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

FORM 10-K

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

For the fiscal year ended December 31, 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.)**
1800 Sierra Point Parkway, Suite 200 Brisbane, CA	**94005**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 484-0899

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on June 30, 2024, was approximately $971.5 million.

The number of shares of Registrant's Common Stock outstanding as of February 20, 2025 was 101,354,516.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to the 2025 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Definitive Proxy Statement will be filed within 120 days of the Registrant's fiscal year ended December 31, 2024. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual 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 our 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, significant political, trade or regulatory developments 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 I, Item 1A, "Risk Factors" and elsewhere in this Annual 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 Annual 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 Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context indicates otherwise, as used in this Annual Report on Form 10-K, the terms "Day One," "the Company," "we," "us," and "our" refer to Day One Biopharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole, unless otherwise noted. "Day One" and all product and product candidate names are our common law trademarks. This Annual 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.

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PART I

Item 1. Business.

Overview

Day One Biopharmaceuticals, Inc. is a commercial-stage company focused on advancing first- or best-in-class medicines for childhood and adult diseases with equal intensity. We were founded to address the lack of new therapies resulting from the traditional drug development model, which has left children with cancer and their families waiting too long for new treatments.

At Day One, we aim to identify and develop breakthrough medicines with the goal of improving the outcomes and life trajectories of patients of any age facing serious diseases — starting from Day One. Our "search & development" strategy enables us to find, acquire, and develop potential best-or first-in-class programs with the goal of introducing new medicines that will make a real difference in the treatment of children and adults.

Our first commercial 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 the cutoff 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 113 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/m2/dose once weekly, and the addition of a once-monthly carboplatin regime as a fourth standard of care option for arm 2. We expect to complete enrollment of FIREFLY-2 in the first half of 2026.

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) 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 $330.0 million in additional commercial launch and sales-based milestone payments based on exchange rates as of the reporting date, 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 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 an inhibitor targeting 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 inhibitor 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. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial.

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 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.

We seek to identify, acquire and develop first- or best-in-class products and product candidates that target high-value oncogenic drivers in childhood and adult cancers with high unmet need. The following table summarizes our product and product candidate pipeline.

Our pipeline

Our goal is to take aim at the gaps that have left patients and their families behind.

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	BRAF-altered relapsed pLGG	FIREFLY-1 (pivotal Phase 2)[2]				ojemda (tovorafenib)	**FDA accelerated approval** April 2024 **Ex-U.S. license agreement** July 2024
	Front-line RAF-altered pLGG	FIREFLY-2 (pivotal Phase 3)					**Enrollment completion expected** 1H 2026
DAY301 PTK7-Targeted ADC	Adult and pediatric solid tumors						**First dose cohort cleared** January 2025
VRK1 Program VRK1 Inhibitor	Adult and pediatric cancers						**In-licensed** August 2023

[1] OJEMDA has received accelerated approval by the U.S. Food and Drug Administration. [2] FIREFLY-1 is an open-label, pivotal Phase 2 trial. [3] Ex-U.S. license agreement with Ipsen to commercialize OJEMDA (tovorafenib) outside the U.S. DAY301 is a license agreement with MabCare Therapeutics for exclusive worldwide rights, excluding Greater China, for MTX-13/CB-002, a novel ADC targeting PTK7. VRK1 Program is a research collaboration and license agreement with Sprint Bioscience AB for exclusive worldwide rights to a research-stage program targeting VRK1. The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

Day One BIOPHARMACEUTICALS

Our first commercial product, tovorafenib, is an oral, brain-penetrant, highly selective type II RAF kinase inhibitor that inhibits both monomeric and dimeric RAF kinase. Approved BRAF products such as vemurafenib and encorafenib are referred to as type I RAF inhibitors, which only inhibit RAF monomers and are therefore limited to use in BRAF V600-altered tumors. Unlike type I RAF inhibitors, tovorafenib has not been shown to cause paradoxical activation in RAF wild-type cells at clinically active doses – a phenomenon wherein undesired increases in MAPK signaling can lead to renewed tumor growth. Tovorafenib's inhibition of both RAF monomers and dimers broadens its potential clinical application to treat an array of RAS- or RAF-altered solid tumors. Furthermore, studies have shown tovorafenib has higher brain penetration, distribution and exposure in comparison to other MAPK pathway inhibitors. Taken together, we believe that tovorafenib has the potential to be a high-impact targeted therapeutic in pLGG, where over half of pLGGs are driven by abnormal signaling due to RAF alterations.

This rationale served as the basis on which researchers at Dana-Farber Cancer Institute initiated the development of tovorafenib in pLGG. In a Phase 1 dose-escalation study, nine pediatric patients (<18 years of age) with relapsed pLGG were treated with tovorafenib. Of the eight patients with RAF fusions, two achieved a complete response by Response Assessment for Neuro-Oncology, or RANO, criteria, three had a partial response, two achieved prolonged stable disease, and one experienced progressive disease as assessed by an independent

radiographic review. The median time to achieve a response was 10.5 weeks, which was a notable observation given pLGG is an indolent, slow-growing tumor. In addition to the rapid anti-tumor activity observed, tovorafenib was also well-tolerated, which is important for achieving and maintaining long-term, durable responses in these patients. Based on these results, tovorafenib has been granted breakthrough therapy designation by the FDA for the treatment of pediatric patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. 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 LGGs harboring an activating RAF alteration in July 2021. On April 23, 2024, we announced that 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. 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 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.

Our second product candidate, DAY301, is a PTK7 targeted ADC composed of a novel humanized anti-PTK7 immunoglobulin G1 monoclonal antibody, or mAb, (referred to as DAY301 mAb) conjugated with a topoisomerase I inhibitor (exatecan mesylate [exatecan]) via a highly stable and hydrophilic modified valine-alanine (VA) cleavable linker. DAY301 is intended for the treatment of patients with advanced solid tumors.

DAY301 demonstrated encouraging preclinical antitumor efficacy in relevant tumor models representing a wide range of solid tumors, including ovarian cancer, non-small cell lung cancer ("NSCLC"), triple-negative breast cancer ("TNBC"), small cell lung cancer ("SCLC"), esophageal squamous cell carcinoma ("ESCC"), cutaneous squamous cell carcinoma ("CSCC"), colorectal cancer, and esophageal adenocarcinoma. DAY301 was tolerated in non-human primate nonclinical toxicology studies with favorable pharmacokinetic (PK) and safety profiles. Collectively, DAY301 could potentially have a wide therapeutic window in clinical testing and therefore provide benefits for cancer patients with high unmet medical needs.

Our third program is aimed at discovery, optimization and development of an inhibitor against 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 inhibitor program are ongoing.

Our Strategy

We have a mission-driven strategy to build a differentiated, global biopharmaceutical company through the identification, development and commercialization of targeted therapeutics for people of all ages with life-threatening diseases. The key elements of our strategy are to:

- **Establish a leadership position in targeted oncology therapeutics for patients of all ages through our unique expertise in pediatrics.** We have built a targeted oncology company with differentiated business and clinical development capabilities. We leverage these capabilities to navigate the unique challenges and nuances of pediatric and adult drug development. We initially focused on pediatric patients as we believe this provides a favorable pathway to approval for tovorafenib. We have established trusted relationships within the pediatric and adult oncology community, and we seek their advice on aligning our clinical development plans with the needs of the patients and their families. We believe we are a leader in this development space and to further this position, we plan to continue to consult and strategically partner with biopharmaceutical companies, academic oncologists and scientists, and patient advocacy groups to identify areas of unmet need and then acquire high-impact assets to address underserved patients.
- **Advance our first commercial product candidate, tovorafenib, through clinical development towards full regulatory approval in pLGG.** We demonstrated clinical proof-of-concept of tovorafenib in pediatric patients for cancers that harbor genetic alterations in RAF. Oral, once-weekly dosed tovorafenib was also well-tolerated in the Phase 1 trial in pLGG, which is important for achieving

and maintaining long-term, durable responses in these patients. Further, tovorafenib received FDA breakthrough therapy designation for the treatment of pediatric patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. Tovorafenib also received orphan drug designation from the FDA for the treatment of malignant glioma. We conducted a pivotal Phase 2 FIREFLY-1 trial of tovorafenib as a monotherapy for pediatric patients with relapsed or refractory pLGG harboring an activating BRAF alteration. In April 2024, OJEMDA received accelerated approval from the FDA for the treatment of patients 6 months of age and older with relapsed or refractory pediatric LGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation based on the FDA's evaluation of the data from FIREFLY-1 as pivotal study, and other supportive data. Results 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. FIREFLY-2 is an ongoing Phase 3, randomized, multicenter study to evaluate the efficacy, safety, and tolerability of tovorafenib monotherapy versus standard of care chemotherapy. FIREFLY-2 is the confirmatory trial that will support the conversion of tovorafenib's accelerated approval by the FDA into a full approval. Approximately 400 patients, less than 25 years of age with an activating RAF alteration pediatric LGG requiring first-line systemic therapy, will be randomized 1:1 to receive either tovorafenib (Arm 1) or an investigator choice of standard of care chemotherapy (Arm 2). The first patient was dosed in FIREFLY-2 in March 2023; we expect to complete enrollment of FIREFLY-2 in the first half of 2026.

- **Deploy our differentiated and proven business development expertise to further expand our targeted oncology pipeline for patients with large unmet medical needs.** Our team has diverse backgrounds—from academia and drug research and development, to biopharmaceutical industry and business development experience. We have a proven track record of identifying and acquiring drug candidates and programs with potentially significant commercial opportunities, including successfully in-licensing our current drug candidates, tovorafenib from Takeda, DAY301 from MabCare and VRK1 from Sprint. We will continue to utilize our broad experience, as well as our network of trusted relationships, to source additional high-impact assets to further expand our targeted oncology pipeline.
- **Evaluate opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties.** We have entered, and may selectively in the future enter, into collaborations where we believe there is an opportunity to accelerate the development and commercialization of our products and product candidates—for example, 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. We intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.

Our Approach: Focused on Advancing First- or Best-in-Class Medicines for People of All Ages with Life-Threatening Diseases

Our company is focused on prioritizing the clinical development of novel targeted therapeutics in children and adults with equal intensity. Historically, most pharmaceutical companies focused discovery and development efforts for new cancer therapies on adult tumor types. An analysis of agents for which the first-in-adult trial, or FHCT, began between 2006 to 2011 found that of the 185 drugs relevant to the pediatric population, only about a one third were evaluated in the pediatric population, of which 30 ultimately received FDA approval (29 were adult only indications; only one received a pediatric indication within nine years of following evaluation in adults). This analysis found a median lag between FHCT and first-in-child trial, or FCCT, for agents that received FDA approval of 5.6 years. In October 2023, the World Health Organization published an analysis spanning 15 years from 2007 to 2022 concluding that of 440 agents used in 2,519 cancer treatment trials worldwide, approximately 41% have also been approved for use in children. Furthermore, only five have been approved for use exclusively in children. The median time between adult and pediatric approvals in this analysis was approximately three years.

We believe that now is the right time to revisit and correct historic assumptions about pediatric oncology drug development. In doing so, we believe there are unique advantages to developing new oncology products and product candidates in pediatric patients, in parallel with, or even in advance of, adult indications:

- ***Enriched responder populations.*** The generation of large-scale molecular profiling datasets necessary to define addressable subpopulations in pediatric oncology has accelerated over the last decade. This has

allowed scientists and drug developers to identify oncogenic drivers underlying numerous pediatric tumor types, and has revealed druggable oncogenic drivers in nearly 50% of pediatric cancers. Moreover, pediatric tumors are less heterogeneous and genomically more stable compared to highly heterogeneous adult tumors. Directly targeting these mutations may lead to deep and sustained anti-tumor activity, as demonstrated by other targeted oncology products.

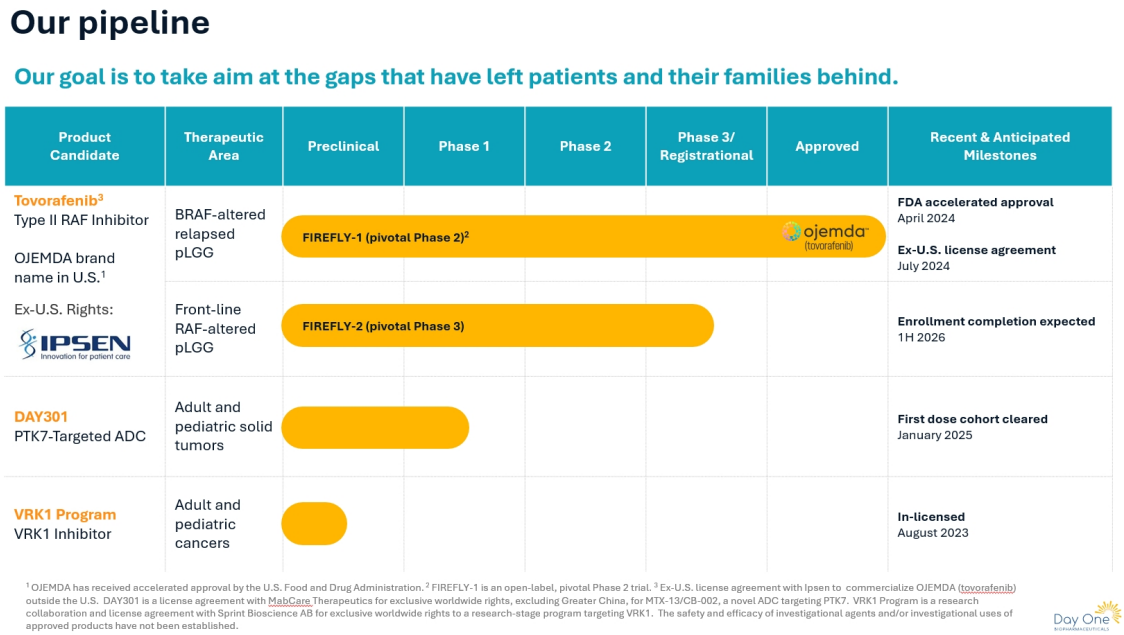
- ***Ability to efficiently advance clinical development.*** Recently, global regulatory authorities have established paths for accelerated feedback on the design and execution of clinical trials in pediatrics. As part of the FDA Reauthorization Act, 205 relevant molecular targets were identified for pediatric cancers. In addition, new tumor-specific pediatric oncology consortia and cooperative groups have been established, allowing industry to sponsor pediatric clinical trials in the same manner as adult clinical trials. Further, the potential to achieve proof-of-concept and regulatory approval can be obtained with relatively smaller-sized clinical trials with clear endpoints.
- ***Regulatory and commercial tailwinds.*** The scarcity of approved products or an established standard of care, particularly in relapsed disease in pediatric oncology, provides multiple opportunities to bring new therapeutics to market. Passionate patient advocacy groups and investigators have the potential to accelerate the uptake of therapies, if approved.

Our company is uniquely positioned to deliver much-needed targeted therapeutics to pediatric oncology patients. We have extensive capabilities and experience with these patients, and our trusted relationships across all key stakeholders in the pediatric medical community enable us to effectively navigate the challenges and nuances of pediatric drug development.

Our Product Candidates

We seek to identify, acquire and develop products and product candidates that target high-value oncogenic drivers in cancers with high unmet need. Although our clinical development begins by leveraging our unique

expertise in the pediatric oncology setting, we are committed to advancing targeted therapies for adult cancer patients with equivalent intensity. The following table summarizes our product and product candidate pipeline.



Tovorafenib

Our first commercial product, tovorafenib, is an oral, brain-penetrant, highly selective type II RAF kinase inhibitor. Tovorafenib has been studied in over 325 patients, and as a monotherapy demonstrated good tolerability and encouraging anti-tumor activity in pediatric and adult populations with specific MAPK pathway-alterations. We have now fully enrolled a pivotal Phase 2 FIREFLY-1 trial of tovorafenib as a monotherapy for patients with pLGG, the most common brain tumor diagnosed in children, for which there are no approved therapies and no recognized standard of care for the majority of patients. The FIREFLY-1 trial has also been expanded to: (a) include two additional study arms to enable expanded access for eligible patients now that the primary cohort has completed enrollment, and (b) evaluate the preliminary efficacy of tovorafenib in patients aged six months to 25 years with a relapsed or progressive extracranial solid tumor with an activating RAF fusion. We reported data from the registrational arm of the Phase 2 FIREFLY-1 trial at the American Society of Clinical Oncology annual meeting in June 2023 and selected analysis at the annual meeting of the Society of Neuro-Oncology in November 2023. In April 2024, 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.

We initiated a pivotal Phase 3 trial, or FIREFLY-2, evaluating tovorafenib as a front-line therapy in patients aged 6 months to 25 years with pLGG in June 2022. The first patient was dosed in FIREFLY-2 in March 2023. To date, patients continue to enroll in the United States, Canada, Europe, Australia and Asia, with approximately 113 sites activated. We expect to complete enrollment of FIREFLY-2 in the first half of 2026.

RAF kinase drives cell proliferation and carcinogenesis

Cell functions such as growth, survival and differentiation are regulated by cascades of signaling events of which RAF kinase is a critical component. RAF is a protein kinase that is normally activated by RAS, a protein that transmits activating signals from extracellular receptors to RAF. Activation of RAF then leads to the activation of MEK kinase and the downstream MAPK pathway. Genetic alterations that result in overactivation of the pathway, such as RAS or RAF alterations, have long been characterized as oncogenic.

