublicensee of each development milestone event set forth in the table below (each a "**Launch Milestone Event**"), Licensee shall make the

corresponding one-time, non-refundable, non-creditable payment (each a "**Launch Milestone Payment**") to Day One in accordance with Section 6.7.1.

#	Launch Milestone Event	Launch Milestone Payment (in Million Euros)
1.	[*]	[*]
2.	[*]	[*]
3	[*]	[*]
4.	[*]	[*]
5	[*]	[*]

Each of the foregoing Launch Milestone Payment in this Section 6.3 shall be payable only once, upon the applicable Launch Milestone Event being achieved. For the avoidance of doubt, the maximum amount payable by Licensee pursuant [*].

6.4 [*]

6.5 Sales Milestones. Upon the first achievement of each sales-based milestone event set forth in the table below (each a "**Sales Milestone Event**"), Licensee shall make the corresponding one-time, non-refundable, non-creditable payment (each a "**Sales Milestone Payment**") to Day One in accordance with Section 6.7.2.

Sales Milestone Event (Annual Aggregated Net Sales in the Licensee Territory)	Sales Milestone Payment (in Million Euros)
[*]	[*]
[*]	[*]
[*]	[*]

Sales Milestone Event (Annual Aggregated Net Sales in the Licensee Territory)	Sales Milestone Payment (in Million Euros)
[*]	[*]

Each of the foregoing Sales Milestone Payments in this Section 6.4 shall be payable only once, regardless of the number of times the applicable Sales Milestone Event is subsequently achieved. For the avoidance of doubt, the aggregate maximum amount payable by Licensee under this Agreement pursuant to this Section 6.3 [*]. For clarity, in the event that in a given Calendar Year during the Term more than one (1) Sales Milestone Event is achieved, Licensee shall pay to Day One each Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such Calendar Year.

6.6 Royalty Payments.

6.6.1 Royalty Payments for Licensed Products. Subject to the remainder of this Section 6.6, during the Royalty Term for the Licensed Product, Licensee shall pay Day One royalties as set forth in the tables below on aggregate annual Net Sales of the Licensed Product in the Licensee Territory, calculated by multiplying the applicable royalty rate by the corresponding portion of aggregate annual Net Sales of such Licensed Product in the Licensee Territory. Such payments, and associated reports, shall be made in accordance with Section 6.7.2.

Aggregate Annual Net Sales in the Territory per Licensed Product	Royalty Rate
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

Illustration: By way of example only, assume in a Calendar Year, during the Royalty Term, that (i) the aggregate annual Net Sales of the Licensed Product in the Licensee Territory total [*], calculated as follows:

[*]

6.6.2 Royalty Reductions.

(a) No Valid Claim. On a Licensed Product-by-Licensed Product and country-by-country basis in the Licensee Territory, if at any time during the Royalty Term for such Licensed Product there is no Valid Claim of the Day One Patents that Covers such Licensed Product as it is sold in

such country, then the royalty rates set forth in the table in Section 6.6.1 for such Licensed Product shall be [*], subject to Section 6.6.2(d).

(b) Third Party Payments. If Licensee or any of its Affiliates or Sublicensees obtains a license or right to any Patent Rights from a Third Party that [*], then Licensee shall have the right to credit or deduct [*] actually paid by Licensee or any of its Affiliates or Sublicensees to such Third Party for such license or right to the extent reasonably allocable to such Licensed Product ("**Third Party Payments**") against the [*] subject to Section 6.6.2(d). If Licensee is not able to fully credit or deduct any such Third Party Payments in a given Calendar Quarter, then Licensee shall [*].

(c) Generic Product. On a Licensed Product-by-Licensed Product and country-by-country basis, if during a Calendar Quarter during the Royalty Term one or more Third Parties are selling a Generic Product and Net Sales of such Licensed Product in such country during such Calendar Quarter are [*], then the royalty rates set forth in the table in Section 6.6.1 for such Licensed Product in such country shall be reduced by [*], subject to Section 6.6.2(d)

(d) Cumulative Reductions Floor. In no event will the amount of royalties due to Day One for a Licensed Product in any given Calendar Quarter be reduced as a result of the reductions set forth in Sections 6.6.2(a), (b) and (c) (cumulatively) to an amount that is less than [*] of the amount that otherwise would have been due and payable to Day One in such Calendar Quarter for such Licensed Product without such reductions.

6.7 Payment Terms.

6.7.1 Launch Milestone and [*] CDx Milestone Payments.

(a) Licensee shall provide Day One with written notice of the achievement of each Launch Milestone Event [*] of such achievement. Day One shall issue Licensee an invoice for the amount of the corresponding Launch Milestone Payment, which invoice Licensee shall pay [*] following receipt of such invoice.

(b) Day One shall provide Licensee with written notice of the achievement of the [*] CDx Milestone Event [*] of such achievement together with an invoice for the amount of the corresponding [*] CDx Milestone Payment, which invoice Licensee shall pay [*] following receipt of such invoice.

6.7.2 Sales Milestone Payments and Royalty Payments. During the Term, following the First Commercial Sale of a Licensed Product in the Licensee Territory, Licensee shall provide Day One with a written report for each Calendar Quarter showing the Net Sales of the Licensed Products in the Licensee Territory during the reporting Calendar Quarter and the royalties payable under this Agreement pursuant to Section 6.6. Each such report shall include, for each Licensed Product in the Licensee Territory: [*]. Such reports shall also include notice of any Sales Milestone Event achieved during such Calendar Quarter. Such reports shall be due no later than [*] following the end of each Calendar Quarter. The corresponding royalties shown to have accrued by a report provided under this Section 6.7.2 shall be due and payable on the date that such report is delivered. With respect to the Sales Milestone Event, no later than [*] after a Sales Milestone Event is achieved, Licensee will notify Day One in writing and will pay Day One the Sales Milestone Payment no later than [*] after receipt by Licensee of an invoice from Day One corresponding to such Sales Milestone Payment. In addition, (i) [*], Licensee shall report to Day One its preliminary, non-binding estimated Net Sales of Licensed Products in the Licensee Territory for such Calendar Month, and (ii) [*], Licensee shall report to Day One its preliminary, non-binding estimated Net Sales of Licensed Products in the Licensee Territory for the following Calendar Year.

6.8 Payment Currency; Exchange Rate; Offset. All payments to be made under this Agreement shall be made in Euros. Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. With respect to sales not denominated in Euros, Licensee shall convert the applicable sales made in foreign currency into Euros by using a rate of exchange as published by the Wall Street Journal, Eastern Edition, under the heading "Currency Trading" averaged on the last Business Day of each of the three (3) consecutive calendar months constituting the Calendar Quarter in which the expense is incurred or sale made.

6.9 Late Payments. Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) the thirty (30)-day Eurozone main refinancing operating (MRO) rate set by the European Central Bank effective for the date that the payment was due as published by The Wall Street Journal Internet Edition at www.wsj.com in the "Money Rates" tab on the date such payments are overdue plus two (2) percentage points per annum or (b) the maximum rate permitted by Applicable Law; in each case calculated on the number of days such payment is delinquent (*provided that* if the payment is disputed, such interest shall be calculated [*] from the time that the dispute is resolved), compounded daily.

6.10 Payments to Third Parties. [*]

6.11 Records and Audit Rights. Licensee shall (and shall cause its Affiliates and Sublicensees to) keep complete, true and accurate books and records for the purpose of determining the amounts payable under this Agreement. Such books and records shall be kept for [*] following the end of the Calendar Year to which they pertain. Licensee and its Affiliates (the "**Audited Party**") shall make such accounting records available, on reasonable notice (the "**Auditing Party**"), for inspection [*], by an independent certified public accounting firm nominated by such Auditing Party and reasonably acceptable to the Audited Party, for the purpose of verifying the accuracy of any statement or report given by the Audited Party and to verify the accuracy of the payments due hereunder for any Calendar Year. Such auditor shall advise the Parties simultaneously promptly upon its completion of its audit whether or not the payments due hereunder have been accurately recorded, calculated, and reported, and, if not, the amount of such discrepancy. Except for cause, the Audited Party's financial records with respect to a given period of time shall only be subject to [*]. The auditor shall be required to keep confidential all information learned during any such inspection in accordance with written confidentiality and non-use provision at least as restrictive as those provided in Article 7 below, and to disclose to the Auditing Party only such details as may be necessary to report the accuracy of the Audited Party's statement or report. The Auditing Party shall be responsible for the auditor's costs, unless the auditor certifies an underpayment by the Audited Party that resulted [*] in which case the Audited Party shall bear the full cost of such audit. If such accounting firm identifies a discrepancy made during such period, any unpaid amounts or overpaid amounts that are discovered shall be [*], or as otherwise agreed upon by the Parties. The Auditing Party shall treat all financial information subject to review under this Section 6.11 in accordance with the confidentiality and non-use provisions of Article 7, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the Audited Party obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

6.12 Taxes.

6.12.1 Withholding Taxes Generally. Except as set forth in this Section 6.12.1 each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement. To the extent Licensee is required by Applicable Law to withhold any taxes, duties, levies, imposts, assessments, deductions, fees, and other similar charges by Applicable Law or any Governmental Authority ("**Withholding Taxes**") on any payment to Day One, then Licensee will pay such Withholding Taxes to the applicable Governmental

Authority, will make the payment to Day One of the net amount due after deduction or withholding of such taxes and will secure and send to Day One written evidence of such payment. If Licensee intends to withhold any taxes from any payment under this Agreement, Licensee shall inform Day One reasonably in advance of making such payment to permit Day One an opportunity to provide any forms or information or obtain any taxing authority exemption or reduction as may be available to reduce or eliminate such withholding. In addition, Licensee agrees to reasonably cooperate with Day One in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect to ensure that any amounts required to be withheld pursuant to this Section 6.12.1 are reduced in amount to the fullest extent permitted by Applicable Law. Notwithstanding the foregoing, if directly as a result of any assignment or transfer of this Agreement or any rights or obligations under this Agreement by Licensee or directly as a result of any redomicile, change in tax residence or similar corporate restructuring by Licensee, the tax withholdings hereunder exceed the tax withholdings that would have resulted in the absence of such action, then Licensee shall pay to Day One such additional amounts that are necessary so that Day One receives the amounts (net of withholding, including with respect to any additional amounts paid under this Section) that it would have received if there had been no such action.

6.12.2 VAT. All payments under this Agreement are exclusive of any value added, sales and use, excise, stamp, or similar country-specific, governmental or local taxes (collectively, "**VAT**"). If any VAT is required in respect of any payments under Applicable Law by the Party making the supply or providing the service, the other Party shall pay VAT at the applicable rate in respect of any such payments upon the receipt of a valid VAT invoice in the appropriate form issued in respect of those payments, such VAT to be payable on the due date of the payments to which such VAT relates. The Parties will reasonably cooperate to issue valid VAT invoices for all amounts due under this Agreement consistent with VAT requirements. A Party shall not be responsible for any penalties and interest resulting from the failure by the other Party to collect (if not included on a valid VAT invoice) or remit any such VAT. The Parties shall reasonably cooperate to report and claim refunds or exemptions from any such VAT imposed on the transactions contemplated in this Agreement to the fullest extent permitted by Applicable Law and to timely file all required VAT tax returns.

ARTICLE 7
CONFIDENTIALITY

7.1 Confidential Information. For purposes of this Agreement, "**Confidential Information**" of a Party means any and all confidential or proprietary information and data, including all Know-How and other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that a Party (or an Affiliate or representative of such Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of such Party) in connection with this Agreement. The terms and conditions of this Agreement shall be the Confidential Information of both Parties.

7.2 Duty of Confidence; Exceptions. Each Party agrees that, during [*], it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (including for the exercise of the rights and licenses granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. The foregoing confidentiality and non-use obligations shall not apply with respect to any information that the receiving Party can demonstrate by competent written proof:

7.2.1 was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Party's Confidential Information,

as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;

7.2.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

7.2.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

7.2.4 was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who, to the knowledge of the receiving Party, had no obligation to the disclosing Party not to disclose such information to others.

Any combination of features shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

7.3 Authorized Disclosures. Notwithstanding Section 7.2 the receiving Party may disclose the disclosing Party's Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances:

7.3.1 to Governmental Authorities in connection with (a) filing, prosecuting, maintaining or listing Patent Rights in accordance with Article 8 or (b) obtaining and maintaining Regulatory Approval for the Licensed Products as permitted by this Agreement;

7.3.2 prosecuting or defending litigation as contemplated herein;

7.3.3 subject to Section 7.5 to comply with Applicable Law;

7.3.4 to its actual or potential acquirors, investors, lenders or other similar sources of financing solely for the purpose of evaluating or carrying out an actual or potential investment, or acquisition;

7.3.5 to its external attorneys, independent accountants or financial advisors for solely for the purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to it; and

7.3.6 to its Affiliates, employees, consultants and agents and actual or potential (sub)licensees, collaborators or contractors to exercise its rights or perform its obligations in accordance with the terms of this Agreement;

provided that in each of the cases of Sections 7.3.4 to 7.3.6 such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement).

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 7.3.1 to 7.3.3, it will, except where impracticable, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an

opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Party's expense. In any such event, each Party agrees to take all reasonable action to minimize disclosure of the other Party's Confidential Information. Any information disclosed pursuant to this Section 7.3 shall remain, subject to Section 7.2 the Confidential Information of the disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 7.

7.4 Prior Confidentiality Agreement. This Agreement supersedes that certain [*] (the "**CDA**"). All information exchanged between the Parties under the CDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 7.

7.5 Public Disclosures; Securities Filings.

7.5.1 Press Release. The Parties have mutually approved a joint press release attached hereto as Schedule 7.5.1 with respect to this Agreement and either Party may make subsequent public disclosure of the contents of such press release. Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms of this Agreement or any of the activities conducted hereunder, including the achievement of milestone payments hereunder, without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed) except as provided herein; and *provided, however*, that Day One shall have the right to make public announcements (a) regarding the progress of the development of the Licensed Products globally or the commercialization of the Licensed Products solely relating to the Day One Territory or (b) with respect to activities under this Agreement to comply with Applicable Law including Securities Regulations.

7.5.2 Securities Filings. Notwithstanding anything herein to the contrary, either Party or its Affiliates may disclose the relevant terms of this Agreement to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency including, without limitation, the French *Autorités des Marchés Financiers* (the "**AMF**"), or with the rules of any stock exchange on which such Party's (or such Party's Affiliates') securities are listed, (such rules and regulations "**Securities Regulations**" and each such agency a "**Securities Regulator**"). If a Party is required by Applicable Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator, such Party agrees to reasonably consult and coordinate with the other Party with respect to such disclosure and, if applicable, the preparation and submission of a confidential treatment request for this Agreement. If a Party is required by Applicable Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (a) promptly notified the other Party in writing of such requirement and any respective timing constraints, (b) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure and (c) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Applicable Law or the applicable Securities Regulator. If a Party seeks to make a disclosure or filing as set forth in this Section 7.5.2 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to incorporate such comments in the disclosure or filing; *provided that* prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.

7.6 Publications.

7.6.1 Global Strategy. The Parties will jointly develop a global strategy for scientific publications and presentations regarding the Licensed Products (each a "**Publication**").

7.6.2 Day One Publications. Day One may make Publications with respect to the Licensed Product, including with respect to any data generated by or on behalf of Day One, its Affiliates or sublicensees in a Clinical Trial for the Licensed Product ([*]), except for [*], in accordance with the global publication strategy and this Section 7.6.2. Day One shall provide Licensee with a copy of each proposed Day One Publication at least [*] prior to the earlier of its presentation or intended submission for publication; *provided that* in the case of abstracts, this period shall be [*] (such applicable period, the "**Review Period**"). Day One agrees that it will not submit or present any such Day One Publication (a) until Licensee has provided written comments during such Review Period on the material in such Day One Publication or (b) until the applicable Review Period has elapsed without written comments from Licensee, in which case Day One may proceed and the Day One Publication will be considered approved in its entirety. If Day One receives written comments from Licensee during the applicable Review Period, it shall consider the comments of Licensee in good faith, but will retain the sole authority to submit the manuscript for such Day One Publication, *provided that* Day One agrees to (i) delete any Confidential Information of Licensee that Licensee identifies for deletion in Licensee's written comments, and (ii) delay such Day One Publication for a period of up to an additional [*] to enable Licensee to draft and file Patent Rights with respect to any subject matter to which Licensee has the applicable intellectual property rights to file such Patent Rights. Day One shall provide Licensee a copy of each Day One Publication at the time of the submission or presentation. Day One agrees to acknowledge the contributions of Licensee, and the employees of Licensee, in all Day One Publications as scientifically appropriate. Day One shall require its Affiliates, (sub)licensees and subcontractors to comply with the obligations of this Section 7.6.2 as if they were Day One, and shall be liable for their non-compliance.

7.6.3 Licensee Publications. Licensee may publicly present or publish any Clinical Data generated by or on behalf of Licensee hereunder from the conduct of a Licensee Territory-Specific Clinical Trial in accordance with the global publication strategy and this Section 7.6.3. In the event Licensee desires to publicly present or publish a Licensee Publication in accordance with the foregoing sentence, Licensee shall provide Day One with a copy of such proposed Publication in accordance with the applicable Review Period prior to the intended submission date. Licensee agrees that it will not submit or present any Licensee Publication (a) until Day One has provided written comments during such Review Period on the material in such Licensee Publication or (b) until the applicable Review Period has elapsed without written comments from Day One, in which case Licensee may proceed and the Licensee Publication will be considered approved in its entirety. If Licensee receives written comments from Day One during the applicable Review Period, it shall consider the comments of Day One in good faith, but will retain the sole authority to submit the manuscript for such Licensee Publication; *provided that* Licensee agrees to (i) delete any Confidential Information of Day One that Day One identifies for deletion in Day One's written comments, and (ii) delay such Licensee Publication for a period of up to an additional [*] to enable Day One to draft and file Patent Rights with respect to any subject matter to which Day One has the applicable intellectual property rights to file such Patent Rights. Licensee shall provide Day One a copy of the Licensee Publication at the time of the submission or presentation. Licensee agrees to acknowledge the contributions of Day One, and the employees of Day One, in all Licensee Publications as scientifically appropriate. Licensee shall require its Affiliates, Sublicensees and subcontractors to comply with the obligations of this Section 7.6.3 as if they were Licensee and shall be liable for their non-compliance.

7.7 Re-Publication. The contents of any press release or other publication that has been reviewed and approved by a reviewing Party in accordance with Section 7.5.1 or Section 7.6 may be re-released by such reviewing Party or publishing Party without a requirement for re-approval, including the repeat of any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party in accordance with Section 7.5.1.