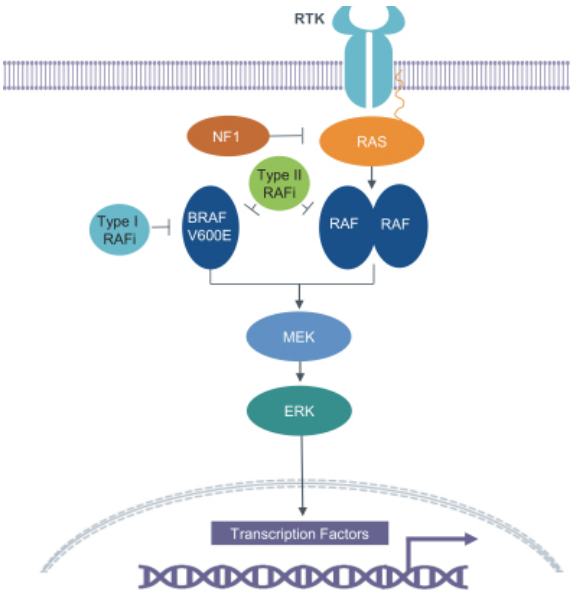


Figure 1. RAF kinases (ARAF, BRAF, CRAF) are critical components of the MAPK pathway. BRAF V600E can signal as a monomer and is sensitive to type I and type II RAF inhibitors. Wild-type RAF dimers are only sensitive to type II RAF inhibitors. Modified from: Solit and Rosen, Cancer Discover, 2014.

One of the most frequently altered genes in this pathway is BRAF, one of three RAF genes in human cells and the form of RAF most easily activated by RAS. The majority of alterations in BRAF are mutations known as V600. Mutations in V600 transform non-mutant or wild-type BRAF into a form of BRAF that has increased signaling activity and is no longer dependent on RAS for activation. The abundance of V600 mutant BRAF and its central role in tumor growth have made it a focus of historical drug discovery efforts.

Another class of important oncogenic BRAF alterations are BRAF wild-type gene fusions. Gene fusions involving BRAF occur through intra- or inter-chromosomal rearrangements in which genes for unrelated proteins are physically joined together resulting in the synthesis of a chimeric protein. BRAF consists of a regulatory domain which modulates the activity of BRAF, and a catalytic kinase domain which then activates downstream signaling to promote cell growth. In BRAF fusions, the regulatory domain of BRAF is replaced with a different sequence, allowing BRAF to signal independent of RAS activation. This uncoupling of the regulatory and catalytic domains of BRAF has important consequences: the resultant novel oncogene is both aberrantly expressed and it also exhibits constitutive, or always-on, activation of the kinase domain. This kinase activity can result in the activation of downstream oncogenic signaling, exacerbating tumor growth. BRAF gene fusions have been observed in patients with prostate cancer, melanoma, radiation-induced thyroid cancer, and pLGG.

Three BRAF inhibitors have been approved by the FDA for the treatment of certain solid tumors containing only BRAF V600E or V600K mutations, including melanoma, non-small cell lung cancer, anaplastic thyroid cancer, and colorectal cancer. 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. However, despite initial clinical responses to monotherapy type 1 RAF inhibitors, most patients relapse within one year following the initiation of treatment.

One way by which resistance develops to type I RAF inhibitors is related to the mechanism of normal RAF activation in cells. In contrast to the constitutively active V600E or V600K variant, which is active as a monomer, normal RAF function requires formation of dimers of RAF. Approved inhibitors of V600E/K BRAF do not block the activity of RAF dimers or other non-V600 BRAF mutations. In fact, the binding of some of these inhibitors to V600E/K BRAF can stimulate the formation of dimers, thereby causing paradoxical activation (undesired increases

in MAP kinase signaling) in RAF wild-type cells – a phenomenon which could potentially lead to renewed tumor growth. Paradoxical activation of wild-type RAF also occurs in non-tumor tissue. This leads to a common adverse event associated with these agents—the development of proliferative pre-malignant and malignant skin lesions. In order to avoid resistance and paradoxical activation, in many instances type I RAF inhibitors need to be given in combination with MEK inhibitors, but again only to patients with BRAF V600E/K mutations.

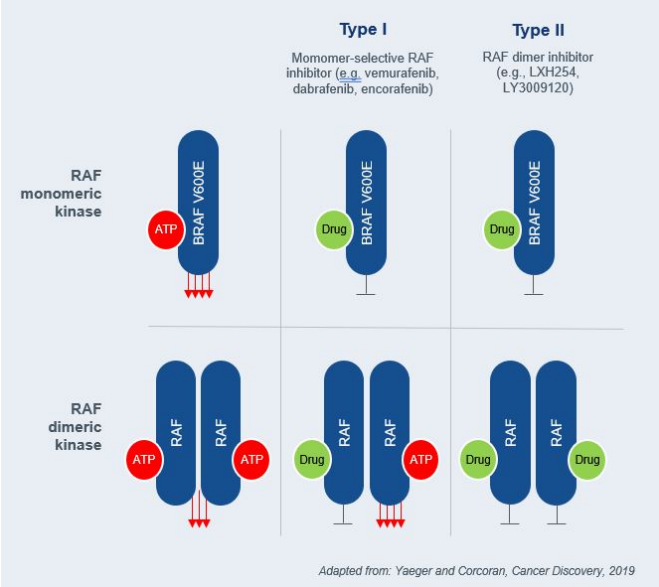


Figure 2. Schema showing the effect of different RAF inhibitors on monomeric RAF kinases (i.e., BRAF V600E; top section) or dimeric RAF kinases (bottom section). ERK activation is strongly activated downstream of BRAF V600E, even more so than seen for dimeric RAF kinase signaling. Monomer-selective type I RAF inhibitors bind to the ATP site in BRAF monomers and inhibit downstream signaling. In RAF dimeric kinases, binding of drug inhibits the bound RAF protomer, but leads to a conformational change in the other protomer in the dimer pair and strong transactivation of this protomer, leading to overall increased ERK activation (paradoxical activation). Type II RAF inhibitors are able to bind to mutant RAF monomers and dimers at equipotent doses and therefore can inhibit mutant RAF monomers and dimers at the same dose. Adapted from Yaeger and Corcoran, Cancer Discovery, 2019.

Type I RAF inhibitors that target V600E/K alterations are not able to inhibit the wild-type RAF kinase domains in KIAA1549-BRAF gene fusions and are thus unable to effectively inhibit the overactive signaling that results from this fusion. Furthermore, because of the potential for paradoxical activation, these RAF inhibitors are contraindicated in patients with BRAF gene fusions.

Tovorafenib's mechanism of action

Tovorafenib is a selective, small molecule RAF inhibitor that can block the activity of multiple forms of RAF including wild-type RAF, BRAF and CRAF fusion proteins, and variants that function as dimers (Class II mutations), as well as variants such as BRAF V600E and non-V600E mutations that function as monomers (Class I mutations). Tovorafenib is known as a type II RAF inhibitor as it's designed to inhibit both monomeric and dimeric RAF kinase. Tovorafenib's inhibition of both RAF monomers and dimers broadens its potential clinical application to treat an array of RAF-altered tumors.

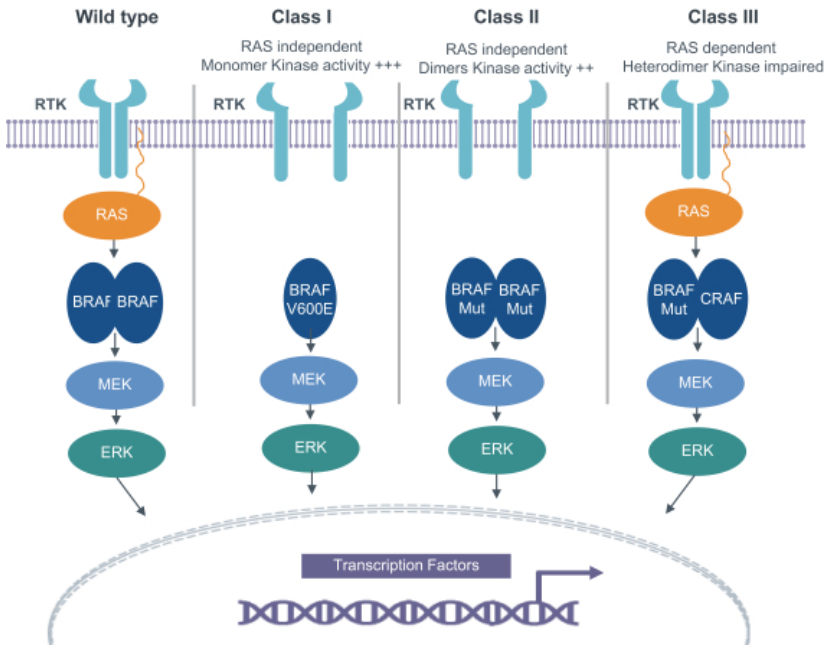


Figure 3. Signaling pathways in different classes of BRAF mutations. BRAF V600 mutations (Class I) are independent of RAS signaling and work as monomers. BRAF non-V600 Class II mutations are also independent of RAS but signal as constitutive dimers. The Class II mutations include BRAF wild-type fusions. Non-V600 Class III BRAF mutations have low or no kinase activity and depend on RAS activation acting as amplifiers of the RAS signaling pathway. Tovorafenib inhibits Class I and Class II RAF alterations, including BRAF wild-type fusions and non-V600E/K variations. Modified from Fontana and Valeri, Clinical Cancer Research, 2019.

Pediatric low-grade glioma disease and treatment overview

Pediatric low-grade glioma is the most common brain tumor diagnosed in children, accounting for 30%-50% of all central nervous system tumors. For the most part, these tumors are slow-growing, chronic, and relentless. While malignant transformation and dissemination of pLGGs are rare there are many long-term consequences of the disease. The growth of pLGG is highly morbid as pLGG tumors are space-occupying lesions that have the potential to compress critical neurovascular structures in the brain. Symptoms can vary from patient to patient depending on the location of the tumor and the amount of pressure it exerts on surrounding tissues. These symptoms can include headaches, nausea, vomiting, lethargy, sixth cranial nerve palsies, seizures and behavioral changes, depending on tumor location. The majority of children with pLGG are long-term survivors and live into adulthood; however, survivors of pediatric glioma often suffer long-lasting functional, neurologic, and endocrine complications from their disease and/or treatment. These patients require more effective treatment strategies that minimize long-term morbidity and treatment-associated toxicity.

Patients with pLGG have historically been treated with surgery, radiation, and chemotherapy. While surgical resection of pLGG is associated with 10-year overall survival rates of 90% or more, the majority of children are unable to undergo complete resection, a procedure which can be associated in some instances with significant and long-lasting morbidity. Incompletely resected or unresectable pLGG is associated with a high rate of disease progression or recurrence. Patients with subtotal resections have a 10-year progression-free survival of only 55%. Although more modern radiation therapy modalities have been shown to lead to improvements in progression free survival, radiotherapy is historically associated with a risk of significant decline in neurocognitive outcomes in younger children, as well as the risk of endocrine dysfunction, secondary malignancy, and an increased risk of stroke. As a result, even modern radiation therapy techniques continue to be reserved for use when all other therapies have failed.

Most patients with pLGG requiring initial systemic therapy are treated with combination chemotherapy such as carboplatin and vincristine or, in certain countries, vinblastine or carboplatin as single-agents. Results from the largest randomized Phase 3 study for children with newly diagnosed pLGG showed a 5-year event-free survival of 47% for vincristine/carboplatin. Outcomes for a subgroup of patients with pLGG not associated with neurofibromatosis, which included those with BRAF alterations, were inferior, showing a 5-year event-free survival of 39%. Of note, the overall response rate to chemotherapy in newly diagnosed patients with pLGG was 30%-35%. In addition to chemotherapy's efficacy limitations, treatment-related morbidity was significant, with more than 95% of patients having experienced at least one Grade 3 or Grade 4 adverse event. A number of therapies targeting pathway have been assessed in tumor types harboring molecular alteration on the MAPK pathway, including BRAF and MEK, as further discussed below. While some of these agents have been approved for the treatment of tumors harboring BRAF V600 mutation including in children with pLGG, there is no consensual standard-of-care therapy for patients whose tumors progress following the failure of these chemotherapy regiment or targeted therapies.

Because many pLGGs undergo senescence when patient ages reach their 20s, the goal of therapy is to maximize tumor control while minimizing treatment-associated toxicities from surgery, chemotherapy, and radiation. As a result, a large number of patients with pLGG will undergo multiple lines of systemic therapy over the course of their disease.

Based on incidence results published in academic journals, we estimate that approximately 1,100 patients under the age of 25 are newly diagnosed with BRAF-altered pLGG every year. We partnered with an epidemiology firm to perform SEER and CBTRUS registry analysis that estimates the prevalence, as of January 1, 2017, in the United States for BRAF-altered patients with pLGG under the age of 25 to be 26,000. The estimated addressable pool of recurrent, progressive, or refractory patients with pLGG for tovorafenib is approximately between 2,000 to 3,000 per year at steady state.

Over the last decade, it has been found that between 50% and 60% of pLGGs are driven by abnormal signaling due to alterations in RAF, approximately 85% to 90% of which are a gene fusion known as KIAA1549-BRAF. This gene alteration results in the expression of a wild-type BRAF catalytic domain without its normal regulatory domain, thereby rendering constitutively active BRAF activity. In addition, between 5% and 17% of children with pLGGs have tumors with a BRAF V600E activating mutation.

With the exception of the combination of dabrafenib-trametinib for patients >6 years of age with relapsed/progressive tumors bearing a BRAF V600E/K mutation, there have been no agents approved for use in this population and as such, are only available via clinical trials or off-label prescription. Off-label use, while common in the pediatric oncology setting, is recognized to be an inferior approach as it exposes children to potential risks without the associated safeguards that accompany comprehensive clinical development activities, such as long-term safety monitoring and pharmacovigilance activities. We believe that the intentional development of a specifically-targeted, brain-penetrant therapy for pLGG is essential to improve outcomes for these patients, particularly those with BRAF fusions, and patients with BRAF V600E mutations who are either <6 years of age or who have progressed on, or cannot tolerate, combined Type I RAF/MEK inhibition.

Clinical trial results for pLGG

Tovorafenib is currently being evaluated in an ongoing investigator-initiated, multi-center study (PNOC014, NCT03429803) in patients with relapsed or refractory gliomas (high- and low-grade) and other tumors that is being conducted by Dana-Farber Cancer Institute in collaboration with PNOC. The trial remains open but is closed to new patient accrual. As of June 2023, a total of 44 patients had been enrolled in Part B of this Phase 1 dose-escalation trial (9 patients in Part A, 35 patients in Part B), which was conducted at multiple institutions within the PNOC network. Once-weekly tovorafenib at doses as high as 420 mg/m^2/week were well-tolerated in patients ≥ 1.5m^2, while doses as high as 530 mg/m^2/week were found to be well-tolerated in patients < 1.5m^2. Data was presented at the 2022 Society for Neuro-Oncology meeting for the 35 patients studied in Part B. For this group, there were two complete responses, seven partial responses, fifteen patients with stable disease and eight patients who had progressive disease. There were six dose limiting toxicities, all at 530 mg/m^2/week, all Grade 3, and five known side effects (two fatigue, three rash, one menorrhagia).

As shown in Figure 4 below, the Phase 1 trial, which initially started in February 2018, was designed to determine maximum tolerated dose, or MTD, in pediatric patients. Part A of this trial was an initial dose-escalation of tovorafenib as monotherapy that utilized a 3+3 design. The starting dose of 280 mg/m2 was 80% of the adult

recommended phase 2 dose, or RP2D, of 600 mg orally once weekly, adjusted for body surface area. Patients enrolled in this trial were treated for a period of up to two years. The trial was amended in December 2019 to continue dose escalation, using an adaptive design, until either dose limiting toxicities, or DLTs, or the MTD was observed.

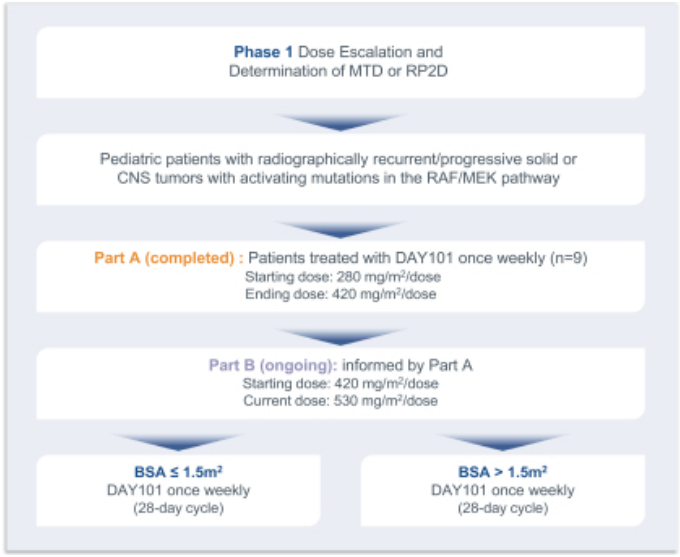


Figure 4. Design of the Phase 1 trial of tovorafenib in pLGG.

Tovorafenib was studied in a Phase 1 investigator-initiated trial (PNOC014; NCT03429803) in which it was administered once weekly as oral immediate release tablets to patients with relapsed or refractory tumors with LGGs and other RAS/RAF/MEK/ERK pathway-activated tumors. Data from Part A of this study was presented in November 2020 in which tovorafenib was evaluated at three different dose levels: 280 mg/m2, 350 mg/m2, and 420 mg/m2, with three patients at each dose level. Tovorafenib was well tolerated at all doses tested with no dose reductions or interruptions in patients receiving doses of 420 mg/m2 or below. None of these patients experienced a DLT. The vast majority of treatment emergent adverse events, or TEAEs, were Grade 1 or 2. No ophthalmologic or cardiac adverse events were observed. The most frequently reported TEAEs across all dose cohorts in Part A were all Grade 1 or 2 in severity and included rash (89%), graying of the hair (achromotrichia) (78%), moles (nevus) (78%), anemia (67%), and itching (pruritis) (67%). One patient experienced a single Grade 3 adverse event (increased creatinine phosphokinase), and there were no Grade 4 adverse events reported. These side effects were found to be reversible and manageable.