7.8 Use of Names. Except as provided herein, neither Party nor its Affiliates shall use the corporate marks or any other name or trademark of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law. Notwithstanding the restrictions of this Section 7.8, [*].

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership.

8.1.1 Inventorship of Arising Know-How and all intellectual property rights therein shall be determined in accordance with principles of inventorship for Patent Rights and other intellectual property under U.S. law, without regard to conflicts of law and irrespective of where or when such conception, reduction to practice, generation, discovery, development, or making occurs, and ownership shall follow inventorship.

8.1.2 [*], in the event there is Arising Know-How that is jointly owned in accordance with Section 8.1.1, then subject to terms and conditions of this Agreement, including the licenses granted in Section 2.1 and Section 2.2.1, the Parties will each own an equal, undivided interest in any and all Joint Arising Know-How and Joint Arising Patents and each Party shall have the right to use and exercise its ownership rights in and to any and all Joint Arising Know-How and Joint Arising Patents without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses granted under this Agreement in Sections 2.2.1 and Section 2.2 and further provided that [*].

8.2 Patent Prosecution and Maintenance.

8.2.1 Day One Patents. Subject to the remainder of this Section 8.2.1, Day One shall control the Prosecution and Maintenance of the Day One Patents in its own name in the Licensee Territory, at [*] provided that [*]. For clarity, Day One shall have the sole right and discretion, at its sole cost and in its own name, to Prosecute and Maintain the Day One Patents in the Day One Territory.

8.2.2 Licensee Arising Patents. Subject to the remainder of this Section 8.2.2, Licensee shall have the sole right, but not the obligation, to Prosecute and Maintain the Licensee Arising Patents worldwide, [*] in its own name. [*]

8.3 Common Interest Disclosures. With regard to any information or opinions exchanged pursuant to this Agreement by the Parties (or their Affiliates) regarding intellectual property owned by Third Parties, the Parties agree that they have a common legal interest in coordinating Prosecution and Maintenance of their respective Patent Rights, as set forth in this Article 8, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the development, manufacturing or commercialization of Licensed Compounds and Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the development, manufacturing or commercialization of Licensed Compounds and Licensed Products. Accordingly, Licensee and Day One agree that all such information and materials obtained by Licensee or Day One from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement and in accordance with Applicable Law. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither

Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

8.4 Patent Enforcement.

8.4.1 Notice. Each Party shall notify the other [*] of becoming aware of any alleged or threatened infringement by a Third Party of any Day One Patent or Licensee Arising Patent, or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights (each a "**Competitive Infringement**").

8.4.2 Enforcement.

(a) Licensee Territory. Licensee or its designee shall have the first right, but not the obligation, to bring and control any legal action to enforce the [*] in the Licensee Territory with respect to a Competitive Infringement (such action an "**Enforcement Action**"), [*]. Licensee shall obtain Day One prior approval (not to be unreasonably delayed or withheld) to start an Enforcement Action and keep Day One reasonably informed as to the status of any such Enforcement Action and shall consider in good faith the comments of Day One with respect thereto. If Licensee or its designee fails to file an Enforcement Action with respect to, or fails to take steps to abate, a Competitive Infringement with respect to the [*] in the Licensee Territory [*] after receiving or giving notice pursuant to Section 8.4.1, then Day One shall have the right, but not the obligation, to bring and control an Enforcement Action with respect to, or take steps to abate, such Competitive Infringement in the Licensee Territory, [*] *provided that* Day One shall keep Licensee reasonably informed as to the status of such Enforcement Action.

(b) Day One Territory. Day One or its designee shall have the sole right to bring and control any Enforcement Action to enforce the [*] in the Day One Territory with respect to a Competitive Infringement, at Day One's cost and expense. Day One shall obtain Licensee prior approval (not to be unreasonably delayed or withheld) to start an Enforcement Action with respect to the [*] and keep Licensee reasonably informed as to the status of any Enforcement Action with respect to the [*] and shall consider in good faith the comments of Licensee with respect thereto.

(c) Cooperation. In a connection with any Enforcement Action, each Party shall provide the enforcing Party with all reasonable assistance in such action, at the enforcing Party's request and expense, including joining such Enforcement Action if required by law or at the reasonable request of the enforcing Party and providing access to relevant documents and other evidence, and making its employees reasonably available during business hours. The non-enforcing Party shall be entitled to separate representation in an Enforcement Action by counsel of its own choice and at its own cost and expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Settlement. A settlement, consent judgment or other voluntary final disposition of a Competitive Infringement may be entered into by the enforcing Party without the consent of the non-enforcing Party; provided, however, that any such settlement, consent judgment or other disposition shall not, without the prior written consent of the non-enforcing Party, [*].

(e) Generic Action. In the event of either Party's receipt of written notice confirming acceptance of an abbreviated new drug application ("**ANDA**") by the FDA pursuant to the Hatch-Waxman Act for a generic version of the Licensed Product (or acceptance of an equivalent application to market a generic version of the Licensed Product by an equivalent Regulatory Authority in another jurisdiction of the Licensee Territory, in the event such acceptance is notified to Licensee by the competent Regulatory Authority), then: (i) the time period for giving notice set forth in Section 8.4.1 shall

be [*], and (ii) the time period for Licensee to bring an Enforcement Action as set forth in Section 8.4.2(a) shall be [*].

(f) Recoveries. Unless otherwise agreed to by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.4.2(a) or Section 8.4.2(b), will be allocated in the following order: [*].

8.4.3 Day One Patents in the Day One Territory. Day One or its designee shall have the sole right to bring and control any legal action to enforce the Day One Patents in the Day One Territory, [*].

8.5 Infringement of Third Party Rights. Each Party shall promptly notify the other Party in writing [*] after receiving a notice of a claim or assertion that the Licensed Compound or any Licensed Product, or the development, manufacture of commercialization thereof, infringes or misappropriates any Third Party's Patent Rights or other intellectual property rights in any country ("**Third Party Infringement Claim**"), which notice shall include [*].

8.6 Patent Marking. Licensee shall mark all Licensed Products in accordance with the applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.

8.7 Trademarks.

8.7.1 Subject to the remainder of this Section 8.7, Licensee shall have the sole authority to select the trademarks for the Licensed Products in the Licensee Territory and will solely own all right, title and interest in and to any trademarks adopted for use with the Licensed Products in the Field in the Licensee Territory, and will be responsible at its own cost and expense for the registration, filing, maintenance and enforcement thereof. Neither Licensee nor any of its Affiliates will use Day One's or any of its Affiliates' Corporate Name or any trademark that is confusingly similar thereto. Notwithstanding the foregoing, in the event Day One develops or adopts trademarks, including trade names, trade dresses, branding, and logos, to be used for a particular Licensed Product in the Day One Territory (including but not limited to Ojemda™) which are owned by Day One (excluding Day One's Corporate Name, the "**Day One Marks**"), at Licensee's sole discretion and provided that Licensee is otherwise in compliance with the terms and conditions of this Agreement, Licensee shall have the right, upon written notice to Day One, to use such Day One Marks for such Licensed Product in the Licensee Territory or in some countries in the Licensee Territory as such Day One Mark may be available for registration and use for such Licensed Product in those countries, in which case, such use will be under the License pursuant to Section 2.1 of this Agreement *provided that* [*].

8.7.2 All use of the Day One Marks by or on behalf of Licensee and any of its Affiliates, Sublicensees and Distributors and all goodwill associated with such use shall inure to the benefit of Day One. All use of the Day One Marks by or on behalf of either Licensee, and any of its Affiliates, Sublicensees and Distributors shall be in full compliance with any trademark use requirements that may be provided by Day One to Licensee from time to time in writing and all Applicable Law (including Applicable Law particularly applying to the proper use and designation of trademarks in the applicable countries or regions in the Licensee Territory) (the "**Trademark Use Requirements**"). All marketing literature, electronic media, product packaging and other materials which contain the Day One Marks that Licensee uses in the Licensee Territory shall comply with the Trademark Use Requirements. Upon reasonable request, Licensee shall provide samples of such materials to Day One so that it can review them for compliance with the Trademark Use Requirements. Neither Licensee nor its respective Affiliates or Sublicensees shall (i) register or use any trademark, domain name, URL or social media identifier which consists of or incorporates, in whole or in part, or is confusingly similar to, the Day One Marks for any products, services

or uses, other than for the Licensed Product hereunder, or (ii) contest the validity of, or take any action that a reasonable person would believe would impair any part of Day One's ownership of the Day One Marks in or diminish or dilute their distinctiveness or validity. Licensee agrees to maintain suitable quality standards with respect to the Licensed Products it provides in connection with the Day One Marks.

ARTICLE 9
REPRESENTATIONS, WARRANTIES, AND COVENANTS

9.1 Representations, Warranties of Each Party. Each Party represents and warrants to the other as of the Effective Date that:

9.1.1 it is duly organized, validly existing and in good standing in its jurisdiction of organization;

9.1.2 it has full corporate power and authority to execute, deliver and perform this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

9.1.3 this Agreement has been duly executed by it and is legally binding upon it and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and

9.1.4 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, the contemplated performance of its covenants and responsibilities hereunder, and the consummation of the transactions contemplated hereby do not (a) conflict with or result in a breach of any provision of its organizational documents, (b) result in a breach of any agreement to which it or its Affiliate is a party, or (c) violate any Applicable Law.