While 420 mg/m2 was initially considered the RP2D because of anti-tumor activity observed at all dose levels in Part A, dose escalation was continued in Part B of this study an attempt to determine a MTD. Upon resumption of the dose-escalation portion in Part B of this trial, the dose escalation was split between two subgroups, based on body surface area, to account for the possibility that at dose levels of 530mg/m2 or higher there might be larger children that may exceed the adult MTD at a given dose level, while smaller children may not. Data from Part B of this study was presented in November of 2022. Thirty-five additional patients were enrolled in Part B PNOC014: 21 patients with gliomas bearing a KIAA1549:BRAF fusion, nine patients with tumors bearing a BRAFV600E mutation, four with a novel RAF- and one with an FGFR1-altered tumor. Histologically, the cohort included 30 LGGs, four high grade gliomas and one soft tissue sarcoma. There were six DLTs: three in each body surface area, or BSA, subgroup, all at 530 mg/m2/dose, all Grade 3, and five known side effects (two fatigue, three rash, one menorrhagia). Across these 35 patients, oral weekly tovorafenib was well tolerated. While the TITE-BOIN continuous reassessment model recommended 530 mg/m2/dose per os, or PO, weekly for patients with BSA < 1.5m2 and 420 mg/m2/dose PO weekly for patients with BSA >1.5m2, the probability of a DLT for patients with a

BSA < 1.5m2 was found to be nearly 20%. As such, 420 mg/m2/dose PO weekly was selected as the dose for the pivotal Phase 2 FIREFLY-1 and pivotal Phase 3 FIREFLY-2 studies.

Overall, data from the now-completed Part A, where the patients received up to two years of continuous treatment, supported by data from Part B, indicate that the tolerability profile of tovorafenib at 420mg/m2 supported the potential for chronic long-term usage of tovorafenib.

Based on the results from Part A of PNOC014, tovorafenib was granted breakthrough therapy designation by the FDA for the treatment of pediatric patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. Tovorafenib also received orphan drug designation from the FDA for the treatment of malignant glioma.

Clinical development plan for pLGG

We have completed enrollment of a pivotal Phase 2 FIREFLY-1 trial of tovorafenib in pediatric patients aged six months to 25 years with relapsed or refractory pLGGs harboring an activating BRAF alteration, such as a KIAA1549-BRAF fusion or a BRAF activating mutation, such as V600E. This is an open-label, global registrational, single-arm trial of oral tovorafenib administered once weekly at a dose of 420 mg/m2. Patients are allowed to continue on tovorafenib until radiographic evidence of disease progression by RANO criteria as determined by treating investigator, unacceptable toxicity, patient withdrawal of consent, or death. The first patient was dosed in FIREFLY-1 in May 2021 and we completed enrollment in the registrational arm in May 2022. The FIREFLY-1 trial was also expanded to: (a) include two additional study arms to enable expanded access for eligible patients now that the primary cohort has completed enrollment, and (b) evaluate the preliminary efficacy of tovorafenib in patients aged six months to 25 years with a relapsed or progressive extracranial solid tumor with an activating RAF fusion. This trial generated a dataset that, in combination with the existing safety database, served as the basis for regulatory approval. The primary endpoint was overall response rate, defined as the proportion of patients with best overall confirmed response rate (complete response and partial response based on the RANO criteria), as determined by independent review. Secondary and exploratory endpoints include the overall response rate based on RAPNO and volumetric analyses, event free survival, safety, functional outcomes, and quality of life measures. In April 2024, evaluation of the data from FIREFLY-1 by FDA resulted in accelerated approval of tovorafenib in the United States for the treatment of patients 6 months of age and older with relapsed or refractory pediatric LGG harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. 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.

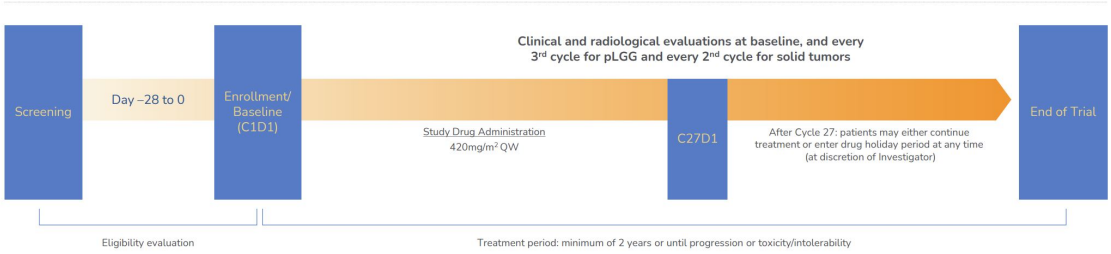


Figure 5. Design of the Phase 2 trial of tovorafenib in pLGG.

Tovorafenib is currently dosed as immediate-release tablets. We have developed a pediatric formulation suitable for oral dosing of children as young as six months of age and have dosed patients with this pediatric formulation in our pivotal Phase 2 FIREFLY-1 trial.

Comprehensive genomic profiling of newly diagnosed or recurrent/progressive pLGG is standard practice within pediatric neuro-oncology programs across the United States, either utilizing CLIA/College of American Pathologists, or CAP, accredited hospital laboratories or third-party commercial vendors. In addition, the 2021 revision of the WHO Classification of Tumors of the Central Nervous System now includes assessment of BRAF

mutation or fusion status as part of the diagnosis of LGGs. As a result, we expect that the vast majority of both patients with newly diagnosed and relapsed pLGG harboring a BRAF alteration will be identified. The technology platforms and solutions for the identification of the BRAF V600E mutation and BRAF wild-type fusions currently in use by individual investigators will be used to meet the clinical trial enrollment criteria, while we continue to work with regulatory authorities to ensure that any requirement for a companion diagnostic assay or device are met, for which we have entered into a collaboration with Foundation Medicine, Inc. to develop.
In January 2025, the FDA approved FoundationOne CDx to be used as a companion diagnostic for OJEMDA.

We have initiated a pivotal Phase 3 FIREFLY-2 trial of tovorafenib as a front-line therapy in pLGG. The first patient was dosed in March 2023. We believe that treating patients before they have undergone multiple rounds of toxic chemotherapy has the potential to both improve the efficacy of tovorafenib and reduce the overall burden of therapy and associated toxicities associated with the use of currently-employed cytotoxic agents. We expect to complete enrollment of FIREFLY-2 in the first half of 2026.

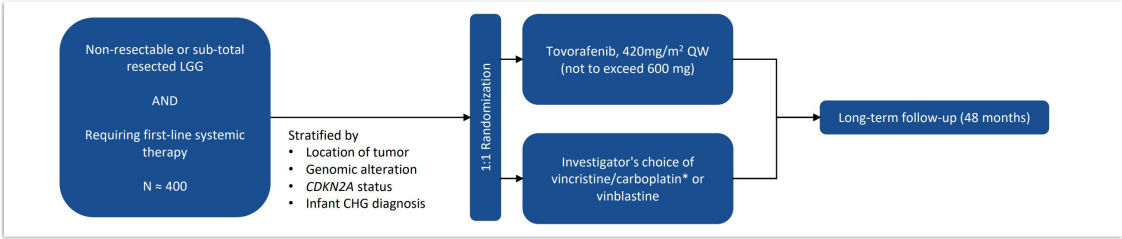


Figure 6. Design of the Phase 3 trial of tovorafenib in pLGG.

Potential market opportunity for tovorafenib in pLGG

Brain tumors are the most frequently occurring solid tumors in children. While pLGG is the most common brain tumor diagnosed, representing approximately 30% of all childhood brain tumors, the annual estimated incidence of pLGG is 1.3 to 2.1 per 100,000 in the United States. Given the incidence of this disease, our team recognized the market opportunity for developing tovorafenib in this patient population based on the following rationale:

- Potential for tovorafenib, a type-II RAF inhibitor, to be a high-impact targeted therapeutic in pLGG where approximately 70% of tumors are BRAF-altered pLGG in the United States.
- Premium reimbursement precedents for high impact therapeutics in rare diseases, oncology and pediatrics.
- Chronic duration of treatment required over many years to address these slow-growing and relentless tumors.
- High unmet medical need with limited current treatment alternatives for patients.
- Strong value proposition for physicians, patients and families.

We believe tovorafenib, if approved, could become the standard of care for the treatment of pLGG. Due to the need for chronic administration, potentially over many years, the standard of care should be an effective, long-term therapeutic while providing a tolerability profile that minimizes long-term morbidity and treatment-associated toxicity. We believe that tovorafenib has the potential to provide long-term benefit—similar to effective therapies for more traditional chronic rare diseases—to patients with pLGG. We also believe that tovorafenib's oral, once-weekly dosing regimen would appeal to physicians, patients and their parents.

Investigator-initiated trials of tovorafenib

We intend to leverage our relationships with academic investigators and pediatric oncology cooperative groups and consortia to explore the potential for tovorafenib in other rare pediatric tumor types. The following investigator-sponsored trials are currently open to enrollment as of January 2025:

A Phase 2 trial in relapsed Langerhans cell histiocytosis was initiated in March 2022 by 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. This study is part of a Written Request issued by the FDA, and is planned as a single-arm non-randomized trial which has an estimated enrollment of 56 participants, who will be administered tovorafenib to determine overall response rate for children and young adults with recurrent or progressive Langerhans cell histiocytosis.

A second Phase 2 trial in craniopharyngioma was initiated in July 2022 by the Pacific Pediatric Neuro-Oncology Consortium. This study was originally designed as a randomized multi-arm trial, where patients would be administered nivolumab and tovorafenib in combination with nivolumab to assess the tolerability and efficacy of combination therapy with PD-1 (nivolumab) and pan-RAF-kinase (tovorafenib) inhibition for the treatment of children and young adults with craniopharyngioma, however, the study was amended in January 2025 as a single-arm study of tovorafenib only with an estimated enrollment of 57 patients.

A Phase 1/2 study of tovorafenib in combination with vinblastine was initiated in 2024 by the Hospital for Sick Kids in Toronto, Canada, in collaboration with the C17 Council, in patients with relapsed/refractory pediatric low-grade glioma. The study is anticipated to enroll approximately 55 patients.

DAY301

Our second product candidate, DAY301, is a PTK7-targeted ADC composed of a novel humanized anti-PTK7 immunoglobulin G1 monoclonal antibody, or mAb, (referred to as DAY301 mAb) conjugated with a topoisomerase I inhibitor (exatecan mesylate [exatecan]) via a highly stable and hydrophilic modified valine-alanine (VA) cleavable linker. DAY301 is intended for the treatment of patients with advanced solid tumors.

DAY301 targets PTK7, a highly-conserved, catalytically inactive transmembrane protein that is overexpressed in multiple adult cancers. DAY301 demonstrated encouraging preclinical antitumor efficacy in relevant tumor models representing a wide range of solid tumors, including ovarian cancer, NSCLC, TNBC, SCLC, ESCC, CSCC, colorectal cancer, and esophageal adenocarcinoma. DAY301 was tolerated in non-human primate nonclinical toxicology studies with favorable pharmacokinetic and safety profiles. Collectively, the data suggest that DAY301 could potentially have a wide therapeutic window in clinical testing and therefore provide benefits for cancer patients with high unmet medical needs.

Clinical development plan

We have initiated a Phase 1a/b dose-escalation and cohort expansion study to evaluate the safety and tolerability of DAY301 in patients with tumor types known to have high PTK7 expression. The objective of the Phase 1a study is to identify two recommended dose levels for further evaluation based on safety and anti-tumor activity. Once the two recommended doses are established, a minimum of two cohorts of patients selected based on PTK7 expression clinical trial assay will be enrolled in the Phase 1b dose expansion and optimization portion of this trial. The objective of the Phase 1b study is to define an optimized dose and to define clinical activity in one or more histologically defined tumor types for a potential single-arm registrational trial for accelerated approval or randomized trial. The primary endpoint for the Phase 1a/b study is safety. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial.

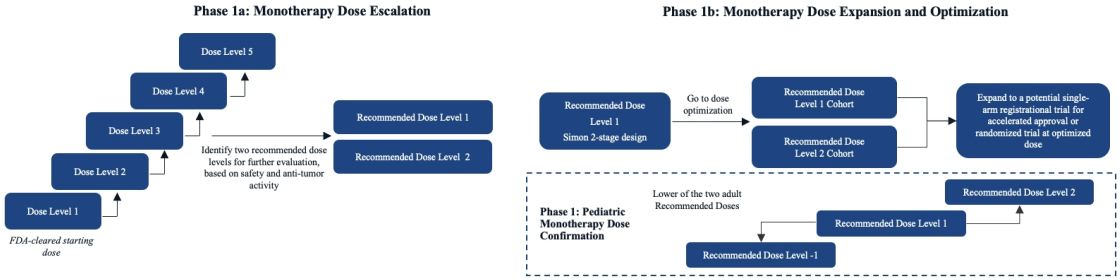


Figure 7. Design of the Phase 1a and Phase 1b trials of DAY301.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well

as for commercial manufacturing. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as our commercial products. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, for tovorafenib, we have contracted to obtain active pharmaceutical ingredients, or API, drug product, and packaging services for our product candidates from STA Pharmaceutical Hong Kong Limited, Quotient Sciences – Philadelphia, LLC, Experic, LLC and Sharp Packaging Services, LLC, respectively, upon whom we currently rely as single-source contract manufacturing organizations, or CMOs. We have agreements under which third-party CMOs will generally provide us with necessary quantities of API, drug product and packaged product on an order by order basis, based on our development needs. For commercial supply of tovorafenib, we have negotiated supply agreements to meet the anticipated commercial demand of the product. As we advance our product candidates through development, we will explore adding backup suppliers for the API, drug product, packaging and formulation for each of our product candidates to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Commercialization

In order to deliver the best outcomes for patients of all ages, we aim to identify and develop first-in-class or best-in-class medicines for childhood and adult diseases with equal intensity. To deliver these medicines to prescribers and patients, we have spent years taking a measured approach to building our commercial capabilities in the United States in preparation for the launch of our first product, OJEMDA. Our commercial team consists of experts in access and distribution, marketing and sales. Our access team engages with managed care, government payers, hospital systems, specialty distributors and specialty pharmacies to ensure the effective distribution and coverage for our product. The marketing team sets the strategy for the brand and delivers the materials needed to engage physicians and patients and provide information about our product. In the United States, pLGG is treated by a focused group of specialists, which has enabled us to build a very efficient sales organization with 18 representatives calling on the approximately 200 accounts that treat over 90% of pLGG patients.

Outside of the United States, we have entered into a collaboration agreement with Ipsen to distribute and commercialize OJEMDA, leveraging a company with established teams and deep expertise in these markets instead of building these capabilities internally. For future molecules, each molecule will be individually assessed to determine our strategy in key markets.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

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 regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval

for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and patient convenience.

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. Dabrafinib, 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 (approximately 10%-20%) of the greater RAF-altered pLGG clinical scope of the tovorafenib development program.

Five 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. Two have been approved for the treatment of pediatric patients, 2 years of age and older, with neurofibromatosis type 1, or NF1, who have symptomatic plexiform neurofibromas not amenable to complete resection, including selumetinib, marketed as Koselugo® by AstraZeneca and mirdametinib, marketed as Gomekli® by SpringWorks.

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 alterations. 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. Pfizer’s PF-07799933 (ARRY-440) is a brain-penetrant BRAF-selective monomer/dimer inhibitor that spares ARAF and CRAF, that is currently being evaluated in a phase 1 trial in adults with solid tumors.

With regard to the treatment of pLGG, dabrafenib, in combination with trametinib, has been evaluated in a Novartis-sponsored randomized Phase 2 clinical trial in newly diagnosed patients with BRAF V600 mutant pLGG. Novartis received full approval of the dabrafenib-trametinib combination in that indication in March 2023.

Further, some MEK inhibitors and some type I RAF inhibitors and other targeted therapies are being studied in academic investigator-initiated clinical trials, and in some regions may be being used in an off-label manner. These agents may represent competition for OJEMDA when it 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. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial. 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, a PTK7-targetted ADC with an auristatin payload. 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, a PTK-7 targeted ADC with an exatecan payload.

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. 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 of the company from an LLC to a corporation 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. 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 of the company from an LLC to a corporation, 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. We paid $2.0 million upfront in cash to Viracta.

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.

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 in exchange for reduced future payment obligations 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.

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.

On December 3, 2024, Viracta assigned the Viracta License Agreement to XOMA (US) LLC, or XOMA, pursuant to a Royalty Purchase Agreement dated March 22, 2021, between Viracta and XOMA, whereby Viracta sold its right, title, and interest in and to the Viracta License Agreement to XOMA. We have agreed to the

assignment and novation of the Viracta License Agreement to XOMA as successor party, now XOMA License Agreement. No material terms of the XOMA License Agreement have been amended or modified in relation to the same.

As of December 31, 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. 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. 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. As of December 31, 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.

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 an inhibitor targeting 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. As of December 31, 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.

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. 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 granted 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. As of December 31, 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.

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 December 31, 2024, we are also eligible to receive up to approximately $330.0 million based on exchange rates as of the reporting date 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.

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.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates, technology and know-how, to operate without infringing the proprietary or intellectual property rights of others and to prevent others from infringing our proprietary or intellectual property rights. We expect that we will seek to protect our proprietary and intellectual property position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and drug candidates that are important to the development and implementation of our business. We also rely on trade secrets, know-how, trademarks, continuing technological innovation and licensing opportunities to develop and maintain our proprietary and intellectual

property position. Presently, our patent portfolio includes issued patents and pending patent applications that are in-licensed, owned and/or co-owned by us.

We currently, and expect that we will continue to, own, co-own or in-license patent applications and issued patents related to our drug candidates, as well as their use in the treatment of various diseases such as pediatric cancers. For our drug candidates, we generally pursue multilayered patent protection covering compositions of matter, methods of use and methods of manufacture. We intend to strengthen the patent protection of our drug candidates and technologies through additional patent application filings.

As of January 1, 2025, we owned or co-owned a patent portfolio consisting of eleven patent families, non-exclusively in-licensed one patent family from Takeda Pharmaceutical Company Limited, exclusively in-licensed one patent family from MabCare Therapeutics and non-exclusively in-licensed three patent families from MabCare Therapeutics. Our owned or co-owned patent families include patent families that cover compositions of matter, pharmaceutical compositions, methods of synthesis, synthetic intermediates, methods of treatment and combination therapies related to tovorafenib. Certain patents and patent applications of our owned or co-owned patent portfolio have been out-licensed to Ipsen Pharma SAS, on an exclusive basis, with the right to commercialize tovorafenib in all territories outside the United States (see License agreement with Ipsen Pharma SAS, herein). The non-exclusively in-licensed patent family from Takeda Pharmaceutical Company Limited covers a catalyst that may be used in a preparation of our product candidate tovorafenib. The patent families in-licensed from MabCare Therapeutics cover the composition of matter, linker, and methods for use of our product candidate, DAY301. Patent terms for our owned, co-owned or licensed patents discussed herein exclude any patent term extension that may be awarded.

Our owned or co-owned patent portfolio, as of January 1, 2025, includes a co-owned patent family that is directed to the compositions of matter and methods of use of tovorafenib with four issued U.S. patents and multiple foreign patents and applications including granted patents in Germany, France, United Kingdom, Belgium, Switzerland, Denmark, Spain, Ireland, Italy, Netherlands, Australia, Brazil, Canada, China, India, Japan, Korea, Mexico, Russia, Singapore, South Africa, Taiwan, and Hong Kong, which are expected to expire between 2028 and 2031.

Our owned or co-owned patent portfolio includes a patent family that is directed to pharmaceutical formulations of tovorafenib with an issued U.S. patent and multiple foreign patents and applications including granted patents in Germany, France, United Kingdom, Belgium, Brazil, Canada, Switzerland, Spain, India, Ireland, Italy, Luxembourg, Monaco, Japan, and China, which are expected to expire in 2035. Our owned or co-owned patent portfolio includes an additional pharmaceutical formulation patent family that is directed to formulations of tovorafenib including pending applications in the United States, Europe, China, Hong Kong, and Japan that, if issued, are expected to expire in 2040. Our owned or co-owned patent portfolio includes a patent family directed to additional formulations of tovorafenib with pending applications in the United States, Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, Kuwait, Mexico, Russia, Saudi Arabia, and the United Arab Emirates, that, if issued, are expected to expire in 2043. Our owned or co-owned patent portfolio also includes a patent family directed to methods of synthesizing tovorafenib including two issued U.S. patents, and granted patents in Australia, Eurasia, Europe, Spain, United Kingdom,,Israel, Japan, India, China, Hong Kong, Singapore, and Mexico which are expected to expire in 2038 as well as pending applications in China, Brazil, Korea, Europe, Canada, Hong Kong, and Singapore that, if issued, are expected to expire in 2038. Our owned or co-owned patent portfolio further includes a patent family directed to methods of treating cancer using tovorafenib in combination with docetaxel with multiple foreign patents including granted patents in China, Germany, France, United Kingdom, Belgium, Switzerland, Spain, Ireland, Italy, Luxembourg, and Monaco that are expected to expire in 2035. Our owned or co-owned patent portfolio includes a patent family directed to methods of treating pLGG including pending applications in the United States, Singapore, Mexico, Korea, Japan, Hong Kong, Europe, China, Canada, and Australia that, if issued, are expected to expire in 2041. Our owned or co-owned patent portfolio includes a patent family directed to methods of treating cancer using tovorafenib in combination with a MEK inhibitor including pending applications in the United States, South Africa, Singapore, New Zealand, Mexico, Korea, Japan, Israel, Europe, China, Canada, Brazil, and Australia that, if issued, are expected to expire in 2042. Our owned or co-owned patent portfolio includes a patent family directed to methods of selecting patients for treatment with tovorafenib with pending applications in the United States and Europe, that, if issued, are expected to expire in 2042. Our owned or co-owned patent portfolio includes a patent family with one U.S. provisional application directed to methods of treatment with a MEK inhibitor that, if converted to a non-provisional application and issued, is expected to expire

in 2045. Our owned or co-owned patent portfolio further includes an additional patent family with a pending PCT application directed to methods of treating pLGG that, if nationalized and issued, is expected to expire in 2044.

Our patent portfolio, as of January 1, 2025, includes patent families in-licensed from Mabcare Therapeutics that cover composition of matter, methods of use, and synthetic intermediates of DAY301. One patent family includes a pending PCT and pending Taiwanese application directed to the composition of matter and use of DAY301, that if nationalized and issued, is expected to expire in 2044. The MabCare in-licensed portfolio also includes three patent families directed to an ADC linker used in DAY301 and includes pending applications in U.S. and foreign jurisdictions that, if issued, are expected to expire in 2042. Details of the terms of the license agreement with Mabcare Therapeutics are discussed under the heading License agreement with MabCare Therapeutics herein.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries in which we file, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. Additionally, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time a drug is under regulatory review while a patent that covers the drug is in force. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our future drug candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, if available. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and, if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see the section titled “Risk Factors–Risks Related to Our Intellectual Property.”

The patent positions of biopharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see the section titled “Risk Factors–Risks Related to Our Intellectual Property.”

In addition to patent protection, we also rely on trade secrets, know-how, trademarks, other proprietary information and continuing technological innovation to develop and maintain our competitive position. Our trademark portfolio currently contains applications and/or registrations for Day One and Day One Biopharmaceuticals in the United States as well as applications for OJEMDA, the marketing name for tovorafenib, in the United States, Canada, the European Union, Iceland, Liechtenstein, Norway, Switzerland and the United Kingdom. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in

specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, marketing, distribution, post-approval monitoring, studies, and reporting, sampling, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA approval process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, pursuant to the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and other federal and state statutes and regulations that govern, among other things, the research, development, testing, manufacture, quality, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, marketing, distribution, post-approval monitoring, studies, and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical holds, FDA refusal to accept new marketing applications or approve pending applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil monetary penalties, and criminal prosecution, penalties and fines.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. The FDA holds broad discretion under the FDCA and other statutes to interpret the conditions and evidence necessary for timely approval of our drugs. Satisfaction of FDA pre-approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials must be conducted: (i) in compliance with federal statutory requirements and regulations; (ii) in compliance with Good Clinical Practices, or GCPs, international standards meant to protect the rights and health of study subjects and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving human clinical testing in the United States and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical study subjects. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board, or IRB, for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the study presents an unacceptable risk to patients, or may impose other

conditions. Additionally, certain clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as Data Safety and Monitoring Boards or Data Monitoring Committees. These groups conduct safety assessments and make recommendations regarding whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, in some instances, early evidence of effectiveness. If the safety profile of the drug in the Phase 1 study is supportive, Phase two studies may be initiated. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single trial may be sufficient in rare instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence.

These Phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose- escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. The FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA is also subject to annual program fees. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

The FDA reviews each submitted NDA before it determines whether to file it, based on the agency's threshold determination that it is sufficiently complete to permit substantive review, and the FDA may request additional information. The FDA must make a decision on whether to file an NDA within 60 days of receipt, and such decision could include a refusal to file by the FDA. If the submission is filed, the FDA begins an in-depth review of the NDA. The FDA has agreed to certain non-binding performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within 10 to 12 months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority NDAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current Good Manufacturing Practices, or cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also typically inspects one or more clinical trial sites to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter, or CRL. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application, such as additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, engage in formal dispute resolution, or request an opportunity for a hearing. The FDA has committed to reviewing resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If, or when, the deficiencies identified in the CRL have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market for and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if the FDA determines that the drug is not safe and effective under the approved conditions of use or if the sponsor fails to comply with certain regulatory requirements.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of an NDA supplement or, in some cases, a new NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of clinical trial information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on clinicaltrials.gov. Information related to the intervention (e.g., drug product), patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, is then made public as part of the registration. Sponsors are also required to submit the results of their clinical trials no later than one year after the primary completion date of the trial. Disclosure of the results of these trials can be delayed in certain circumstances upon timely submission of a certification, but results must be submitted not later than 2 years after the certification's submission. Extensions may be available for good cause. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which the FDA has granted orphan designation is entitled to a seven-year exclusivity period in the United States for the specific product and the specific indication for which orphan designation was granted. During the seven-year exclusivity period, the FDA may not approve any other sponsor's application to market the same drug for the same indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues or consent by the exclusivity holder. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same indication, or the same drug for a different indication. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the user fee required to submit an NDA, as long as the NDA does not seek approval of an indication that has not received orphan drug designation.

In September 2021, the U.S. Court of Appeals for the Eleventh Circuit held in *Catalyst Pharmaceuticals, Inc. v. Becerra* that the FDA had erred by limiting the scope of orphan drug exclusivity for FIRDAPSE® (amifampridine) to the product's approved indication, an action that the FDA took in accordance with its regulations interpreting the Orphan Drug Act. The court held that under the Orphan Drug Act, FIRDAPSE®'s orphan drug exclusivity instead protected the rare disease or condition that received orphan drug designation. Following this court decision in the Catalyst case, the FDA announced in January 2023 that it would continue to apply the FDA's regulations limiting the scope of orphan drug exclusivity to a product's approved uses or indications. As a result of the FDA's announcement, the scope of orphan drug exclusivity and other issues relating to the FDA's implementation of the Orphan Drug Act with respect to previously approved and future products may be the subject of further litigation or legislation.

Breakthrough therapy designation

The FDA is also required to expedite the development and review of applications for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Accelerated approval

Accelerated approval of an NDA may be granted for a product that is intended to treat a serious or life-threatening disease or condition on the basis of either 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. Drugs granted accelerated approval generally provide a meaningful therapeutic advantage to patients over existing treatments.

The accelerated approval pathway is often used in settings in which the course of a disease is relatively long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Accelerated approval is frequently used in the development and approval of products for treatment of a variety of cancers in which the ultimate goal of therapy is to improve overall survival or decrease serious long-term morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a survival or long-term clinical benefit.

The accelerated approval pathway generally requires a sponsor's agreement to conduct an additional post-approval confirmatory study or studies to verify and describe the product's clinical benefit. Any such confirmatory trial must be completed with due diligence and the FDA may require that the trial be underway prior to approval. Failure to conduct such required post-approval studies with due diligence, or to confirm a clinical benefit during such studies, would allow the FDA to withdraw the product from the market on an expedited basis. In addition, the FDA currently requires, as a condition of accelerated approval, the pre-submission of promotional materials, which can adversely impact the timing of the commercial launch of a product. The accelerated approval pathway does not always lead to a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

Pediatric information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Alternatively, for an original NDA for a new active ingredient, the application could instead be required to include reports on a molecularly targeted pediatric cancer investigation, if the drug is intended for the treatment of an adult cancer and directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The FDA may grant full or partial waivers, or deferrals, for either requirement. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. This exemption does not apply to an original NDA for a new active ingredient for an indication that is orphan-designated if the NDA is subject to the molecularly targeted pediatric cancer investigation requirement.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of unexpired exclusivity if certain conditions are met. For NDAs, pediatric exclusivity will attach to unexpired nonpatent and patent exclusivity listed in the Approved Drug Products With Therapeutic Equivalence Evaluations for any drug containing same active moiety as the drug studied. Conditions for earning pediatric exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, the applicant agreeing to perform and completing those studies, and the applicant reporting on the requested studies within the statutory timeframe for pediatric exclusivity to be granted. Applications and supplements proposing a labeling change as a result of a pediatric study conducted under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-approval requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the advertising, promotion, marketing, and communications relating to approved drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and communications on social media and on the Internet. Drugs may be marketed only for their approved indications and in a manner consistent with the FDA-approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require, or ask the sponsor to commit to, certain post-marketing surveillance, studies, and/or testing. These post-approval obligations are known as post-marketing requirements or post-marketing commitments depending on the authorities under which they are imposed. The FDA also may require enhanced safety surveillance to monitor potential adverse events relating to the approved product or impose a REMS to ensure that the benefits of the product outweigh the risks. Depending on the severity of the safety concern, a REMS may place conditions restricting the distribution or use of the product.

Further, FDA extensively regulates all aspects of manufacturing quality for pharmaceuticals under their cGMP regulations. Quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs.

Manufacturing quality and other post-approval regulatory compliance is heavily scrutinized by FDA and may result in government investigations, regulatory and legal actions, product recalls and seizures, product approval withdrawals, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in new product approvals or line extensions or supplemental approvals of current products pending resolution of any issues, any of which have and could adversely affect our business and reputation.

Rare pediatric disease designation and priority review vouchers

Under the Rare Pediatric Disease Priority Review Voucher Program, the FDA may award a priority review voucher to the sponsor of an approved marketing application for a product that treats or prevents a rare pediatric disease. A rare pediatric disease is a serious or life-threatening disease or condition that affects less than 200,000 persons in the United States; affects more than 200,000 persons in the United States with no reasonable expectation of recovering the cost of developing and making the drug available in the United States; or is an orphan subset of a disease or condition that otherwise affects 200,000 or more persons in the United States. A voucher may be awarded only upon approval of a rare pediatric disease product application. A rare pediatric disease product application is a marketing application that meets the following criteria: the application is for a product that treats or prevents a rare pediatric disease; the application must be deemed eligible for priority review; the application must not seek approval for an adult indication; the product must not contain an active moiety or ingredient (as applicable) that has been previously approved by the FDA; the application must be submitted under section 505(b)(1) of the FD&C Act; and the application must rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population such that the approved product can be adequately labeled for the pediatric population. At a sponsor's request, the FDA may designate a product as a product for a rare pediatric disease and the application for the new product as a rare pediatric disease product application.

A sponsor must notify the FDA, upon submission of the rare pediatric disease application, of its intent to request a voucher. The FDA may revoke a rare pediatric disease priority review voucher if the product for which it was awarded is not marketed in the United States within 365 days of the product's approval. The voucher, which is transferable to another sponsor, may be submitted with a subsequent application and entitles the holder to priority review of that application. The sponsor using a rare pediatric disease priority review voucher must notify FDA of its intent to submit the voucher with the NDA at least 90 days prior to submission of the application and must pay a priority review user fee determined by the FDA in addition to any other required user fee. Under the FDA's current performance goals, the FDA's goal is to take action on a priority review application within six months.

In December 2020, Congress reauthorized the rare pediatric disease priority review voucher program. Under the terms of that reauthorization, after September 30, 2024, the FDA will be able to award vouchers only if the designations were granted on or before that date, although in September 2024 this date was extended by Congress to December 20, 2024. Under current law, the FDA may not award rare pediatric disease priority review vouchers after September 30, 2026.

The Hatch-Waxman amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the HatchWaxman Amendments or Hatch-Waxman, NDA applicants are required to submit to the FDA information about each patent for which a patent infringement claim could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug, and that claims the applicant's drug (i.e., and is a drug substance or drug product patent), or that claims a method of using the drug, or listing requirements, based on the proposed labeling. Upon approval of a drug, the applicant must again submit patent information to the FDA based on the approved labeling in a timely fashion regarding patents that satisfy the listing requirements for the drug, and information about each of these patents is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

A drug listed in the Orange Book potentially may be identified by a generic manufacturer as a reference listed drug in an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, dosage form, and labeling as the reference listed drug, subject to certain exceptions, and is bioequivalent to the reference listed drug. An approved ANDA product generally is considered to be therapeutically equivalent to the reference listed drug. Other than any data submitted to show bioequivalence, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests

to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the reference listed drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to submit an appropriate certification or statement to the FDA concerning each patent identified in connection with the reference listed drug in the Orange Book. Specifically, the applicant may make one of the following four patent certifications: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the proposed product (a type of certification known as a Paragraph IV certification). For listed patents that claim an approved method of use, under certain circumstances the ANDA applicant may elect to submit a section viii statement, instead of a patent certification, certifying that the proposed ANDA labeling does not contain (or carves out)an indication or other condition of use that is covered by the method-of-use patent. By carving out relevant portions of the drug's labeling, an ANDA applicant can avoid patent litigation with respect to the method-of-use patent, and the patent will not impact the ANDA applicant's ability to secure FDA approval for its generic product. Otherwise, if the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA will not be eligible for approval until all the listed patents for the reference listed drug have expired. If the ANDA applicant has submitted a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the "notice letter"). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification, if certain requirements are met, prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date a settlement order or consent decree is signed and entered by the court stating that the patent that is the subject of the Paragraph IV certification is invalid or not infringed, or a decision in the patent litigation that the patent is invalid or not infringed.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference listed drug has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and the FDA permits, the omission of the exclusivity-protected information from the ANDA prescribing information.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case an ANDA may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug for which new clinical investigations conducted or sponsored by the applicant are essential to approval, which may include, among other changes, the approval of a new indication, the approval of a new strength, or the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which the FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and the FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Patent term extension

Hatch-Waxman permits the extension of one patent further to the approval of a product as compensation for patent term lost during the FDA regulatory review process pertaining to that drug. Patent term extension, however, cannot extend the term of a patent beyond a date that provides the patent with 14 years of effective patent life from the product's approval date. One or more patent term extension applications may be filed after NDA approval, but ultimately only one patent can be extended. The allowable patent term extension is calculated based on the post-patent issuance period that includes half of the drug's testing phase (from the date the IND application became effective up to NDA submission) and all of the review phase (the time between NDA submission and approval), up

to a maximum of five years. The time can be reduced for any time the FDA determines that the applicant did not pursue approval with due diligence.

The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may decide not to grant an extension because of a failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. If granted, an interim patent extension will increase the patent term by up to one year and may be renewed up to four times, depending on the amount of extension to which an applicant is entitled. Interim patent extensions are also available as to patents that may expire prior to NDA approval; however, such interim patent extension will only apply if an application for product approval has been submitted to the FDA.

FDA regulation of companion diagnostics

If use of an in vitro diagnostic is essential to safe and effective use of a drug product, then the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic, at the same time that the FDA approves the drug product. With respect to cancer drugs specifically, the FDA has generally required companion diagnostics intended to select the patients who are likely to respond to a particular cancer treatment to obtain a pre-market approval, or PMA, simultaneously with approval of the drug, except in limited circumstances. The review of these companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health. Approval of the drug and corresponding approval or clearance of a companion diagnostic also requires a high level of coordination between the drug manufacturer and device manufacturer, if different companies.