9.2 Representations and Warranties of Day One. Day One represents and warrants to Licensee as of the Effective Date that:

9.2.1 it has the right under the Day One Technology to grant to Licensee the License, and it has not granted and will not grant, any license or other right under the Day One Technology that is inconsistent with the License;

9.2.2 **Schedule 1.48** sets forth a complete and accurate list of all Day One Patents existing as of the Effective Date;

9.2.3 Day One exclusively owns or otherwise Controls the Day One Technology;

9.2.4 to Day One's knowledge, the issued Day One Patents are valid, subsisting, and enforceable, and have been prosecuted and maintained in material compliance with Applicable Law;

9.2.5 there are no pending or, to Day One's knowledge, threatened, adverse actions, suits, or proceedings against Day One or any of its Affiliates involving the Day One Technology;

9.2.6 with respect to any Day One Technology owned by Day One, Day One and its Affiliates have obtained from all individuals who contributed to the conception or reduction to practice

thereof, effective assignments of all ownership rights of such individuals in such Day One Technology, either pursuant to written agreement or by operation of law;

9.2.7 there is no pending or, to Day One's knowledge, threatened litigation, nor has Day One received any written notice from any Third Party, asserting or alleging that the exploitation of the Licensed Product or practice of the Day One Technology prior to the Effective Date infringed, misappropriated, or otherwise violated the intellectual property rights of such Third Party;

9.2.8 to Day One's knowledge, the exploitation of the Licensed Product and practice of the Day One Technology as contemplated under this Agreement does not infringe, misappropriate, or otherwise violate any valid and enforceable intellectual property rights of any Third Party; and

9.2.9 to Day One's knowledge, no Third Party is infringing, misappropriating or otherwise violating, or threatening to infringe, misappropriate or otherwise violate the Day One Technology.

9.3 Mutual Covenants. Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, such Party shall, and shall cause its Affiliates and (sub)licensees and subcontractors to, comply with Applicable Law, including, as applicable, GMP, GLP and GCP and the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act and any other equivalent Applicable Law. Without limiting the foregoing, the Parties additionally agree as follows:

9.3.1 Data Privacy. Each Party shall: (a) comply with Applicable Law in relation to data protection, privacy, or restrictions on, or requirements in respect of, the processing of Personal Data of any kind, including the Health Insurance Portability and Accountability Act, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), and any equivalent Applicable Law in any other jurisdiction (as any of the foregoing may be amended from time to time, collectively, "**Data Protection Laws**") with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other Personal Data (as defined in the applicable Data Protection Laws, collectively, "**Personal Data**") in connection with its activities under or in connection with this Agreement, including the development and commercialization of any Licensed Product hereunder; (b) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws; (c) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to the other Party and to permit the other Party to use and disclose such Personal Data for its own purposes in accordance with this Agreement, and (d) complies with the terms provided in Schedule 9.3.1.

9.4 No Debarment or Regulatory Sanction. Neither Party shall employ (or, to its knowledge, use any contractor, subcontractor, distributor or other Persons that provide services to such Party in connection with this Agreement that employs) any Person that is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority (including, as applicable, the FDA pursuant to its authority under Sections 306(a) and (b) of the FFDCA) or that is the subject of any investigation or proceeding which may result in debarment, disqualification, blacklisting, banning or any similar sanction by any applicable Regulatory Authority; in each case, in connection with the performance of its activities under this Agreement. Each Party shall notify the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority or becomes the subject of any such investigation or proceeding.

9.5 No Other Warranties. EXCEPT AS EXPRESSLY SET FORTH HEREIN, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF DAY ONE, LICENSEE OR THEIR RESPECTIVE AFFILIATES; AND (B) ALL OTHER WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY DISCLAIMED BY THE PARTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. DAY ONE MAKES NO WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE LICENSED COMPOUNDS OR LICENSED PRODUCTS WILL BE SUCCESSFUL OR ACHIEVE ANY PARTICULAR RESULT.

9.6 Day One agrees to use Commercially Reasonable Efforts to [*].

ARTICLE 10
INDEMNIFICATION

10.1 Indemnification by Licensee. Licensee hereby agrees to defend, indemnify and hold harmless Day One, its Affiliates and (sub)licensees and its and their respective directors, officers, employees and agents (each an "**Day One Indemnitee**") from and against any and all liabilities, costs, expenses, and losses (including reasonable legal expenses and attorneys' fees) (collectively, "**Losses**") as a result of any claim, demand, action or other proceeding by a Third Party (each, a "**Third Party Claim**") arising out of: [*].

10.2 Indemnification by Day One. Day One hereby agrees to defend, indemnify and hold harmless Licensee, its Affiliates and Sublicensees, and its and their respective directors, officers, employees and agents (each, a "**Licensee Indemnitee**") from and against any and all Losses as a result of any Third Party Claim arising out of [*].

10.3 Procedure.

10.3.1 Notice. The Party seeking indemnification under Section 10.1 or Section 10.2 (the "**Indemnified Party**") shall inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to the obligation to indemnify pursuant to such section within [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.

10.3.2 Procedure. The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Party's right to control such defense. With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: [*]. If the Parties cannot agree as to the application of Section 10.1 or Section 10.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 12.5, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or Section 10.2, as applicable, upon resolution of the underlying claim. If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, [*].

10.4 Insurance. [*], each Party shall (and shall cause its Affiliates and Sublicensees to) maintain commercial general liability, including public and product liability and other appropriate insurance

in an amount consistent with industry standards in light of its obligations under this Agreement. With respect to product liability insurance after Regulatory Approval obtained for the Licensed Product in the Licensee Territory, each Party will secure minimum limit of liability of [*]. The product liability insurance will have a territoriality in line with each Party's territory. Each Party will also maintain Clinical Trial insurance in compliance with all Applicable Law pertaining to the jurisdictions in which such Clinical Trials are conducted. These insurance policies shall be obtained from [*]. Such insurance shall not be construed to create a limit of Licensee's liability under this Agreement.

10.5Limitation of Liability. A PARTY AND ITS AFFILIATES SHALL NOT BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR (A) ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES, OR (B) ANY LOSS OF PROFITS OR REVENUE, IN EACH CASE (A) AND (B) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH CLAIM IS IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT [*].

ARTICLE 11
TERM AND TERMINATION

11.1Term. This Agreement shall be effective commencing on the Effective Date and shall expire (a) on a Licensed Product-by-Licensed Product and country-by-country basis upon the expiration of the Royalty Term for such Licensed Product in such country, and (b) in its entirety upon the expiration of the last to expire Royalty Term with respect to all Licensed Products and all countries in the Licensee Territory (the "**Term**"), unless terminated earlier in accordance with this Article 11 or by mutual written agreement of the Parties. Following the expiration of the Royalty Term for a Licensed Product in a country in the Licensee Territory, the License shall become non-exclusive, fully paid-up, royalty-free, perpetual and irrevocable for such Licensed Product in such country in the Licensee Territory. Upon the expiration of the Term, (a) the License shall become non-exclusive, transferable, sublicensable, fully-paid, royalty-free, perpetual and irrevocable in its entirety in the Licensee Territory, and (b) the license to Day One in Section 2.2.1 shall become non-exclusive, transferable, sublicensable, fully-paid, royalty-free, perpetual and irrevocable on a worldwide basis.

11.2Termination by Licensee for Convenience [*] Licensee may terminate this Agreement for convenience in its entirety, or on a Region-by-Region basis [*], in each case upon [*]. For purposes of this Section, "**Region**" shall mean each of the following countries or regions: [*].

11.3Termination for Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach [*] following receipt of notice of such breach from the non-breaching Party; provided however, that if the breach is capable of being cured, but cure of such breach cannot reasonably be effected within such [*] period, then the cure period shall be extended an additional [*]. Notwithstanding the foregoing, if the allegedly breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such allegedly breaching Party provides the other Party notice of such dispute [*], then the other Party shall not have the right to terminate this Agreement pursuant to this Section 11.3 unless and until [*].

11.4Termination for Bankruptcy. Each Party shall have the right to terminate this Agreement effective immediately upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment

of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed [*] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

11.5[*]

11.6Termination Mandated by Regulatory Authority. Licensee may terminate this Agreement or on a country-by-country basis and/or Licensed Product-by-Licensed Product basis, upon prior written notice to Day One if a Regulatory Authority in a country has ordered Licensee to stop all sales of a Licensed Product in such country due to a safety concern. Such termination shall be effective [*].

11.7Full Force and Effect During Notice Period. This Agreement shall remain in full force and effect during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement, including that Licensee shall owe royalties on Net Sales of Licensed Products made during such period, and shall be obligated to make any Launch Milestone Payment or Sales Milestone Payment achieved during such period, even if the due date of such payment comes after the effective date of termination.

11.8Effect of Termination. Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of termination of this Agreement in its entirety for any reason (or on a Region-by-Region basis pursuant to Section 11.2), the terms of this Section 11.8 will apply as of the effective date of such termination.

11.8.1 License. The License shall terminate, and all sublicenses granted under the License by Licensee or its Affiliates shall also terminate.

11.8.2 Sublicense Survival. Upon the request of any Sublicensee, Day One will enter into a direct license with such Sublicensee on the same terms as this Agreement, taking into account [*]. Notwithstanding the foregoing, Day One will not be obligated to enter into a New License Agreement with a Sublicensee of Licensee unless such Sublicensee notifies Day One within [*] that it wishes to enter into a New License Agreement.