The PMA process, including the gathering of preclinical and clinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to a substantial application fee, which is typically increased annually.

In addition, PMAs must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic has adequate sensitivity and specificity, has adequate specimen and reagent stability, and produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA may issue an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register their establishment(s), including payment of an annual establishment registration fee, and list their device(s) with the FDA. A medical device manufacturer's manufacturing processes and those of any contract manufacturers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to

periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States. Medical device manufacturers are also subject to requirements for reporting certain adverse events and malfunction associated with the device and for reporting certain corrections and removals of their devices.

Other healthcare laws

In addition to FDA regulation of pharmaceutical products, several other types of state and federal laws govern certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency, health information privacy laws, and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The federal Anti-Kickback Statute has been broadly interpreted by the courts. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary's selection of a provider, practitioner, or supplier of items or services reimbursed by these programs, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, requires certain manufacturers of prescription drugs to collect and annually report information on certain payments or transfers of value to certain prescribers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis, which can be accessed by competitors and regulators. Failure to submit required information may result in civil monetary penalties.

We may also be subject to analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in those states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Additionally, we may also be subject to state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal, and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. healthcare reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which 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, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions, which triggered a 2% reduction in payments under certain government programs, including Medicare. This reduction will remain in effect for Medicare spending through fiscal year 2032. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, 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. The FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. The Biden and Trump administrations both issued executive orders intended to favor government procurement from domestic manufacturers. In addition, the first Trump administration issued an executive order specifically aimed at the procurement of pharmaceutical products, which instructed the federal government to develop a list of "essential" medicines and then buy those and other medical supplies that are manufactured, including the manufacture of the API, in the United States.

Further, on November 20, 2020, the U.S Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back to January 1, 2027 by the Bipartisan Safer Communities Act. The Inflation Reduction Act of 2022, or the IRA, further delayed implementation of this rule to January 1, 2032. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Most recently, in August 2022, President Biden signed into law the IRA, which, among other things, directs the U.S. Department of Health and Human Services, or HHS, to engage in price-capped negotiation for certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. Specifically, the IRA's Price Negotiation Program will apply to high-expenditure single-source drugs and biologics that have been approved for at least seven and 11 years, respectively, among other negotiation criteria, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The negotiated prices will be capped at a statutory ceiling price. There are certain statutory exemptions from the IRA's Price Negotiation Program, such as 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 IRA's Price Negotiation Program is currently the subject of legal challenges, although to date those challenges have not been successful. Beginning in October 2023, 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. Failure to comply with the IRA may be subject to various penalties, including civil monetary penalties, which could be significant.

At the state level, governments have and continue to consider and pass legislation and implement regulations designed to control pharmaceutical and biological product pricing. Some of these measures include restricting price, reimbursement, discounts, product access, and marketing; imposing drug price, cost, and marketing disclosure and transparency requirements; permitting importation from other countries; and encouraging bulk purchasing. Furthermore, a growing number of state attorneys general are filing legal challenges (including use of state antitrust laws) related to drug pricing and reimbursement against various supply chain entities such as pharmacy benefit managers, and such litigation could involve drug manufacturers to a greater degree in the future.

We expect that additional state and federal healthcare reform measures will be adopted in the future. The effect of reducing prices and reimbursement for our products would significantly impact our business and consolidated results of operations.

Coverage and reimbursement

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products is dependent on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations. Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products, particularly if more established or lower-cost therapeutic alternatives are available. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process for determining coverage and reimbursement is often time-consuming and costly—including requiring us to provide scientific, clinical, and economic support for the use of our products to each payor separately—with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our future drug products. Additionally, we may develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. We, or our collaborators, if any, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a drug on their formularies or otherwise restrict patient access to a drug when a less costly generic equivalent or other alternative is available.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage, and requirements for substitution of generic products for branded prescription drugs. Adoption and implementation of government controls and measures could exclude or limit our products from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities will continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Business Segments

We view our operations and manage our business as one operating segment, which includes all activities related to the identification, development and commercialization of first- or best-in-class medicines for childhood and adult diseases with equal intensity. For financial information related to our one operating segment, see our Financial Statements and related notes.

Employees and Human Capital Resources

We are committed to creating and maintaining a diverse, inclusive and safe work environment where our employees can bring their best selves to work each day. Our commitment to diversity extends through our recruitment, retention, learning and engagement and community partnerships. As part of our diversity, equity, inclusion and belonging strategy, we made an active decision to pursue opportunities for learning and engagement that bring people from different backgrounds together into conversation.

As of December 31, 2024, we had 181 full-time employees. Of these employees, 48 held Ph.D., Pharm.D. or M.D. degrees, and 57 were engaged in research, development and technical operations. From time to time, we also

retain independent contractors to support our organization. Approximately 22.7% of our employees are based at our headquarters in Brisbane, California, with the remaining others working remotely. We have never experienced a work stoppage, none of our employees are represented by a labor union or covered by collective bargaining agreements, and we strive to attract and retain qualified employees in order to foster long-term working relationships.

We focus on employee development, engagement, and diversity and inclusion to identify, hire, develop, and retain the best talent. The principal purpose of our incentive share plan is to attract, retain and motivate selected employees, consultants and directors through the granting of incentive share-based compensation awards and cash-based performance bonus awards. We provide competitive compensation and benefits that are tailored specifically to the needs and requests of our employees and are designed to help us achieve our goals of attracting, hiring and retaining qualified personnel.

Facilities

Our principal executive office is located in Brisbane, California, where we lease approximately 19,000 square feet of office space. The lease expires in January 2032. There is no option to extend the lease term nor is there an option to terminate the lease prior to its expiration. We believe these facilities are sufficient to meet our ongoing needs and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Corporate Information

We were formed as a limited liability company under the laws of the State of Delaware in November 2018, under the name Hero Therapeutics Holding Company, LLC. We subsequently changed our name to Day One Therapeutics Holding Company, LLC in December 2018 and to Day One Biopharmaceuticals Holding Company, LLC in March 2020. In connection with our initial public offering, we converted from a Delaware limited liability company to a Delaware corporation and changed our name to Day One Biopharmaceuticals, Inc. Our principal executive offices are located at 1800 Sierra Point Parkway, Suite 200, Brisbane, CA 94005, and our telephone number is (650) 484-0899. Our website address is www.dayonebio.com.

Available Information

Our Internet website address is http://www.dayonebio.com. On our website, we make available, free of charge, our annual, quarterly, proxy statements and current reports, including amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website at www.sec.gov that contains reports as well as other information regarding us and other companies that file materials with the SEC electronically.

Also available on our website is information relating to corporate governance at Day One and our board of directors, including our Corporate Governance Guidelines; our Code of Business Conduct and Ethics (for our directors, officers and employees), and our Board Committee Charters. We will provide any of the foregoing information without charge upon written request to our Corporate Secretary, Day One Biopharmaceuticals, Inc., 1800 Sierra Point Parkway, Suite 200, Brisbane, CA 94005.

We use our Investor Relations website (http://ir.dayonebio.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD promulgated by the SEC. These disclosures are included in the “Press Releases” and “Events and Presentations” sections of our website. Accordingly, investors should monitor these portions of our website, in addition to following our press releases, SEC filings and public conference calls and webcasts.

The information contained on our website does not constitute, and shall not be deemed to constitute, a part of this Annual Report on Form 10-K, or any other report we file with, or furnish to, the SEC. Our references to the URLs for websites are intended to be inactive textual references only.

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 annual 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 are a commercial stage biopharmaceutical company with a limited operating history in the initial stages of the commercialization 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. 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 may 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 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

We are a commercial stage biopharmaceutical company with a limited operating history in the initial stages of the commercialization 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. Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in 2018, and, to date, we have devoted substantially all of our resources to identifying, acquiring and developing OJEMDA and our product candidates, including DAY 301, which we licensed from MabCare Therapeutics in June 2024, 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.

As of December 31, 2024, we have generated approximately $57.2 million of net revenue from product sales of OJEMDA and we have financed our operations primarily through the sale and issuance of redeemable convertible preferred shares, the completion of our initial public offering, or IPO, and follow-on public offerings of our common stock.

We are continuing to transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in such transition. We are still at the early stages of demonstrating our ability to manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution 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. If we do not adequately address these risks and difficulties or successfully make a commercial transition, our business will suffer.

We have incurred significant net losses since our inception. 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, and as of December 31, 2024, we have generated approximately $57.2 million of revenue from product sales of OJEMDA. We have financed our operations principally through the sale and issuance of redeemable convertible preferred shares, the completion of our initial public offering, or IPO, and follow-on public offerings of our common stock. For the years ended December 31, 2024, 2023, and 2022, we reported a net loss of $95.5 million, $188.9 million and $142.2 million, respectively. We had an accumulated deficit of $554.1 million as of December 31, 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 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.

The success of OJEMDA will depend on several factors, including the following:

- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of OJEMDA and ensuring a resilient, effective supply chain that produces supply that outpaces demand;
- implementing marketing, pricing and reimbursement strategies, as well as adequate demand forecasts for supply and sales planning;
- establishing sales, marketing and distribution capabilities for OJEMDA, 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 OJEMDA 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;
- 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;
- 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.

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 commercialization of OJEMDA and development of our product candidates. We are early in our development efforts for other indications, and our product tovorafenib is currently in a pivotal Phase 3 clinical trial as a potential front-line therapy in pLGG. 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 ongoing clinical trials or obtain marketing authorization.

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 support Ipsen 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;
- 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;
- demonstrate an acceptable safety profile of our product and our product candidates, including 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 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 and management.

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 early 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 may 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 commercialize our product, OJEMDA, and advance 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 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 $531.7 million in cash, cash equivalents and short-term investments as of December 31, 2024. Based on our cash, cash equivalents and short-term investments, as of December 31, 2024, we estimate that our current liquidity will be sufficient to satisfy our capital requirements at least twelve months after the date that this Annual 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 may 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 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 may 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 December 31, 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, significant political, trade or regulatory developments, 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 our product candidates, our reputation may be harmed and our business will suffer.

The risk of failure for our product candidates is high. It is impossible to predict when or if 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 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 is now 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 treatment options. 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 regulatory delays, result in an inability to obtain regulatory approvals or 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 and capacity of clinical researchers to conduct our clinical trials;
- 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;
- 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.

Five 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. Two have been approved for the treatment of pediatric patients, 2 years of age and older, with neurofibromatosis type 1, or NF1, who have symptomatic plexiform neurofibromas not amenable to complete resection, including selumetinib, marketed as Koselugo® by AstraZeneca and mirdametinib, marketed as Gomekli® by SpringWorks. 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 alterations. 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. Pfizer's PF-07799933 (ARRY-440) is a brain-penetrant BRAF-selective monomer/dimer inhibitor that spares ARAF and CRAF, that is currently being evaluated in a phase 1 trial in adults with solid tumors.

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. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial. 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, a PTK7-targetted ADC with an auristatin payload. 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, a PTK-7 targeted ADC with an exatecan payload.

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 timelines for the FDA review and approval process may be delayed as a result of future organizational changes and/or staffing reductions. 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 December 20, 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, impose 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, reputation, results of operations, financial condition and prospects. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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 first Trump administration. 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 addition, there have been legal challenges to the constitutionality of the ACA and certain requirements such as the individual mandate. Although these challenges have been unsuccessful to date, there may be other efforts to challenge the individual mandate or to challenge, repeal or replace the ACA. It is unclear how any pending or future litigation and the healthcare reform measures of the future presidential administration and Congress 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, recent presidential administrations were focused on drug pricing and have used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. 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 began taking 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 in connection with the 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 certain U.S. individuals and entities 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 or gaining an improper advantage. 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 where 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 and therefore our interactions with these individuals are subject to regulation under the FCPA.

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 are 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 economic sanctions, 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 United States. 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, significant political, trade or regulatory developments, 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.

Our existing License Agreement with Ipsen is important to our business. If Ipsen fails to fulfill its contract obligations, or if any of the Ipsen License Agreement is terminated, our ability to commercialize OJEMDA in territories outside the United States may be delayed or prevented and we may never receive milestone payments or future royalties under the License Agreement.

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. Ipsen shall have the right to grant sublicenses to third -parties. A significant portion of our future revenue and cash resources may be derived from the Ipsen License Agreement, or other similar agreements into which we may enter in the future.

Under the Ipsen License Agreement, we are eligible to receive up to approximately $330.0 million based on exchange rates as of the reporting date 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.

Under the terms of the Ipsen License Agreement, Ipsen will have significant discretion in determining the efforts and resources that they will apply to their marketing efforts and their management of the ex-U.S. regulatory activities and they may not perform their obligations as expected. Disputes may arise between Ipsen and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources. Furthermore, they may have changes in their strategic focus or available funding, or experience external factors, such as an acquisition, may divert resources or create competing priorities. Any of these events would have a material adverse effect on our business, financial condition and results of operations.

The Ipsen License Agreement may be terminated by either party for material breach or bankruptcy. In addition, Ipsen may terminate the Ipsen License Agreement after the second anniversary of the effective date for convenience with six months' prior written notice or for certain other specified reasons.

If the Ipsen License Agreement is terminated, then, depending on the event:

- our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate internal resources to the commercialization or other activities that were previously shared by Ipsen;
- we would bear all of the risks and costs related to the further commercialization and development activities that were previously the subject of the Ipsen License Agreement;
- in order to fund further commercialization activities, we may need to seek out and establish alternative strategic collaborations with third-party partners, which may not be possible; or
- we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs or increase our expenditures and seek additional funding by other means.

Any of these events would have a material adverse effect on our business, financial condition and results of operations.

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

We may seek third-party collaborators for the development and commercialization of our product candidates on a select basis, such as our collaboration with Ipsen with respect to commercialization of tovorafenib in all territories outside the United States. 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 additional arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our 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 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 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 additional collaborations in the future, 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 year ended December 31, 2024, two individual customers accounted for 94.3% of our total net product revenue, with these individual customers representing 66.2% and 28.1% of total net product revenue. As of December 31, 2024, two customers accounted for 88.7% of the accounts receivable balance, with these individual customers representing 64.5% and 24.2% 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, 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 181 full-time employees as of December 31, 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 intellectual property, trade secrets, proprietary business information, personal information and protected health information). 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 utilize, 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. These risks extend 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, confidential and sensitive 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, distributed 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. 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, confidential or sensitive 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.

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 OJEMDA or 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. If the information technology systems of our CROs, CMOs, vendors, contractors, consultants and other third-party partners become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Any 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 may have contractual and other legal obligations to notify relevant stakeholders of security breaches. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities and others of security breaches involving certain types of data. 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.

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.

While we maintain cybersecurity insurance coverage, 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 our 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 states, countries, or conflict with other requirements. 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 health information privacy and security laws, data breach notification laws, health information privacy laws and consumer protection laws 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.

Over a third of U.S. states have adopted comprehensive privacy and security laws and regulations, which govern the privacy, processing and protection of personal information, including certain specific requirements and laws with respect to health-related information. For example, Washington state has passed the My Health My Data Act, which is focused on the collection of consumer health data, which has a broader scope than HIPAA and includes a private right of action.

In California, the CCPA, grants 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 is enforced by 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, and provides for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation.

We are also subject to foreign data protection laws, including the General Data Protection Regulation, or GDPR, which applies to personal information (including health-related data) obtained from individuals in the European Economic Area, or the EEA (as well as substantially similar laws that govern the collection of data from individuals

in the UK and Switzerland). The GDPR 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 (17.5 million GBP in the UK) 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. Changes in international 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 their relevant authorities 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. 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.

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. For example, for tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act requires taxpayers to capitalize and amortize, rather than deduct, R&D expenses. R&D expenses are amortizable over five years for research performed in the United States and 15 years for research performed outside the United States. Although there are legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified.

Effective for transactions occurring on or after January 1, 2023, the Inflation Reduction Act imposed a new one percent excise tax on certain repurchases of stock by publicly traded U.S. domestic corporations. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. For purposes of calculating the base excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. Certain repurchases are not counted in the base of the excise tax.

Future 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, 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. 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 is limited to 80% of current year taxable income (without regard to certain deductions).

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. During the year ended December 31, 2024, the Company has completed a Section 382 study to determine whether an ownership change per the provisions of Section 382 of the Internal Revenue Code, as well as similar state provisions, has occurred. The study found that one of our predecessor companies experienced an ownership change on June 16, 2022 and that the tax attributes that it generated are subject to a change pursuant to Section 382; however, based on the study all of these attributes are fully available for use as of December 31, 2023. The Company's current year utilization of net operating losses and income tax credits is not impacted by the provisions of Section 382 or 383. As a result, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use 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 December 31, 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 OJEMDA 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 operating results will be affected by numerous factors, including:

- our ability to generate revenue from the sales of our product, OJEMDA;
- 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, significant political, trade or regulatory developments, 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:

- the success of our commercialization efforts for our product, OJEMDA;

- 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, changes in interest rates and significant political, trade or regulatory developments, 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 8,502,776 shares of our outstanding common stock as of December 31, 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 December 31, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 47.3% 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. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, volatile interest rates and increasing inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. A severe or prolonged economic downturn or recession and a continued increase in inflation rates or interest rates could result in a variety of risks to our business, including weakened demand for OJEMDA and our ability to raise additional capital when needed on acceptable terms, if at all. 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 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

The Company's board of directors, or the Board, recognizes the critical importance of maintaining the trust and confidence of our patients, investors, business partners and employees. The Board is actively involved in oversight of the Company's risk management program, and cybersecurity represents an important component of the Company's overall approach to risk management. The Company's cybersecurity policies, standards, processes and practices are fully integrated into the Company's risk management program and are based on recognized frameworks established by the National Institute of Standards and Technology, the International Organization for Standardization and other applicable industry standards. In general, the Company seeks to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that the Company collects and stores by identifying, preventing, mitigating and remediating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of the Company's overall risk management approach, the Company's cybersecurity program is focused on the following key areas:

Governance: As discussed in more detail under the heading "Governance," the Board's oversight of cybersecurity risk management is supported by the Audit Committee of the Board, or the Audit Committee, which regularly interacts with the Company's Head of Information Technology and other members of management, including members of management's Data Privacy and Security Committee.