11.8.3 Winddown; Sell-Off.

(a) Sell-Off. Licensee shall be responsible, at its cost, for the prompt wind-down of its, its Affiliates' and its Sublicensees' development, manufacturing and commercialization of Licensed Products in the Licensee Territory in compliance with Applicable Law. Notwithstanding the foregoing, other than in the event of termination this Agreement by Day One pursuant to Section 11.3 or Section 11.4, [*], Licensee and its Affiliates and Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products then in its or their respective inventory and any in-progress inventory, *provided that* Licensee shall continue to make payments to Day One on Net Sales of such Licensed Products in accordance with Sections 6.4 and 6.6, and the rights and licenses granted to Licensee hereunder shall survive to the extent necessary for Licensee (and its Affiliates and Sublicensees) to conduct such sell-off. Except in connection with activities pursuant to the foregoing, Licensee, its Affiliates and, subject to Section 11.8.2 Sublicensees shall cease all development, manufacturing, commercialization and exploitation of Licensed Products in the Licensee Territory.

(b) Ongoing Licensee Territory-Specific Clinical Trials. If, as of the effective date of termination of this Agreement, Licensee, its Affiliates or its or their Sublicensees are conducting any Licensee Territory-Specific Clinical Trials involving any Licensed Compound or Licensed

Product, then, unless prohibited by any Regulatory Authority or Applicable Law, at Day One's written request on a Clinical Trial-by-Clinical Trial basis, at Day One's option, Licensee will do one of the following as soon as reasonably possible: [*].

11.8.4 [*]

11.9Confidential Information. Upon the expiration or termination of this Agreement in its entirety, at the disclosing Party's election, the receiving Party shall return or destroy all tangible materials to the extent comprising, bearing or containing any Confidential Information of the disclosing Party that are in receiving Party's or its Affiliates' possession or control and provide written certification of such destruction (if applicable) to the disclosing Party, *provided that* the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein or may retain such Confidential Information for which it has any continuing rights, and provided further that the receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures.

11.10Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies in law or equity shall remain available except as agreed to otherwise herein.

11.11Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. In addition, the following provisions of this Agreement shall survive expiration or termination of this Agreement: [*].

ARTICLE 12
MISCELLANEOUS

12.1Assignment. This Agreement may not be assigned or transferred by either Party in whole or in part without the prior written consent of the other Party. Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement or its rights and obligations hereunder to (i) an Affiliate, or (ii) its successor in interest in connection with a Change of Control or a sale of all or substantially all of the business or assets of such Party, whether by merger consolidation, divestiture, restructure, sale of asset or otherwise. A Party shall notify the other Party in writing of any assignment of this Agreement by such Party [*]. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Any attempted assignment not in accordance with this Section 12.1 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

12.2Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement through any of its Affiliates, including with respect to Licensee, but not limited to, Ipsen Biopharmaceuticals, Inc. (U.S.A). In each case where a Party's Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement and (b) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.

12.3Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.

12.4Governing Law; English Language. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

12.5Dispute Resolution.

12.5.1 Disputes. Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination of this Agreement that is not subject to Section 3.4 or that is not an Excluded Claim (as defined below) (each a "**Dispute**") shall be finally resolved in accordance with Section 12.5.2. Notwithstanding the foregoing, any decisions that are subject to mutual agreement of the Parties will not be subject to the provisions of this Section 12.5 so long as such decisions are made in accordance with this Agreement.

12.5.2 Early Resolution; Arbitration.

(a) [*]

(b) [*]

(c) Confidentiality. Except to the extent necessary to comply with Applicable Law, legal process or a court order or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant to Section 12.5.2, all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.

12.5.3 Excluded Claims. As used in this Section 12.5, the term "Excluded Claim" means a dispute, controversy or claim that concerns (a) the validity or infringement of a Patent Right, trademark, copyright or trade secret, or (b) any antitrust-, anti-monopoly- or competition- related Applicable Law. Any action concerning Excluded Claims may be brought in any court having jurisdiction.

12.5.4 Equitable Relief. Nothing in this Section 12.5 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, either prior to or during any arbitration, to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

12.6Force Majeure. Except for payment obligations hereunder, neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder, if such delay or nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, worldwide spread of epidemic or pandemic (that lead to decisions from the national or local authorities imposing lock-downs, curfews, or travel restrictions), act of God or of the government of any country or of any local government (including emergency shut-down, lock-down or stay-at-home orders) or by any other cause unavoidable or beyond the control of any Party hereto ("**Force Majeure**"). In such event, the Party affected will provide prompt notice thereof to the other

Party and will use all reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto, and the performance of any obligations of the Party not so affected, which obligations are directly dependent upon such performance by the affected Party, shall be tolled during such period. If any such failure or delay in a Party's performance hereunder [*].

12.7Waivers and Amendments. The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Any waivers under this Agreement must be in writing to be effective. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

12.8Relationship of the Parties. The Parties have the relationship of independent contractors to each other under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute one Party as a partner, agent, or joint venturer of the other Party. In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party or its Affiliates to or under any contract, agreement, or undertaking with any Third Party.

12.9Notices. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, where, when such message is received, a read receipt e-mail is received by the sender, or (b) the earlier of when received by the addressee or five (5) days after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party or Licensee may designate by notice):

If to Day One:

Day One Biopharmaceuticals, Inc.
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005
Attention: Adam Dubow and Sishir Mokkapati
Emails: [*]
[*]

With a copy (which shall not constitute notice) to:

Fenwick and West, LLP
555 California Street, 12th Floor
San Francisco, CA 94104
Attention: Julia Forbess and Stefano Quintini
Emails: [*]

If to Licensee:

Ipsen Pharma SAS
65 Quai Georges Gorse
Boulogne-Billancourt, 92100 France
Attn: EVP General Counsel & Chief Business Ethics Officer
Email: [*]

With a copy to (which shall not constitute notice) to:

Ipsen Pharma SAS
65 Quai Georges Gorse
Boulogne-Billancourt, 92100 France
Attn: Strategic Alliance Management
Email: [*]

12.10No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with this Agreement or any provision contained herein or contemplated hereby.

12.11Further Assurances. Day One and Licensee hereby agree without the necessity of any further consideration to execute, acknowledge and deliver any and all administrative documents and take any ministerial action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

12.12Entire Agreement. This Agreement, including all Exhibits and Schedules hereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the CDA.

12.13Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "**Electronic Delivery**") shall be treated in all manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

12.14Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.

12.15Construction; Interpretation.

12.15.1Construction. The Parties hereto acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement.

12.15.2Interpretation. The captions and headings in this Agreement are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of or to this Agreement and references to this Agreement include all Exhibits and Schedules hereto. If any conflict exists between the main body of this Agreement and any Exhibit or Schedule hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a

calendar day or year unless otherwise specified; (c) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (e) the word "or" shall have the inclusive meaning commonly associated with "and/or"; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.

12.16Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

12.17Export. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Licensee or Day One from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other Governmental Authority approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.

[*Signature Page follows*]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

DAY ONE BIOPHARMACEUTICALS, INC. **IPSEN PHARMA SAS**

By: /s/ Jeremy Bender By: /s/ David Loew

Name: Jeremy Bender Name: David Loew

Title: CEO Title: CEO

List of Exhibits and Schedules:

Exhibit A: Licensed Compound and Licensed Product

Exhibit B: Initial Global Development Plan

Schedule 1.48: Day One Patents

Schedule 4.1.1: Day One Know How and Regulatory Materials as of Effective Date

Schedule 5.6.1: Terms of Supply Agreement

Schedule 6.2: Investment Agreement

Schedule 7.5.1: Joint Press Release

Schedule 8.7.1: Day One Marks

Schedule 11.2: Regions

Exhibit A: Licensed Compound

[*]

Exhibit B: Initial Global Development Plan

[*]

Schedule 1.48: Day One Patents

[*]

Schedule 4.1.1: Day One Know How and Regulatory Materials as of Effective Date

[*]

Schedule 5.6: Terms of Supply Agreement

[*]

Schedule 6.2: Investment Agreement

DAY ONE BIOPHARMACEUTICALS, INC.

INVESTMENT AGREEMENT

This Investment Agreement (this "***Agreement***") is made and entered into as of July 23, 2024 (the "***Effective Date***"), by and between **Day One Biopharmaceuticals, Inc.,** a Delaware corporation (the "***Company***"), and **Ipsen Biopharmaceuticals, Inc.**, a Delaware corporation (the "***Investor***").

RECITALS

Whereas, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.0001 per share, of the Company (the "***Common Stock***");

Whereas, simultaneously with the execution of this Agreement, the Company and Ipsen Pharma SAS ("***Ipsen***"), are entering into an Exclusive License Agreement (the "***License Agreement***"); and

Whereas, in partial consideration for the rights and licenses granted by the Company to Ipsen under the License Agreement, the Investor, a fully-owned Affiliate (as defined in the License Agreement) of Ipsen, has agreed to pay the Company forty million USD ($40,000,000) (the "***Purchase Price***") to acquire newly issued shares of Common Stock (the "***Shares***") at a price per share equal to a dollar amount (the "***Premium Share Price***") that represents a premium of 17% to the volume weighted average price, as reported by Bloomberg, of the Common Stock as traded on The Nasdaq Stock Market LLC for the ten consecutive trading days prior to and including the date of the Company's public release of U.S. GAAP revenue for the quarter ended June 30, 2024 (the "***Revenue Release***") and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in this Agreement.