Collaborative Approach: The Company has implemented a comprehensive, cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and processes that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.

Information Security: We implement organizational, administrative and technical measures based on commercially reasonable procedures using (i) industry standard information security measures prescribed for use by National Institute of Standards and Technology, (ii) security measures aligned with the ISO/IEC 27000 series of standards, (iii) the Sarbanes-Oxley Act and SSAE 18/ISAE 3402, (iv) privacy regulations such as the European Union's General Data Protection Regulation and the California Consumer Privacy Act, (v) business continuity management measures aligned with the ISO/IEC 22301 standard and (vi) other generally recognized industry standards, in each case, designed to safeguard the confidentiality, integrity, and availability of our infrastructure and data and the resiliency of our operations.

Technical Safeguards: The Company deploys technical safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

Incident Response and Recovery Planning: The Company has established and maintains comprehensive incident response and recovery plans that fully address the Company's response to a cybersecurity incident, and such plans are tested and evaluated on a regular basis.

Third-Party Risk Management: The Company maintains a comprehensive, risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of the Company's systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

Education and Awareness: The Company provides regular, mandatory training for personnel and contractors regarding cybersecurity threats as a means to equip the Company's personnel with effective tools to address cybersecurity threats, and to communicate the Company's evolving information security policies, standards, processes and practices.

Risk and Readiness Assessments: The Company engages in the periodic assessment and testing of the Company's policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, tabletop exercises, threat modeling, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. The Company regularly engages third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to the Audit Committee and the Board, and the Company adjusts its cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

Insurance: We maintain information security risk insurance coverage.

Governance

The Board, in coordination with the Audit Committee, oversees the Company's risk management process, including the management of risks arising from cybersecurity threats. The Board and the Audit Committee each receive regular presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends and information security considerations arising with respect to the Company's

peers and third parties. The Board and the Audit Committee also receive prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed. On an annual basis, the Board and the Audit Committee discuss the Company's approach to cybersecurity risk management with members of the Data Privacy and Security Committee, which includes the Company's Head of Information Technology.

The Head of Information Technology, in coordination with the Data Privacy and Security Committee, which includes our Chief Executive Officer, or CEO, Chief Operating and Financial Officer, or COO and CFO, and General Counsel, works collaboratively across the Company to implement a program designed to protect the Company's information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with the Company's incident response and recovery plans. To facilitate the success of the Company's cybersecurity risk management program, multidisciplinary teams throughout the Company are deployed to address cybersecurity threats and to respond to cybersecurity incidents. Through ongoing communications with these teams, the Head of Information Technology and the Data Privacy and Security Committee monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time, and report such threats and incidents to the Audit Committee when appropriate.

The Head of Information Technology has served in various roles in information technology and information security for over 20 years, including serving as Vice President, Information Technology at three public companies. The Head of Information Technology holds an undergraduate degree in Business Administration, Management Information Systems. The Company's CEO, COO and CFO, and General Counsel each hold undergraduate and graduate degrees in their respective fields, and have extensive experience managing risks at the Company and at similar companies, including risks arising from cybersecurity threats.

We have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. If we were to experience a material cybersecurity incident in the future, such incidents may have a material effect, including on our operations, business strategy, results of operations or financial condition. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the risk factor titled "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."

Item 2. Properties.

Our principal executive office is located in Brisbane, California, where we lease approximately 19,000 square feet of office space. The lease expires in December 2031. There is no option to extend the lease term nor is there an option to terminate the lease prior to its expiration. We believe these facilities are sufficient to meet our ongoing needs and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

The Company, from time to time, may be party to litigation arising in the ordinary course of business. 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

We became a public company on May 26, 2021. Our common stock is listed for trading on the NASDAQ Capital Market under the symbol "DAWN."

Holders of Record

As of February 20, 2025, there were approximately 32 stockholders of record of our common stock based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash or stock dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends on common stock will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

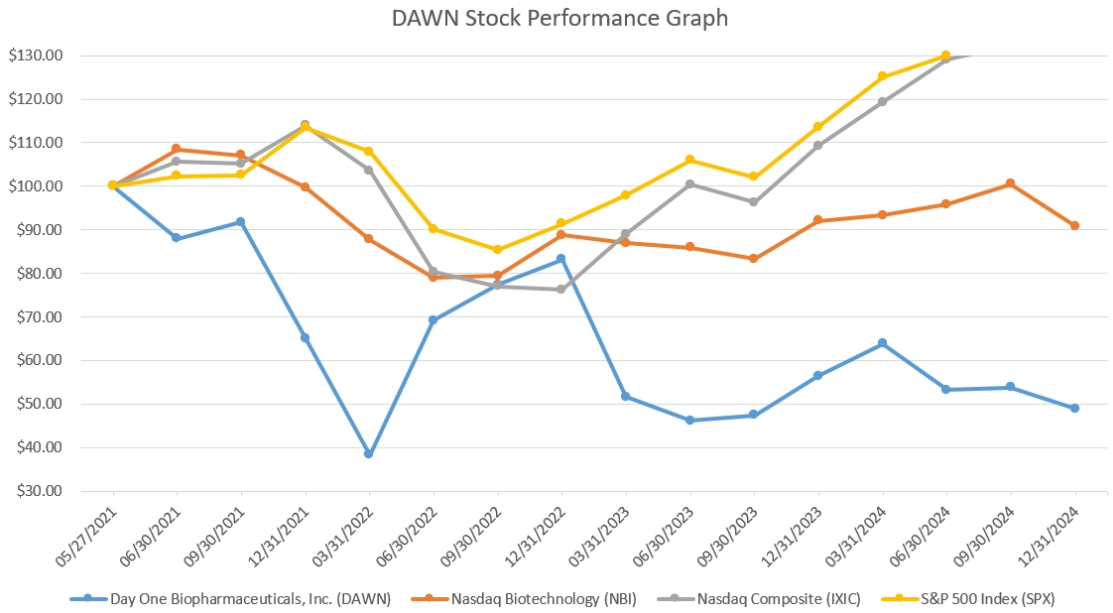
The information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or "filed" with the SEC for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act generally, except as shall be expressly set forth by specific reference in such filing.

The following graph shows the cumulative total return to our stockholders between May 27, 2021 (the date our common stock commenced trading on the Nasdaq Global Select Market) and December 31, 2024, in comparison to the Nasdaq Biotechnology Index, the Nasdaq Composite Index, and the Standard & Poor's 500 Index. An initial investment of $100 and reinvestment of dividends is assumed to have been made in our common stock and in each

index. The historical stock price performance of our common stock shown in the performance graph is not necessarily indicative of, or intended to forecast, future stock price performance.



Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved

Item 7. 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 financial statements and related notes appearing in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, 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. For the comparison of the financial results for the fiscal years ended December 31, 2023 and 2022, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 26, 2023. As used in this report, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Day One" refer to Day One Biopharmaceuticals, Inc.

Overview

Day One Biopharmaceuticals, Inc. is a commercial-stage company focused on advancing first- or best-in-class medicines for childhood and adult diseases with equal intensity. We were founded to address the lack of new therapies resulting from the traditional drug development model, which has left children with cancer and their families waiting too long for new treatments.

At Day One, we aim to identify and develop breakthrough medicines with the goal of improving the outcomes and life trajectories of patients of any age facing serious diseases — starting from Day One. Our "search & development" strategy enables us to find, acquire, and develop potential best-or first-in-class programs with the goal of introducing new medicines that will make a real difference in the treatment of children and adults.

Our first commercial 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 the cutoff 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 113 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/m2/dose once weekly, and the addition of a once-monthly carboplatin regime as a fourth standard of care option for arm 2. We expect to complete enrollment of FIREFLY-2 in the first half of 2026.

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) 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 $330.0 million based on exchange rates as of the reporting date 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.

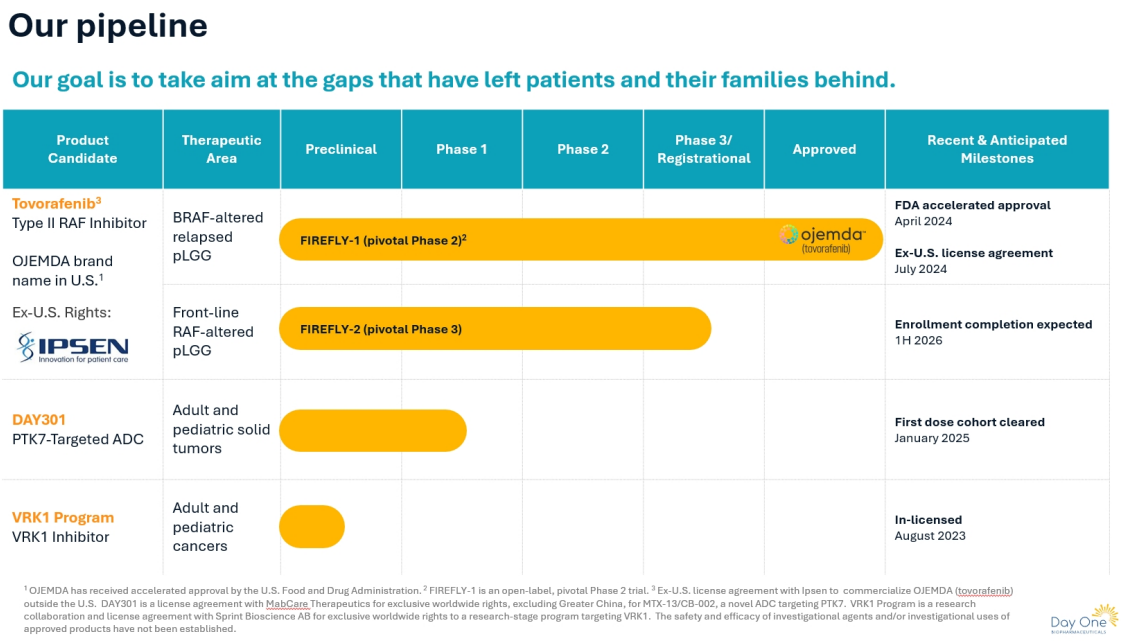
In August 2023, we entered into a research collaboration and license agreement, or the Sprint License Agreement, with Sprint Bioscience AB, or Sprint, a Swedish corporation located in Huddinge, Sweden. Under the Sprint License Agreement, Sprint granted to us an exclusive, worldwide license, with the 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 an inhibitor targeting 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 inhibitor 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. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial.

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 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.



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. 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 of the company from an LLC to a corporation 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. 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 of the company from an LLC to a corporation, 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. We paid $2.0 million upfront in cash to Viracta.

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.

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 in exchange for reduced future payment obligations 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.

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.

On December 3, 2024, Viracta assigned the Viracta License Agreement to XOMA (US) LLC, or XOMA, pursuant to a Royalty Purchase Agreement dated March 22, 2021, between Viracta and XOMA, whereby Viracta sold its right, title, and interest in and to the Viracta License Agreement to XOMA. We have agreed to the assignment and novation of the Viracta License Agreement to XOMA as successor party, now XOMA License Agreement. No material terms of the XOMA License Agreement have been amended or modified in relation to the same.

As of December 31, 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. 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. 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. As of December 31, 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.

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 an inhibitor targeting 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. As of December 31, 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.

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. 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 granted 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. As of December 31, 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.

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 December 31, 2024, we are also eligible to receive up to approximately $330.0 million based on exchange rates as of the reporting date 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.

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 portion of the transaction price allocated to the licenses was recognized as revenue upon delivery of the licenses in the year ended of December 31, 2024. The transaction price 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. We expect to use inventory previously expensed to research and development within the next seven months, and accordingly, we expect our cost of product revenue of OJEMDA to increase as a percentage of product revenue in future periods as we produce and sell inventory that reflects the full cost of manufacturing the product.

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 activities 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, 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 I, Item 1A "Risk Factors" in this Annual Report on Form 10-K.

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 year ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,			
	2024	2023	$ Change	% Change
Revenue:				
Product revenue, net	$ 57,217	$ —	$ 57,217	*
License revenue	73,944	—	73,944	*
Total revenues	131,161	—	131,161	*
Cost and operating expenses:				
Cost of product revenue	5,279	—	5,279	*
Research and development	227,702	130,521	97,181	74.5%
Selling, general and administrative	115,450	75,543	39,907	52.8%
Total cost and operating expenses	348,431	206,064	142,367	69.1%
Loss from operations	(217,270)	(206,064)	(11,206)	5.4%
Non-operating income (expense):				
Gain from sale of priority review voucher	108,000	—	108,000	*
Investment income, net	19,701	17,187	2,514	14.6%
Other income (expense), net	1,217	(40)	1,257	*
Total non-operating income, net	128,918	17,147	111,771	*
Loss before income taxes	(88,352)	(188,917)	100,565	(53.2)%
Income tax expense	(7,144)	—	(7,144)	*
Net Loss	$ (95,496)	$ (188,917)	$ 93,421	(49.5)%

** Amount and/or percentage not meaningful*

Product revenue, net

For the year ended December 31, 2024, we recorded net product revenue of $57.2 million from sales of OJEMDA in the United States, which included $2.8 million related to our named patient program in territories outside of the United States. Beginning in 2025, Ipsen has assumed primary responsibility for delivering these programs to patients in territories outside of the United States.

License revenue

For the year ended December 31, 2024, we recorded license revenue of $73.9 million related to the Ipsen License Agreement.

Cost of product revenue

For the year ended December 31, 2024, we recorded cost of product revenue of $5.3 million related to sales of OJEMDA in the United States.

Research and development expenses

Research and development expenses increased $97.2 million, from $130.5 million for the year ended December 31, 2023 to $227.7 million for the year ended December 31, 2024. Third-party expenses increased by $18.1 million due primarily to an increase in clinical trial and manufacturing activities, personnel related expenses increased by $6.6 million driven by headcount growth, and other research and development costs increased by $0.5 million. Additionally, license agreement payments increased by $72.0 million due to the payment of the MabCare license agreement upfront payment, accrual of the MabCare license agreement milestone payment, and payment of the Viracta license agreement amendment payment during the year ended December 31, 2024.

The following table summarizes our external and internal research and development expenses for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
External costs:		
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 89,400	$ 71,294
MabCare license agreement upfront payment	55,000	—
MabCare license agreement milestone payment	20,000	—
Viracta license agreement payment	5,000	5,000
Sprint license agreement upfront payment	—	3,000
Other research and development costs	8,949	8,465
Internal costs:		
Employee related expenses	49,353	42,762
Total research and development expenses	$ 227,702	$ 130,521

(1) Third-party CRO, CMO and other clinical trial costs for the tovorafenib, pimasertib, DAY301, and VRK1 programs were $74.8 million, $3.8 million, $4.2 million, and $6.6 million, respectively, for the year ended December 31, 2024 compared to $65.5 million, $4.0 million, $0, and $1.8 million, respectively, for the year ended December 31, 2023.

Selling, general and administrative expenses

Selling, general and administrative expenses increased $39.9 million, from $75.6 million for the year ended December 31, 2023 to $115.5 million for the year ended December 31, 2024. The increase in selling, general and administrative expenses was primarily due to an increase of $21.4 million in personnel related expenses driven by headcount growth, an increase of $13.1 million in professional services driven by commercial launch activities, and an increase of $5.4 million in other selling, general and administrative costs.

Income tax expense

Income tax expense for the year ended December 31, 2024, was $7.1 million resulting in an effective tax rate of (8.1)% compared to 0.0% in 2023. The increase in income tax expense (and resulting negative 8.1% effective tax rate) is driven primarily by current US federal and state income tax expense recognized after considering available net operating losses and credits while we continue to maintain a valuation allowance against the full amount of our net deferred tax assets. We did not record an income tax provision for the year ended December 31, 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 PIPE Investors, pursuant to which we agreed to sell and issue to the PIPE Investors in a private placement, or the Private Placement, an aggregate of (i) 10,551,718 shares of our 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 our 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 placement agent fees, offering costs and other expenses, 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 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 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 closing 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 December 31, 2024.

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

As of December 31, 2024, we had an accumulated deficit of $554.1 million and $531.7 million in cash, 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 Annual 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 December 31, 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 December 31, 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:

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (78,113)	$ (146,853)
Net cash (used in) provided by investing activities	(230,994)	128,378
Cash provided by financing activities	203,291	163,997
Net (decrease) increase in cash and cash equivalents	$ (105,816)	$ 145,522

Operating activities

Net cash used in operating activities for the year ended December 31, 2024 was $78.1 million consisting of our net loss of $95.5 million and non-cash charges of $9.1 million, which were offset by changes in net operating assets and liabilities of $26.5 million. Non-cash charges consisted primarily of a gain from sale of PRV of $108.0 million and accretion of discounts on short-term investments of $6.4 million partially offset by acquired in-process research and development assets of $55.0 million, shared-based compensation expense of $48.3 million, amortization of intangible assets of $1.5 million, and amortization of operating right-of-use asset of $0.5 million. Changes in operating assets and liabilities were primarily related to increases in accrued expenses and other current liabilities of $42.1 million, deferred revenue of $4.8 million, accounts payable of $0.7 million, other long-term liability of $0.8 million, and a decrease in deposits and other long-term assets of $0.1 million. This was partially offset by an increase in accounts receivable of $13.9 million, prepaid expenses and other current assets of $4.6 million, inventory of $3.2 million, and a decrease of operating lease liabilities of $0.3 million.