AGREEMENT

Now, Therefore, in consideration of the mutual promises, representations, warranties and covenants hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **AGREEMENT TO SELL AND PURCHASE.**

1.1 Sale and Purchase. Subject to the terms and conditions hereof, at the Closing (as defined below), the Company hereby agrees to issue and sell to the Investor, and the Investor hereby agrees to purchase from the Company the Shares in partial consideration for the rights and licenses granted by the Company to the Investor pursuant to the Licensing Agreement.

1.2 Calculation of Number of Shares. For purposes of calculating the number of Shares to be purchased by the Investor at the Closing, the Parties shall divide the Purchase Price by the Premium Share Price and round down to the nearest whole share. Notwithstanding the foregoing, in no event shall the number of Shares issued hereunder be equal to or greater than 20% of the Company's shares of Common Stock or voting power outstanding immediately prior to such issuance.

2. CLOSING**, DELIVERY AND PAYMENT.**

2.1 Closing. Upon the satisfaction of the conditions set forth in Sections 5.1 and 5.2, the closing of the sale and purchase of the Shares under this Agreement (the "***Closing***") shall take place

remotely, upon the physical or electronic exchange among the parties and their counsel of all documents and deliverables required under this Agreement (such date is hereinafter referred to as the "***Closing Date***") but (i) in no event earlier than the business day after the 10th trading day following the Revenue Release and (ii) in no event later than [August 27, 2024].

2.2 Payment. On or prior to the Closing Date, the Investor shall deliver or cause to be delivered to the Company, via wire transfer of immediately available funds pursuant to the wire instructions delivered to the Investor by the Company on or prior to the Closing Date, an amount equal to the Purchase Price.

2.3 Delivery. At the Closing, the Company shall issue, or cause to be issued, to the Investor the Shares, registered in book entry form in the name of the Investor on the Company's share register, and shall provide to the Investor evidence of such issuance from the Company's transfer agent.

3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

The Company hereby represents and warrants to the Investor, as of the date of this Agreement and as of the Closing Date, as set forth below.

3.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement, to issue and sell the Shares, and to carry out the provisions of this Agreement and to carry on its business as presently conducted and as presently proposed to be conducted. The Company is duly qualified to do business and is in good standing as a foreign corporation in all jurisdictions in which the nature of its activities and of its properties (both owned and leased) makes such qualification necessary, except for those jurisdictions in which failure to do so would not have a material adverse effect on the Company or its business.

3.2 Authorization; Binding Obligations. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization of this Agreement, the performance of all obligations of the Company hereunder at the Closing and the authorization, sale, issuance and delivery of the Shares pursuant hereto has been taken or will be taken prior to the Closing. This Agreement, when executed and delivered, will be the valid and binding obligation of the Company enforceable in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other laws of general application relating to or affecting the enforcement of creditors' rights generally, and (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies. When issued and delivered to the Investor against payment therefor in accordance with the terms of this Agreement, the Shares will be validly authorized and issued, fully paid and non-assessable, free and clear of all liens, and will not have been issued in violation of or subject to any preemptive or similar rights.

3.3 Compliance with Other Instruments. The execution, delivery, and performance of and compliance with this Agreement, and the issuance and sale of the Shares pursuant to this Agreement, will not, with or without the passage of time or giving of notice: (a) result in a violation of the organization documents of the Company, (b) result in any violation, or be in conflict with or constitute a default under any term or provision under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company is a party, (c) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to the Company or (d) result in the creation of any mortgage, pledge, lien, encumbrance or charge upon any of the properties or assets of the Company or the suspension,

revocation, impairment, forfeiture or nonrenewal of any permit, license, authorization or approval applicable to the Company, its business or operations or any of its assets or properties.

3.4 Company SEC Documents; Financial Statements; Nasdaq Stock Market. Since January 1, 2023, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed by it under the Securities Act of 1933, as amended (the "***Securities Act***"), and the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and any required amendments to any of the foregoing (the "***Company SEC Documents***"), with the U.S. Securities and Exchange Commission (the "***SEC***"). As of its respective filing date, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

3.5 Offering Valid. Assuming the accuracy of the representations and warranties of the Investor contained in Section 4.3, the offer, sale and issuance of the Shares will be exempt from the registration requirements of the Securities Act, and will have been registered or qualified (or are exempt from registration and qualification) under the registration, permit, or qualification requirements of all applicable state securities laws. Neither the Company nor any agent on its behalf has solicited or will solicit any offers to sell or has offered to sell or will offer to sell all or any part of the Shares to any person or persons so as to bring the sale of such Shares by the Company within the registration provisions of the Securities Act or any state securities laws.

4. Representations and Warranties of the Investor.

The Investor hereby represents and warrants to the Company as follows, as of the date of this Agreement and as of the Closing Date:

4.1 Requisite Power and Authority. The Investor has all requisite corporate power and authority to execute and deliver this Agreement and to carry out the provisions of this Agreement. All action on the Investor's part required for the lawful execution, delivery and performance of this Agreement has been taken. Upon its execution and delivery, this Agreement will be the valid and binding obligation of the Investor, enforceable in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other laws of general application relating to or affecting the enforcement of creditors' rights generally and (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

4.2 No Conflicts. The execution, delivery and performance by the Investor of this Agreement and the consummation by the Investor of the transactions contemplated hereby will not (a) result in a violation of the organizational documents of the Investor, (b) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of any agreement, indenture or instrument to which the Investor is a party, or (c) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to the Investor, except in the case of clauses (a) and (b) above, for such conflicts, defaults, rights or violations which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of the Investor to perform its obligations hereunder.

4.3 Investment Representations. The Investor understands that the Shares are

being offered and sold pursuant to an exemption from registration contained in the Securities Act based in part upon the Investor's representations contained in this Agreement. The Investor also understands that the Shares are "restricted securities" as defined in Rule 144 promulgated under the Securities Act as in effect from time to time and must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. The Investor hereby further represents and warrants as follows:

(a) The Investor Bears Economic Risk. The Investor has substantial experience in evaluating and investing in private placement transactions of securities of companies in a similar stage of development as the Company so that it is capable of evaluating the merits and risks of its investment in the Company and has the capacity to protect its own interests. The Investor can bear the economic risk of this investment indefinitely. The Investor understands that the Company has no present intention of registering the Shares. The Investor also understands that there is no assurance that any exemption from registration under the Securities Act will be available and that, even if available, such exemption may not allow the Investor to transfer all or any portion of the Shares under the circumstances, in the amounts or at the times the Investor might propose.

(b) Acquisition for Own Account. The Investor is acquiring the Shares for the Investor's own account for investment only, not as a nominee or agent, and not with a view towards their resale or distribution. The Investor has no present intent of selling, granting any participation in, or otherwise distributing the Shares. By executing this Agreement, the Investor further represents that the Investor does not presently have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to any of the Shares. The Investor has not been formed for the specific purpose of acquiring the Shares.

(c) Sophisticated Investor. The Investor represents that by reason of its, or of its management's, business or financial experience, the Investor has the capacity to protect its own interests in connection with the transactions contemplated in this Agreement. Neither the Investor nor any of its officers, directors, employees, agents, stockholders or partners (i) has either directly or indirectly, including through a broker or finder, engaged in any general solicitation, (ii) has either directly or indirectly, including through a broker or finder, published any advertisement in connection with the offer and sale of the Shares, or (iii) is aware of any publication of any advertisement in connection with the transactions contemplated in this Agreement.

(d) Accredited Investor. The Investor represents that it is an accredited investor within the meaning of Regulation D under the Securities Act.

(e) Company Information. The Investor has received all the information it considers necessary or appropriate for deciding whether to purchase the Shares. The Investor has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company and has had the opportunity to review the Company's operations and facilities. The Investor has also had the opportunity to ask questions of, receive answers from and obtain additional information from (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) the Company and its management regarding the terms and conditions of this investment.

(f) Residence. The office of the Investor in which its decision to purchase the Shares was made is located at the address set forth on the signature page hereto.

4.4 No Governmental Review. The Investor understands that no United States federal or state agency or any other government or governmental agency has passed on or made any

recommendation or endorsement of the Shares or the fairness or suitability of the investment in the Shares nor have such authorities passed upon or endorsed the merits of the offering of the Shares.

4.5 Transfer Restrictions. The Investor acknowledges and agrees that the Shares are subject to restrictions on transfer as set forth in this Agreement. The Investor understands that the Shares and any securities issued in respect of or exchange for the Shares, may bear one or all of the following legends:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "***ACT***"), OR QUALIFIED OR REGISTERED UNDER STATE SECURITIES OR BLUE SKY LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF, AND NEITHER THESE SECURITIES NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED OR DISPOSED OF IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT WITH RESPECT TO THE SECURITIES UNDER THE ACT OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACT."

Any legend required by the securities laws of any state to the extent such laws are applicable to the Shares represented by the certificate so legended. The Investor consents to the Company making a notation on its records and giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer established in Section 4.

5. **Conditions To Closing.**

5.1 Conditions to the Investor's Obligations at the Closing. The Investor's obligations to purchase the Shares at the Closing is subject to the satisfaction, at or prior to the Closing Date, of the following conditions, unless otherwise waived by the Investor:

(a) Representations and Warranties. The representations and warranties made by the Company in Section 3 that are qualified as to materiality shall be true and correct in all respects as of the Closing Date, and the representations and warranties made by the Company in Section 3 that are not qualified as to materiality shall be true and correct in all material respects as of the Closing Date, in each case with the same force and effect as if they had been made as of the Closing Date.

(b) Performance of Obligations. The Company shall have performed all obligations, covenants and conditions herein required to be performed or observed by it on or prior to the Closing.

(c) License Agreement. The License Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

(d) Consents, Permits and Waivers. The Company shall have obtained any and all consents, permits and waivers necessary or appropriate for consummation of the transactions contemplated by this Agreement, except for such as may be properly obtained subsequent to the Closing.

5.2 Conditions to Obligations of the Company. The Company's obligation to issue and sell the Shares at the Closing is subject to the satisfaction, at or prior to the Closing, of the following conditions, unless otherwise waived by the Company:

(a) Representations and Warranties. The representations and warranties in Section 4 made by the Investor shall be true and correct in all material respects at the date of the Closing, with the same force and effect as if they had been made on and as of said date.

(b) Performance of Obligations. The Investor shall have performed and complied with all agreements and conditions herein required to be performed or complied with by the Investor on or before the Closing.

(c) **License Agreement. The License Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.**

6. **Rule 144 Reporting; Legend Removal.**

6.1 Rule 144. In order to make the benefits of the rules and regulations of the SEC that may permit the sale of the Shares to the public without registration available to the Investor, the Company agrees to use commercially reasonable efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144(c)(1) or any similar or analogous rule promulgated under the Securities Act, at all times after the Closing Date;

(b) file with the SEC, in a timely manner, all reports and other documents required of the Company under the Exchange Act; and

(c) so long as the Investor owns any of the Shares, furnish the Investor forthwith upon request: (i) a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act, and of the Exchange Act; (ii) a copy of the most recent annual or quarterly report of the Company; and (iii) such other reports and documents as the Investor may reasonably request in availing itself of any rule of regulation of the SEC allowing it to sell any such securities without registration.

6.2 Legend Removal. The Company shall direct its transfer agent to remove the transfer restriction set forth in Section 4.5 applicable to any portion of the Shares upon the written request of the Investor, within two (2) business days of the Company's receipt of such request, at such time as such portion of Shares (a) are being sold by the Investor pursuant to Rule 144 under the Securities Act or (b) may be transferred without the requirement that the Company be in compliance with the public information requirements and without volume or manner-of-sale restrictions under Rule 144 under the Securities Act. The Investor, or if the Company's transfer agent requires, the Company, shall provide such opinions of counsel reasonably requested by the Company's transfer agent in connection with the removal of legends pursuant to this Section 6.2.

7. **Miscellaneous.**

7.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles that would require application of the law of a jurisdiction outside of the State of New York. Any disputes arising under or in connection with this Agreement, will be resolved through binding arbitration conducted pursuant to Section 12.5 of the License Agreement.

7.2 Survival. The representations, warranties, covenants and agreements made herein shall survive the Closing. All statements as to factual matters contained in any certificate or other

instrument delivered by or on behalf of the Company pursuant hereto in connection with the transactions contemplated hereby shall be deemed to be representations and warranties by the Company hereunder solely as of the date of such certificate or instrument. The representations, warranties, covenants and obligations of the Company, and the rights and remedies that may be exercised by the Investor, shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or knowledge of, the Investor or any of its representatives.

7.3 Successors and Assigns. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon the parties hereto and their respective successors, assigns, heirs, executors and administrators and shall inure to the benefit of and be enforceable by each person who shall be a holder of the Shares from time to time; *provided*, *however*, that prior to the receipt by the Company of adequate written notice of the transfer of any Shares specifying the full name and address of the transferee, the Company may deem and treat the person listed as the holder of such Shares in its records as the absolute owner and holder of such Shares for all purposes.

7.4 Entire Agreement. This Agreement (including any exhibits hereto), and the other documents delivered pursuant hereto constitute the full and entire understanding and agreement between the parties hereto with respect to the subject matter hereof and thereof. No party hereto shall be liable or bound to any other party in any manner with respect to the subject matter hereof or thereof by any warranties, representations or covenants except as specifically set forth herein or therein.

7.5 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

7.6 Amendments and Waivers. This Agreement may be amended or modified, and the obligations of the Company and the Investor under this Agreement may be waived, discharged or terminated, only upon the written consent of the Company and the Investor. Any such waiver, discharge or termination effected in accordance with this Section 7.6 shall be binding upon the Investor and each transferee of the Shares, each future holder of all such securities and the Company.

7.7 Delays or Omissions. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any party, upon any breach, default or noncompliance by another party under this Agreement shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on any party's part of any breach, default or noncompliance under this Agreement or any waiver on such party's part of any provisions or conditions of this Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement, the Company's Certificate of Incorporation or the Company's Bylaws, or otherwise afforded to any party, shall be cumulative and not alternative.

7.8 Notices. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, by express courier service (signature required) to the party to which it is directed at its address shown below or such other address as such party shall have last given by notice to the other party.

If to the Company, addressed to:

Day One Biopharmaceuticals, Inc.

2000 Sierra Point Parkway, Suite 501

Brisbane, CA 94005

USA

Attention: Adam Dubow

Email:

With a copy, which shall not constitute notice, to:

Fenwick & West LLP 801 California Street

Mountain View, CA 94041 USA

Attention: Stefano Quintini

Email:

If to the Investor, addressed to:

Ipsen Biopharmaceuticals, Inc.

One Main Street

Cambridge, MA 02142

Attn: François Garnier, EVP General Counsel & Chief Business Ethic Officer

Email:

With a copy, which shall not constitute notice, to:

Orrick, Herrington & Sutcliffe LLP

2100 Pennsylvania Ave. NW

Washington, D.C. 20037

Attention: Tony Chan

Email:

7.9 Expenses. Each party hereto shall pay all fees, costs and expenses that it incurs with respect to the negotiation, execution, delivery and performance of this Agreement.

7.10 Titles and Subtitles. The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement. All references in this Agreement to sections and exhibits shall, unless otherwise provided, refer to sections hereof and exhibits attached hereto.

7.11 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original. Electronic signatures that comply with applicable law are deemed original signatures.

7.12 Third Parties. Nothing in this Agreement, express or implied, is intended to confer upon any person, other than the parties hereto and their successors and assigns, any rights or remedies under or by reason of this Agreement.

7.13 Broker's Fees. Each party hereto represents and warrants that no agent, broker, investment banker, person or firm acting on behalf of or under the authority of such party hereto is or will be entitled to any broker's or finder's fee or any other commission directly or indirectly in connection with the transactions contemplated herein. Each party hereto further agrees to indemnify and to hold harmless each other party for any claims, losses or expenses incurred by such other party as a result of the representation in this Section 7.13 being untrue.

7.14 Pronouns. All pronouns contained herein, and any variations thereof, shall be deemed to refer to the masculine, feminine or neutral, singular or plural, as the identity of the parties hereto may require.

7.15 Further Assurances. Each party hereto agrees to execute and deliver, by the proper exercise of its corporate, limited liability company, partnership or other powers, all such other and additional instruments and documents and do all such other acts and things as may be necessary to more fully effectuate this Agreement.

7.16 No Publicity. The parties hereto agree that the provisions of Section 7.5 of the License Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by this Agreement and the License Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 7.5 of the License Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

[Remainder of Page Intentionally Left Blank]

In Witness Whereof, the parties hereto have executed this Investor Agreement as of the date first written above.

THE COMPANY:

DAY ONE BIOPHARMACEUTICALS, INC.

By:/s/ Jeremy Bender

Name: Jeremy Bender
Title: Chief Executive Officer

INVESTOR:

IPSEN BIOPHARMACEUTICALS, INC.

By:/s/ David Loew

Name: David Loew
Title: CEO of the Ipsen Group of Companies
Address: One Main Street, Cambridge MA, 02142

Schedule 7.5.1: Joint Press Release

Press release

Intended for international media and investor audiences only

Ipsen and Day One enter into exclusive ex-U.S. licensing agreement to commercialize tovorafenib for the most common childhood brain tumor

- ***Ipsen secures ex-U.S. regulatory and commercial rights to tovorafenib for most common childhood brain tumor, pediatric low-grade glioma (pLGG), and any future indications***
- ***OJEMDA™ (tovorafenib) is the first FDA-approved treatment for relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or V600 mutation, following the pivotal Phase II trial, FIREFLY-1***
- ***Day One receives approximately $111 million upfront in cash and equity investment with up to approximately $350 million in milestone payments and double-digit tiered royalties***
- ***Ongoing Phase III trial, FIREFLY-2, is evaluating tovorafenib as a monotherapy for newly diagnosed children and young adults with RAF-altered low-grade glioma requiring first-line systemic therapy***

PARIS, FRANCE, and BRISBANE, CALIFORNIA U.S., 25 July 2024 - Ipsen (Euronext: IPN; ADR: IPSEY) and Day One Biopharmaceuticals (Nasdaq: DAWN) (Day One), announced today a new global partnership outside the U.S. for tovorafenib, an oral, once-weekly, type II RAF inhibitor for pediatric low grade glioma (pLGG), the most common form of childhood brain cancer,[i] and any future indications developed by Day One.

Tovorafenib was granted Orphan Drug Designation and received U.S. FDA approval in April 2024[ii] as a monotherapy treatment for patients six months and older with relapsed or refractory pLGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.[iii] These BRAF alterations account for more than half of pLGG cases worldwide and there are no approved targeted treatments for people with pLGG harboring BRAF fusions outside the U.S.[i,iii,iv] Day One will maintain exclusive global development and U.S. commercial rights for tovorafenib.