Net cash used in operating activities for the year ended December 31, 2023 was $146.9 million, consisting of our net loss of $188.9 million, changes of approximately $9.5 million in net operating assets and liabilities and by non-cash charges of $32.6 million, which is primarily comprised of share-based compensation expense of $39.3 million. Changes in operating assets and liabilities were primarily related to an increase in accrued expenses and other current liabilities of $10.6 million and accounts payable of $2.3 million and a decrease in deposits and other long-term assets of $0.3 million. This was partially offset by an increase of prepaid expenses and other current assets of $3.3 million and a decrease of operating lease liabilities of $0.4 million.

Investing activities

Net cash used in investing activities for the year ended December 31, 2024 was $231.0 million attributable to the purchase of short-term investments of $658.6 million, acquisition of in-process research and development assets of $55.0 million, acquisition of intangible assets of $17.1 million, and the purchase of property and equipment of $2.2 million. This was partially offset by the proceeds from maturity of short-term investments of $314.5 million, the sale of the PRV of $108.0 million, and the sale of short-term investments of $79.4 million.

Net cash provided by investing activities for the year ended December 31, 2023 was $128.4 million attributable to the proceeds from the maturity of short-term investments of $575.4 million. This was partially offset by the purchase of short-term investments of $443.8 million, cash paid for acquired in-process research and development assets of $3.0 million, and cash paid for the purchase of property and equipment of $0.2 million.

Financing activities

Cash provided by financing activities for the year December 31, 2024 was $203.3 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 $4.2 million.

Cash provided by financing activities for the year ended December 31, 2023 was $164.0 million, primarily attributable to the net proceeds from the issuance of common stock in connection with our June 2023 follow-on offering of common stock. Additionally, there was $2.6 million of 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 December 31, 2024, we had $531.7 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 Annual 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, significant political, trade or regulatory developments, 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 financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of 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 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 Financial Statements appearing within Item 8 of this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our 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 Annual Report on Form 10-K for a summary of recently issued and adopted accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As of December 31, 2024 and 2023, we had cash, cash equivalents and short-term investments of $531.7 million, and $366.3 million, respectively. This consisted of interest-bearing money market funds and investments in U.S. treasury securities and U.S. government agency securities, which create an exposure to interest rate risk. A hypothetical 100 basis point increase or decrease in interest rates as of December 31, 2024 and 2023 would not have resulted in a material effect on the fair market value of our cash, cash equivalents and short-term investments. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the financial statements and notes thereto beginning at page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure of Controls and Procedures

Our management, with the participation of our Chief Executive Officer and President and our Chief Operating Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2024. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is designed 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework (2013 framework)*. Based on our evaluation, management has concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2024.

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the most recent quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Policies and Arrangements

The Company's directors and Section 16 officers (as defined in Rule 16a-1(f) under the Exchange Act) are only permitted to trade in the Company's securities pursuant to a prearranged trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act, or a Rule 10b5-1 Plan. During the three months ended December 31, 2024, three of the Company's Section 16 officers, including the Company's Chief Executive Officer, who also serves as a member of the Company's board of directors, and one member of the Company's board of directors, adopted new Rule 10b5-1 Plans. The Plans (as defined below) were entered into during an open trading window in accordance with the Company's Insider Trading Policy and Trading Plan Policy.

On November 8, 2024, Jeremy Bender, our Chief Executive Officer and a member of our board of directors, entered into a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "Bender Rule 10b5-1 Plan") under the Exchange Act for the sale of shares of our common stock. The Bender Rule 10b5-1 Plan was entered into during an open trading window in accordance with our policies regarding transactions in our securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The Bender

Rule 10b5-1 Plan provides for the potential sale of shares of our common stock, including upon the vesting and settlement of restricted stock units/vesting and exercise of stock options, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the Bender Rule 10b5-1 Plan, between February 25, 2025 and February 28, 2026. The aggregate number of shares of common stock that will be available for sale under the Bender Rule 10b5-1 Plan is not yet determinable because the shares available will be net of shares sold to satisfy tax withholding obligations that arise in connection with the vesting and settlement of such restricted stock unit awards. As such, for purposes of this disclosure, the aggregate number of shares of common stock available for sale is approximately 720,000, which reflects the aggregate maximum number of shares underlying Jeremy Bender's restricted stock units which may be sold, without excluding the shares that will be sold to satisfy the tax withholding obligations. The Bender Rule 10b5-1 Plan expires on February 28, 2026.

On November 4, 2024, Samuel Blackman, our former Head of Research & Development, entered into a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "Blackman Rule 10b5-1 Plan") under the Exchange Act for the sale of shares of our common stock. The Blackman Rule 10b5-1 Plan was entered into during an open trading window in accordance with our policies regarding transactions in our securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The Blackman Rule 10b5-1 Plan provides for the potential sale of shares of our common stock, including upon the vesting and settlement of restricted stock units, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the Blackman Rule 10b5-1 Plan, between March 7, 2025 and January 31, 2026. As such, for purposes of this disclosure, the aggregate number of shares of common stock available for sale is approximately 1,300,000. The Blackman Rule 10b5-1 Plan expires on January 31, 2026.

On November 14, 2024, Charles N. York II, our Chief Operating and Financial Officer, entered into a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "York Rule 10b5-1 Plan") under the Exchange Act for the sale of shares of our common stock. The York Rule 10b5-1 Plan was entered into during an open trading window in accordance with our policies regarding transactions in our securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The York Rule 10b5-1 Plan provides for the potential sale of shares of our common stock, including upon the vesting and settlement of restricted stock units/vesting and exercise of stock options, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the York Rule 10b5-1 Plan, between February 25, 2025 and February 18, 2026. The aggregate number of shares of common stock that will be available for sale under the York Rule 10b5-1 Plan is not yet determinable because the shares available will be net of shares sold to satisfy tax withholding obligations that arise in connection with the vesting and settlement of such restricted stock unit awards. As such, for purposes of this disclosure, the aggregate number of shares of common stock available for sale is approximately 310,601, which reflects the aggregate maximum number of shares underlying Charles York's restricted stock units which may be sold, without excluding the shares that will be sold to satisfy the tax withholding obligations. The York Rule 10b5-1 Plan expires on February 18, 2026.

On December 1, 2024, William Grossman, one of our directors, entered into a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "Grossman Rule 10b5-1 Plan" and collectively with the Bender Rule 10b5-1 Plan, Blackman Rule 10b5-1 Plan, and York Rule 10b5-1 Plan, the "Plans") under the Exchange Act for the sale of shares of our common stock. The Grossman Rule 10b5-1 Plan was entered into during an open trading window in accordance with our policies regarding transactions in our securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The Grossman Rule 10b5-1 Plan provides for the potential sale of shares of our common stock, including upon the vesting and exercise of stock options, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the Grossman Rule 10b5-1 Plan, between March 2, 2025 and March 1, 2026. There are 30,132 aggregate number of shares of common stock available for sale under the Grossman Rule 10b5-1 Plan. The Grossman Rule 10b5-1 Plan expires on March 1, 2026.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in our Proxy Statement for the 2025 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in our Proxy Statement for the 2025 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in our Proxy Statement for the 2025 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in our Proxy Statement for the 2025 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our Proxy Statement for the 2025 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements:

The financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 "Financial Statements and Supplementary Data."

(2) Financial Statement Schedules

The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

(3) Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation, dated June 1, 2021, as amended June 22, 2023.	10-Q	001-40431	August 7, 2023	
3.2	Amended and Restated Bylaws, dated February 17, 2023.	8-K	001-40431	February 23, 2023	
3.3	Certificate of Ownership and Merger, dated December 23, 2021	10-K	001-40431	March 7, 2022	
4.1	Form of Common Stock Certificate	S-1/A	333-255754	May 24, 2021	
4.2	Amended and Restated Investors' Rights Agreement, dated February 1, 2021, by and among Day One Biopharmaceuticals Holding Company, LLC and certain of its stockholders.	S-1	333-255754	May 4, 2021	
4.3	Form of Pre-Funded Warrant	8-K	001-40431	July 30, 2024	
4.4	Form of Registration Rights Agreement	8-K	001-40431	July 30, 2024	
4.5	Description of Registrant's Securities	10-K	001-40431	March 7, 2022	
10.1^	Form of Indemnification Agreement with directors and officers	S-1	333-255754	May 4, 2021	
10.2^	Form of Change in Control and Severance Agreement	10-K	001-40431	March 7, 2022	
10.3^	2021 Equity Incentive Plan and forms of award agreements	S-8	333-276372	January 4, 2024	

10.4^	2021 Employee Stock Purchase Plan and forms of award agreements	S-8	333-276372	January 4, 2024	
10.5^	2022 Equity Inducement Plan and forms of agreement	S-8	333-268071	October 31, 2022	
10.6†	Office Lease, dated June 26, 2024, by and between Arcus Biosciences, Inc., a Delaware corporation, and Day One Biopharmaceuticals, Inc.				X
10.7†	Asset Transfer and License Agreement, effective as of December 16, 2019, by and between DOT Therapeutics-1, Inc. and Millennium Pharmaceuticals, Inc.	S-1	333-255754	May 4, 2021	
10.8†	License Agreement for RAF, effective as of December 16, 2019, by and between Sunesis Pharmaceuticals, Inc. and DOT Therapeutics-1, Inc.	S-1	333-255754	May 4, 2021	
10.9†	License Agreement, dated February 10, 2021, by and between Merck KGaA, Darmstadt, Germany and Day One Biopharmaceuticals, Inc.	S-1	333-255754	May 4, 2021	
10.10	Stock Exchange Agreement, dated May 4, 2021, by and between Day One Biopharmaceuticals Holding Co., LLC and Millennium Pharmaceuticals, Inc.	S-1	333-255754	May 4, 2021	
10.11†	Amendment No. 1 to the License Agreement for RAF, dated March 4, 2024, by and between Day One Biopharmaceuticals, Inc. and Sunesis Pharmaceuticals, Inc.	8-K	001-40431	March 7, 2024	
10.12†*	Asset Purchase Agreement, dated May 29, 2024.	10-Q	001-40431	August 2, 2024	
10.13†*	Exclusive License Agreement by and between MabCare Therapeutics and Day One Biopharmaceuticals, Inc. dated June 17, 2024.	10-Q	001-40431	August 2, 2024	
10.14†*	Exclusive License Agreement by and between Day One Biopharmaceuticals, Inc. and Ipsen Pharma SAS dated July 23, 2024.	10-Q	001-40431	October 30, 2024	
19.1	Insider Trading Policy				X
21.1	Subsidiaries of the Registrant				X

23.1	Consent of Pricewaterhouse Coopers LLP, Independent Registered Public Accounting Firm	X
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	X
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 and 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
97.1	Compensation Recovery Policy	X
101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101)	X

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

^ Indicates management contract or compensatory plan.

* 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

** 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 25, 2025

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

DAY ONE BIOPHARMACEUTICALS, INC.

Date: February 25, 2025

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)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jeremy Bender, Ph. D., M.B.A and Charles N. York II, M.B.A., and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jeremy Bender, Ph.D., M.B.A. Jeremy Bender, Ph.D., M.B.A.	Chief Executive Officer and President (Principal Executive Officer)	February 25, 2025
/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)	February 25, 2025
/s/ Garry Nicholson, M.B.A. Garry Nicholson	Chair and Director	February 25, 2025
/s/ Habib Dable Habib Dable	Director	February 25, 2025
/s/ Scott Garland Scott Garland	Director	February 25, 2025
/s/ Michael Gladstone Michael Gladstone	Director	February 25, 2025
/s/ William Grossman, M.D., Ph.D. William Grossman, M.D., Ph.D.	Director	February 25, 2025
/s/ Natalie Holles Natalie Holles	Director	February 25, 2025
/s/ John A. Josey, Ph.D., M.B.A. John A. Josey, Ph.D., M.B.A.	Director	February 25, 2025
/s/ Saira Ramasastry, M.S., M.Phil. Saira Ramasastry, M.S., M.Phil.	Director	February 25, 2025

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Day One Biopharmaceuticals, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheets of Day One Biopharmaceuticals, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations, of comprehensive loss, of redeemable convertible preferred shares, redeemable noncontrolling interest and stockholders' equity/members' (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

PricewaterhouseCoopers LLP, 601 South Figueroa Street, Los Angeles, California 90017
T: (213) 356 6000, www.pwc.com/us

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Trial Expenses

As described in Notes 2 and 4 to the financial statements, the Company records accrued liabilities for estimated costs of clinical trials conducted by third-party service providers. As disclosed by management, these costs are accrued based on factors such as estimates of the work completed and in accordance with terms established with third-party service providers under the service agreements. Management makes judgments and estimates in determining the accrued liabilities for estimated costs of clinical trials each reporting period and monitors patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with clinical research organizations ("CROs") and review of contractual terms. Within accrued expenses and other current liabilities, management has recorded $13.1 million of accrued research and development expenses as of December 31, 2024, a portion of which relates to accrued clinical trial expenses.

The principal considerations for our determination that performing procedures relating to accrued clinical trial expenses is a critical audit matter are (i) the significant judgment by management when developing the estimate of the accrued clinical trial expenses; and (ii) a high degree of auditor judgment and effort in performing procedures related to management's estimate of the accrued clinical trial expenses.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included testing the effectiveness of controls relating to management's estimate of accrued clinical trial expenses, including controls over the estimates of the work completed in accordance with terms established with third-party service providers under the service agreements. These procedures also included, among others, (i) testing management's process for estimating accrued clinical trial expenses, (ii) evaluating the appropriateness of

the method used by management to develop the estimate, (iii) testing the completeness and accuracy of the data used by management to develop the estimate related to invoicing to date under the contracts and costs incurred for services received, and (iv) evaluating the reasonableness of the estimated costs incurred for the services which have not been invoiced by tracing to underlying supporting documentation, such as underlying contracts, invoices and information received from certain third party service providers, where applicable.

/s/ PricewaterhouseCoopers LLP
Los Angeles, California
February 25, 2025

We have served as the Company's auditor since 2023.

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

To the Stockholders, Members and the Board of Directors of
Day One Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Day One Biopharmaceuticals, Inc. (the Company) as of December 31, 2022, the related statement of operations, comprehensive loss, redeemable convertible preferred shares, redeemable noncontrolling interest and stockholders' equity/members' (deficit) and cash flow for the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and the results of its operations and its cash flows for the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2021 to 2023.

San Mateo, California

March 6, 2023

Day One Biopharmaceuticals, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 124,968	$ 230,784
Short-term investments	406,752	135,563
Accounts receivable, net	13,876	—
Inventory	3,321	—
Prepaid expenses and other current assets	13,413	8,927
Total current assets	562,330	375,274
Property and equipment, net	2,285	208
Operating lease right-of-use asset	2,422	352
Intangible assets, net	15,630	—
Deposits and other long-term assets	121	214
Total assets	$ 582,788	$ 376,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,262	$ 2,576
Accrued expenses and other current liabilities	68,625	26,524
Current portion of deferred revenue	1,554	—
Current portion of operating lease liabilities	10	408
Total current liabilities	73,451	29,508
Long-term portion of deferred revenue	3,233	—
Long-term portion of operating lease liabilities	2,592	—
Other long-term liability	761	—
Total liabilities	80,037	29,508
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 101,116,162 and 87,227,132 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	10	9
Additional paid-in-capital	1,056,738	805,107
Accumulated other comprehensive income	84	9
Accumulated deficit	(554,081)	(458,585)
Total stockholders' equity	502,751	346,540
Total liabilities and stockholders' equity	$ 582,788	$ 376,048

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenue:			
Product revenue, net	$ 57,217	$ —	$ —
License revenue	73,944	—	—
Total revenues	131,161	—	—
Cost and operating expenses:			
Cost of product revenue	5,279	—	—
Research and development	227,702	130,521	85,618
Selling, general and administrative	115,450	75,543	61,291
Total cost and operating expenses	348,431	206,064	146,909
Loss from operations	(217,270)	(206,064)	(146,909)
Non-operating income:			
Gain from sale of priority review voucher	108,000	—	—
Investment income, net	19,701	17,187	4,746
Other income (expense), net	1,217	(40)	(18)
Total non-operating income, net	128,918	17,147	4,728
Loss before income taxes	(88,352)	(188,917)	(142,181)
Income tax expense	(7,144)	—	—
Net loss	(95,496)	(188,917)	(142,181)
Net loss per share - basic	$ (1.02)	$ (2.37)	$ (2.17)
Net loss per share - diluted	$ (1.02)	$ (2.37)	$ (2.17)
Weighted-average number of common shares used in net loss per share - basic	93,234,195	79,773,004	65,466,773
Weighted-average number of common shares used in net loss per share - diluted	93,234,195	79,773,004	65,466,773

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Net loss	$ (95,496)	$ (188,917)	$ (142,181)
Other comprehensive income:			
Unrealized gain (loss) on available-for-sale securities	75	80	(71)
Total comprehensive loss	$ (95,421)	$ (188,837)	$ (142,252)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity/Members' (Deficit)
	Shares	Amount				
Balance at December 31, 2021	61,952,292	$ 6	$ 408,629	$ —	$ (127,487)	$ 281,148
Issuance of common stock pursuant to follow-on offering, net of issuance costs of $10,864	11,500,000	1	161,609	—	—	161,610
Issuance of common stock upon exercise of stock options	235,474	—	3,649	—	—	3,649
Issuance of common stock upon release of restricted stock units	79,441	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	97,413	—	642	—	—	642
Unvested common stock forfeiture	(406,444)	—	—	—	—	—
Share-based compensation expenses	—	—	27,242	—	—	27,242
Unrealized loss on available-for-sale securities	—	—	—	(71)	—	(71)
Net loss attributable to common stockholders/members'	—	—	—	—	(142,181)	(142,181)
Balance at December 31, 2022	73,458,176	$ 7	$ 601,771	$ (71)	$ (269,668)	$ 332,039
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	88,459	—	1,338	—	—	1,338
Issuance of common stock upon release of restricted stock units	317,245	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	115,421	—	1,250	—	—	1,250
Unvested common stock forfeiture	(21,400)	—	—	—	—	—
Share-based compensation expenses	—	—	39,341	—	—	39,341
Unrealized gain on available-for-sale securities	—	—	—	80	—	80
Net loss attributable to common stockholders	—	—	—	—	(188,917)	(188,917)
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	172,163	—	2,267	—	—	2,267
Issuance of common stock upon release of restricted stock units	680,963	—	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	171,442	—	1,906	—	—	1,906
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
Unvested common stock forfeiture	(28,751)	—	—	—	—	—
Share-based compensation expenses	—	—	48,341	—	—	48,341
Unrealized gain on available-for-sale securities	—	—	—	75	—	75
Net loss	—	—	—	—	(95,496)	(95,496)
Balance at December 31, 2024	101,116,162	$ 10	$ 1,056,738	$ 84	$ (554,081)	$ 502,751