David Loew, Chief Executive Officer, Ipsen, commented "Today's announcement marks an exciting addition to our portfolio. Tovorafenib has the potential to make a significant impact on children living with cancer and is an excellent example of our biomarker-driven strategy as we expand our portfolio. Pediatric low-grade glioma is the most common form of childhood brain cancer, and, outside the U.S., there are still no approved targeted treatments for people with pLGG caused by BRAF alterations, including BRAF fusions or V600 in the refractory/relapsed setting. We are delighted to partner with the team at Day One as we work to bring tovorafenib to every eligible patient around the world, who may benefit from this important new treatment option."

Jeremy Bender, Ph.D., Chief Executive Officer, Day One commented, "Our collaboration with Ipsen to bring tovorafenib to patients worldwide highlights our shared commitment to bring novel therapeutics to patients who have limited treatment options. We believe Ipsen's footprint in Europe and major regions outside of the U.S., in addition to their track record of bringing innovative medicines to market in oncology and rare pediatric diseases, will be an enormous benefit to tovorafenib and to the pediatric oncology community worldwide."

Ipsen's deep heritage and expertise in oncology means we can accelerate the delivery of this innovation as teams focus on regulatory activities outside the U.S. pLGG is the most common brain tumor diagnosed in children, with patients suffering profound tumor- and treatment-associated morbidities that can impact their life trajectory.[i] Depending on the tumor's size, location and growth rate, pLGG can present with a

variety of symptoms including vision, hearing and speech problems, neurological symptoms, premature puberty, physical changes and generalized symptoms such as balance problems, fatigue and nausea.[v] Mortality is relatively rare, however due to the chronic nature of pLGG and potential morbidity associated with treatment, the disease can significantly affect the development, cognition, education and overall quality of life of affected children, whilst negatively impacting the mental health of parents and caregivers.[vi,vii]

Under the terms of the agreement, Ipsen will be responsible for the regulatory and commercial activities for tovorafenib in all territories outside of the U.S. Day One will receive an upfront payment of approximately $111 million, which includes approximately $71 million in cash as well as a $40 million equity investment at a premium and up to approximately $350 million in additional launch and sales milestone payments. Day One will receive tiered double-digit royalties starting at mid-teens percentage on sales.

ENDS

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience.

Our pipeline is fueled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 80 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

About Day One Biopharmaceuticals

Day One Biopharmaceuticals believes when it comes to pediatric cancer, we can do better. Day One was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by “The Day One Talk” that physicians have with patients and their families about an initial cancer diagnosis and treatment plan, Day One aims to re-envision cancer drug development and redefine what’s possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important targeted cancer treatments. Day One’s pipeline includes tovorafenib (OJEMDA™), pimasertib and DAY301.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or follow Day One on LinkedIn or X.

About tovorafenib

Tovorafenib (known as OJEMDA™ in the U.S.) is a Type II RAF kinase inhibitor mutant BRAF V600, wild-type BRAF, and wild-type CRAF kinases. Tovorafenib is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. This indication is approved under accelerated approval based, in part, on response rate and duration of response according to multiple response assessment criteria: Response Assessment in Neuro-Oncology High-Grade Glioma (RANO-HGG) criteria, Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma (RAPNO LGG) criteria, and Response Assessment for Neuro-Oncology Low-Grade Glioma (RANO LGG) criteria. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Tovorafenib is under evaluation as a therapy for patients aged 6 months to 25 years with pLGG harboring BRAF fusion or rearrangement, or BRAF V600 mutation requiring front-line treatment (Phase III FIREFLY-2/LOGGIC). It is also being studied in combination with the MEK inhibitor pimasertib for adolescent and

adult patient populations with recurrent or progressive solid tumors with MAPK pathway alterations (FIRELIGHT-1).

Tovorafenib was granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration, and it was evaluated by the FDA under priority review. Tovorafenib has also received Orphan Drug designation from the FDA for the treatment of malignant glioma and from the European Commission for the treatment of glioma.

For more information, please visit www.ojemda.com.

About FIREFLY-1

FIREFLY-1 is evaluating tovorafenib as once-weekly monotherapy in patients aged 6 months to 25 years with relapsed or progressive pLGG harboring a known activating BRAF alteration. The trial is being conducted in collaboration with the Pacific Pediatric Neuro-Oncology Consortium. The pivotal and ongoing Phase II FIREFLY-1 study[v] evaluated the safety and efficacy of tovorafenib in 137 relapsed or refractory BRAF-altered pLGG patients, who had received at least one line of prior therapy, across two study arms. Arm 1 (n=77) was used for the efficacy analyses and Arm 2 provided safety data for an additional 60 patients, initiated to enable access to tovorafenib once Arm 1 had fully recruited.[ii,iii] The primary endpoint in Arm 1 of best overall response rate (ORR), determined by independent radiology review committee (IRC) and based on Response Assessment in Neuro-Oncology High-Grade Glioma (RANO-HGG) criteria, achieved ORR of 67% and median time to response (TTR) of 3 months. At the time of data cutoff on 5 June 2023 there was a median duration of response (DOR) of 16.6 months. The secondary endpoint of best ORR by IRC according to Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma (RAPNO LGG) criteria was 51% with a median DOR of 13.8 months and median TTR of 5.3 months. Among 137 patients (arms 1 and 2), the most common all-grade treatment-related adverse events (TRAEs) were hair color changes (76%), elevated creatine phosphokinase (56%) and anemia (49%). Grade ≥3 TRAEs occurred in 42% of patients with elevated creatine phosphokinase (12%) and anemia (10%) as the most common. Nine (7%) patients had TRAEs leading to discontinuation of tovorafenib.[vi] Additional information about FIREFLY-1 may be found at ClinicalTrials.gov, using Identifier NCT04775485.

About Pediatric Low-Grade Glioma

Pediatric low-grade glioma (pLGG) is the most common brain tumor with an estimated US incidence of 1,100 and Europe incidence of 700 children per year who are eligible for front-line systemic therapy.[i,viii] BRAF is the gene most commonly altered in pLGG, which include two primary types of BRAF alterations – a BRAF gene fusion and BRAF point mutation. These BRAF alterations account for >50% of pLGG cases worldwide and until now there were no approved treatments for people with pLGG driven by BRAF fusions.[i,vi]

Pediatric low-grade gliomas can be chronic and relentless, with patients suffering profound side effects from both the tumor and the treatment, which may include chemotherapy and radiation. These side effects can impact their life over the long term, and may include muscle weakness, loss of vision, and difficulty speaking. This type of tumor has a high risk of progression, and many children with pLGG require long-term treatment. While most children with pLGG survive their cancer, children who do not achieve a complete resection following surgery may face years of increasingly aggressive treatment.

Ipsen contacts

Email: corporate.communications@ipsen.com

Investors

Craig Marks | + 44 7584 349 193
Nicolas Bogler | +33 (0) 6 52 19 98 92

Media

Amy Wolf | +41 7 95 76 07 23
Jess Smith | + 44 7557 267 634

Day One biopharmaceuticals contacts

Investors
PJ Kelleher, LifeSci Advisors pkelleher@lifesciadvisors.com

Media
Laura Cooper, Day One media@dayonebio.com

Disclaimers and/or Forward-Looking Statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's

business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's latest Universal Registration Document, available on ipsen.com.

Day One Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One's entry into the exclusive global licensing agreement with Ipsen, Day One's plans to develop cancer therapies, expectations from current clinical trials, and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One's ability to develop, obtain regulatory approval for or commercialize any product candidate, Day One's ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts and the sufficiency of Day One's cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

---

[i] Ryall S, et al. *Acta Neuropathol Commun*. 2020;8(1):30.

[ii] FDA grants accelerated approval to tovorafenib for patients with relapsed or refractory BRAF-altered pediatric low-grade glioma | FDA (last accessed July 2024)

[iii] Day One Press Release. April 2024. Available here: Day One's OJEMDA™ (tovorafenib) Receives US FDA Accelerated Approval for Relapsed or Refractory BRAF-altered Pediatric Low-Grade Glioma (pLGG), the Most Common Form of Childhood Brain Tumor | Day One Biopharmaceuticals, Inc. (last accessed July 2024)

[iv] Sholl LM. *Precis Cancer Med*. 2020;3:26

[v] Dana-Farber Cancer Institute. Childhood low-grade gliomas. https://www.dana-farber.org/cancer-care/types/childhood-low-grade-gliomas Last accessed: July 2024

[vi] Traunwieser T, et al. *Neurooncol Adv.* 2020;2(1):vdaa094.

[vii] Armstrong GT, et al. *Neuro Oncol.* 2011;13(2):223-234.

[viii] Estimates of annual incidence and prevalence for addressable patient population in E.U. 4 + U.K. are based on Ipsen calculations from publicly available data (Eurostat, <25yo population; Global Burden of Disease 2019; Desandes et al. Incidence and survival of children with central nervous system primitive tumors in the French National Registry of Childhood Solid Tumors. Neuro Oncol. 2014 Jul;16(7):975-83. doi: 10.1093/neuonc/not309; Qaddoumi et al. Outcome and prognostic features in pediatric gliomas: a review of 6212 cases from the Surveillance, Epidemiology, and End Results database. Cancer. 2009 Dec 15;115(24):5761-70. doi: 10.1002/cncr.24663)

Schedule 8.7.1: Day One Marks

[*]

Schedule 9.3.1: Specific terms relating to controller to controller setting

[*]

Schedule 11.2: Regions

[*]

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: October 30, 2024

/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: October 30, 2024

/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, 2024 (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: October 30, 2024

/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, 2024 (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: October 30, 2024

/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)