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net loss	$ (95,496)	$ (188,917)	$ (142,181)
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	48,263	39,341	27,242
Depreciation expense	92	36	63
Accretion of discounts on short-term investments, net	(6,389)	(10,078)	(2,030)
Amortization of intangible assets	1,470	—	—
Amortization of operating right-of-use asset	467	347	468
Gain from sale of priority review voucher	(108,000)	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(13,876)	—	—
Inventory	(3,243)	—	—
Prepaid expenses and other current assets	(4,556)	(3,322)	(546)
Deposits and other long-term assets	93	255	(300)
Accounts payable	686	2,316	(1,484)
Accrued expenses and other current liabilities	42,101	10,574	9,241
Deferred revenue	4,787	—	—
Operating lease liability	(273)	(405)	(347)
Other long-term liability	761	—	—
Net cash used in operating activities	(78,113)	(146,853)	(109,874)
Cash flows from investing activities:			
Cash paid for purchase of short-term investments	(658,616)	(443,838)	(394,206)
Proceeds from maturity of short-term investments	314,482	575,440	139,158
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	(2,169)	(224)	(26)
Net cash (used in) provided by investing activities	(230,994)	128,378	(255,074)
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	161,610
Proceeds from issuance of common stock upon stock option exercises	2,267	1,338	3,649
Proceeds from issuance of common stock upon Employee Stock Purchase Plan purchase	1,906	1,250	642
Cash provided by financing activities	203,291	163,997	165,901
Net (decrease) increase in cash and cash equivalents	(105,816)	145,522	(199,047)
Cash and cash equivalents, beginning of period	230,784	85,262	284,309
Cash and cash equivalents, end of period	$ 124,968	$ 230,784	$ 85,262
Supplemental disclosure of cash flow information:			
Income taxes paid	1,898	—	—
Supplemental disclosures of noncash activities:			
Cash not yet paid for license agreement milestone payment	20,000		
Right-of-use asset obtained in exchange for new operating lease liabilities	2,554	—	940

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

Day One Biopharmaceuticals, Inc.
Notes to the Financial Statements

1. Description of Business and Organization

Organization and Business

Day One Biopharmaceuticals, Inc. is a commercial-stage company focused on advancing medicines for childhood and adult diseases with equal intensity. The Company was founded in November 2018 and is headquartered in Brisbane, CA.

Risks and Uncertainties

The Company is subject to risks common to commercial-stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to clinical effectiveness of the product, commercialization of products, regulatory approvals, dependence on key products, key personnel and third-party service providers such as contract research organizations ("CROs"), protection of intellectual property rights and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and include the accounts of the Company's subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

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.

Going Concern

The Company assesses and determines its ability to continue as a going concern in accordance with the provisions of ASC Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires the Company to evaluate whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that its annual and interim financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. Determining the extent, if any, to which conditions or events raise substantial doubt about the Company's ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgment by management.

Use of Estimates

The preparation of 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 financial statements, and the reported amounts of expenses during the reporting period. Estimates and assumptions made in the accompanying 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

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment.

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 year ended December 31, 2024, two individual customers accounted for 94.3% of total net product revenue, with these individual customers representing 66.2% and 28.1% of the Company's total net product revenue. As of December 31, 2024, two customers accounted for 88.7% of the accounts receivable balance, with these individual customers representing 64.5% and 24.2% 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. The Company’s cash equivalents consist of investments in money market funds, U.S. government agency securities, and U.S. treasury securities. Cash equivalents are recognized at amortized cost, which approximates fair value.

Investments

The Company’s investments are comprised of U.S. treasury securities and U.S. government agency securities. Investments are classified at the time of purchase, based on management’s intent, as held-to-maturity, available-for-sale, or trading. All of the Company’s investments are classified as available-for-sale. Available-for-sale securities are carried at estimated fair value with unrealized holdings gains and losses (net of tax effects) on such investments reported in other comprehensive income as a separate component on the statements of comprehensive loss. Fair value is determined based on quoted market rates when observable or by utilizing data points that are observable, such as quoted prices, interest rates, and yield curves.

For available-for-sale securities, the Company determines if any impairment is related to credit loss or non-credit loss. In making the assessment of whether a loss is from credit or other factors, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency and adverse conditions related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows is less than the amortized cost basis, a credit loss exists and an allowance is created, limited by the amount that the fair value is less than amortized cost basis. Subsequent activity related to the credit loss component in the form of write-offs or recoveries is recognized as part of the allowance for credit losses on available-for-sale securities.

Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the accompanying balance sheets for cash equivalents, prepaid expenses, other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values, due to their short-term nature.

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 year ended December 31, 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 year ended December 31, 2024.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets ranging from three to five years, and leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. As of December 31, 2024 and 2023, property and equipment, net was not material. Depreciation expense for each of the years ended December 31, 2024, 2023, and 2022 was immaterial.

Leases

Contractual arrangements that meet the definition of a lease are classified as operating or finance leases and are recorded on the balance sheets as both a right-of-use asset, or ROU asset, and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company’s incremental borrowing rate, or IBR. Lease ROU assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The Company currently does not have any finance leases.

Operating lease ROU assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rate for the operating leases are not determinable, the Company determines its IBR based on the information available at the applicable lease commencement date. 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. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. Variable lease costs are recorded when incurred. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term for these types of leases.

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.

Impairment of Long-Lived Assets

The Company evaluates its long-lived asset group, which consist of property and equipment and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. To date, no impairments have been recognized in the financial statements.

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 $330.0 million based on exchange rates as of the reporting date 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 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.

Research and Development Expenses

Research and development expenses consist of costs associated with acquiring technology and intellectual property licenses that have no alternative future uses; costs incurred under agreements with third-party contract

research organizations, contract manufacturing organizations and other third parties that conduct clinical trials on the Company's behalf; other costs associated with research and development programs, including laboratory materials and supplies; employee-related costs, including salaries, benefits and share-based compensation expense, for the Company's research and development personnel; and facilities and other overhead expenses, including expenses for rent and facilities maintenance, and amortization. The Company expenses research and development costs as incurred. The Company is obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as expense as the related goods are delivered or the related services are performed, or such time when the Company does not expect the goods to be delivered or services to be performed.

Accrued Research and Development Expenses

The Company records accrued liabilities for estimated costs of our clinical trials conducted by third-party service providers. The Company records the estimated costs of the clinical trials as research and development expense based upon the estimated amount of services provided but not yet invoiced. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with terms established with third-party service providers under the service agreements. The Company makes judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred.

The Company makes payments in connection with the clinical trials under contracts with contract research organizations 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. In the event the Company makes advance payments for goods or services that will be used or rendered for future research and development activities, the payments are deferred and capitalized as a prepaid expense and recognized as expense as the goods are received or the related services are rendered. Such payments are evaluated for current or long-term classification based on when they are expected to be realized.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty of the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statements of operations.

Share-Based Compensation

The Black-Scholes option-pricing model, used to estimate fair value of stock options awards, requires the use of the following assumptions:

- *Fair Value of Common Stock*—The Company's closing price on the Nasdaq market at the grant date.
- *Expected Term*—The expected term represents the period that the share-based awards are expected to be outstanding. The expected term for stock options is calculated using the simplified method, as the weighted-average vesting term of the award and the award's contract period (generally 10 years). The Company utilizes this method due to lack of historical exercise data and the plain-vanilla nature of the Company's service condition share-based awards. For the Company's performance condition stock option awards, the Company calculated the expected term by taking into consideration the options' contractual life, the timing of when milestones are expected to be achieved, and the expected exercise period by a holder from the vesting date until the contractual term (generally 10 years).
- *Expected Volatility*—Since the Company does not have sufficient trading history for its common stock, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable biopharmaceutical companies are chosen based on their size, stage in the life cycle

or area of specialty. The Company will continue to apply this process until sufficient historical information regarding the volatility of the common stock price becomes available.

- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected Dividend Yield*—The Company has never paid dividends on the common stock and has no plans to pay dividends on its common stock. Therefore, the expected dividend yield use is zero.

The fair value of restricted stock units granted is determined based on the stock price on the date of grant. The Company uses the straight-line attribution method for recognizing share-based compensation expense for awards with service condition. The Company recognizes share-based compensation expense for awards with performance conditions when it is probable that the condition will be met, and the award will vest. The Company recognizes forfeitures by reducing the expense in the same period the forfeitures occur. The Company classifies share-based compensation expense in the statements of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

Income Taxes

Income taxes are accounted for using the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. These reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its filings or positions is more likely than not to be realized following resolution of any potential contingencies related to the tax benefit. Potential interest related to the underpayment of income taxes will be classified as a component of income tax expense and any related penalties will be classified as income tax expense.

Net Loss per Share

The Company calculates basic and diluted net loss per share in conformity with the two-class method required for participating securities. Under the two-class method, basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss, after adjusting it for loss attributable to redeemable noncontrolling interest, in any, by the sum of the weighted average number of common stock shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include incentive shares, unvested restricted common

shares and redeemable convertible preferred shares, prior to the IPO. Potentially dilutive securities include unvested restricted stock awards, unvested restricted stock units and stock options, after the IPO. For all periods presented, diluted net loss per share is the same as basic net loss per share since the effect of including potential common stock shares is anti-dilutive and incentive shares participation thresholds were not met.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' equity except those resulting from and distributions to stockholders. The Company's unrealized gains and losses on available-for-sale securities represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the statements of comprehensive loss.

Recently Issued Accounting Pronouncements

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.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, which requires disclosure, in the notes to financial statements, of specified information about certain costs and expenses at each interim and annual reporting period. The ASU is effective for fiscal years beginning after December 15, 2026 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the effect of this update on its financial statement disclosures.

Recently Adopted 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 adopted ASU 2023-07 on January 1, 2024, which resulted in additional disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. See Note 13 "Segment Reporting" in the accompanying notes to the financial statements for further detail.

3. Recurring Fair Value Measurements

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

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 16,728	$ —	$ —	$ 16,728
U.S. treasury securities	—	311,487	—	311,487
U.S. government agency securities	—	183,375	—	183,375
Total assets measured at fair value	$ 16,728	$ 494,862	$ —	$ 511,590

	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 December 31, 2024 and 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):

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 16,728	$ —	$ —	$ 16,728
U.S. government agency securities	75,163	—	—	75,163
U.S. treasury securities	12,947	—	—	12,947
Total cash equivalents	104,838	—	—	104,838
Short-term investments				
U.S. government agency securities	108,210	13	(11)	108,212
U.S. treasury securities	298,457	85	(2)	298,540
Total short-term investments	$ 406,667	$ 98	$ (13)	$ 406,752

	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):

	December 31, 2024	
	Amortized Cost	Fair Value
Mature in one year or less	$ 511,505	$ 511,590
Total	$ 511,505	$ 511,590

	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 December 31, 2024 and 2023, there were no securities that were in an unrealized loss position for more than 12 months. As of December 31, 2024 and 2023, 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 year ended December 31, 2024. There were no realized gains and losses for the year ended December 31, 2023.

4. Balance Sheet Items

Prepaid Expenses and Other Current Assets

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

	December 31, 2024	December 31, 2023
Prepaid research and development expenses	$ 8,216	$ 5,657
Prepaid insurance	830	918
Other prepaid expenses and other assets	4,367	2,352
Total prepaid expenses and other current assets	$ 13,413	$ 8,927

Accrued Expenses and Other Current Liabilities

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

	December 31, 2024	December 31, 2023
Accrued research and development expenses	$ 18,760	$ 12,643
Accrued milestone payment	20,000	—
Accrued payroll related expenses	13,943	9,165
Accrued professional service expenses	3,758	3,675
Other	12,164	1,041
Total accrued expenses and other current liabilities	$ 68,625	$ 26,524

5. Intangible Assets

Intangible assets, net consisted of the following:

	December 31, 2024	December 31, 2023
Intangible assets with finite lives:		
License agreement milestone payment	$ 9,000	$ —
PRV-related obligation payment	8,100	—
Intangible assets, gross	17,100	—
Less accumulated amortization	(1,470)	—
Intangible assets, net	$ 15,630	$ —

The Company incurred amortization expense of $1.5 million for the year ended December 31, 2024.

The estimated aggregate amortization expense for amortizable finite-lived intangible assets as of December 31, 2024 is as follows:

Year Ending December 31,		Estimated Amortization Expense
2025	$	2,345
2026		2,345
2027		2,345
2028		2,345
2029		2,345
Thereafter		3,905
Total future expected amortization expense	$	15,630

6. 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 of the company from an LLC to a corporation 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 of the company from an LLC to a corporation, 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 year ended December 31, 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 and was capitalized as a finite-lived intangible asset, which will be amortized on a straight-line basis over its estimated useful life. The gross proceeds of $108.0 million were recorded as a gain from sale of priority review voucher in the accompanying statements of operations during the year ended December 31, 2024. As of December 31, 2024, the unamortized finite-lived intangible asset was $7.4 million. Related amortization expense will be recorded as cost of product revenue in the Company's statements of operations.

On December 3, 2024, Viracta assigned the Viracta License Agreement to XOMA (US) LLC, or XOMA, pursuant to a Royalty Purchase Agreement dated March 22, 2021, between Viracta and XOMA, whereby Viracta sold its right, title, and interest in and to the Viracta License Agreement to XOMA. The Company has agreed to the assignment and novation of the Viracta License Agreement to XOMA as successor party, now XOMA License Agreement. In connection with such assignment, the parties also agreed to assign all rights, title and interest in related intellectual property. No material terms of the XOMA License Agreement have been amended or modified in relation to the same.

As of December 31, 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 XOMA 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 December 31, 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 an inhibitor targeting 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 December 31, 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 granted 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 December 31, 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. In January 2025, we cleared the first cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the DAY301 Phase 1a/b clinical trial. As of December 31, 2024, the Company accrued a milestone liability of $20.0 million.

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 December 31, 2024, the Company is also eligible to receive up to approximately $330.0 million based on exchange rates as of the reporting date 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, and 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 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 year ended December 31, 2024. The portion of the transaction price allocable to the relapsed or refractory, front-line and companion diagnostic research and development services performance obligations 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 year ended December 31, 2024, $73.9 million of license revenue was recognized with $1.6 million and $3.2 million of the undelivered services included in current and non-current deferred revenue, respectively.

7. Commitments and Contingencies

Leases

The Company entered into a lease agreement for its corporate office facility in South San Francisco, California in March 2020. 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 Company can extend the lease term for an additional three years at market rates upon the notice of extension. The Company is obligated to pay monthly rent expense and its pro rata share of utilities, common area maintenance expenses, and property taxes. The landlord also provided an allowance of $10,000 for tenant improvements. The Company concluded that it is an operating lease. Common area expenses are a non-lease component and a variable consideration and included in operating expenses as incurred. The extension period has not been included in the determination of the Right of Use,

or ROU, asset or the lease liability for operating leases as the Company concluded that it is not reasonably certain that it would exercise this option. In October 2022, the Company terminated this lease agreement prior to its scheduled expiration in January 2023.

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 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 December 31, 2024, the weighted-average remaining lease term and weighted-average discount rate were 7.0 years and 12.9%, 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 $0.6 million, $0.4 million, and $0.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $0.5 million, $0.5 million, and $0.4 million for the years ended December 31, 2024, 2023 and 2022, respectively. Variable payments expensed during the years ended December 31, 2024, 2023, and 2022 were immaterial.

As of December 31, 2024, the future lease obligations were as follows (in thousands):

Year Ending December 31,	
2025	350
2026	432
2027	445
2028	459
2029	711
Thereafter	1,981
Total future minimum lease payments	4,378
Less: imputed interest	(1,776)
Present value of operating lease liabilities	2,602
Less: current portion of operating lease liabilities	(10)
Long-term portion of operating lease liabilities	$ 2,592

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 December 31, 2024 and 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 remaining amount of future minimum purchase obligations under the manufacturing and supply agreement over the next five years is approximately $14.1 million, in aggregate, as of December 31, 2024. For the year ended December 31, 2024, the Company has made $3.0 million of purchases under the purchase obligation.

Legal Proceedings

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

Indemnification Agreements

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at its request in such capacities. There have been no claims to date, and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had not recorded any liabilities for these agreements as of December 31, 2024 and 2023.

8. 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 December 31, 2024, 101,116,162 shares of common stock were issued and outstanding.

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

	December 31, 2024
Common stock options issued and outstanding	12,127,435
Common stock available for future grants	3,482,006
Common stock available for ESPP	2,421,745
Restricted stock units issued and outstanding	1,774,287
Pre-funded warrants	1,517,241
Total	21,322,714

2024 Private Placement

In July 2024, the Company entered into a securities purchase agreement with certain institutional and accredited investors, or the PIPE Investors, pursuant to which the Company agreed to sell and issue to the PIPE Investors in a private placement, or the Private Placement, an aggregate of (i) 10,551,718 shares of the Company's common stock, par value $0.0001 per share, 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 the Company's 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 Company's 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 placement agent fees, offering costs, and other expenses, 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 closing 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.

June 2022 Follow-On Offering

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

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 December 31, 2024.

9. Share-based Compensation

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

	Year Ended December 31,		
	2024	2023	2022
Research and development expense	$ 16,710	$ 14,381	$ 8,486
Selling, general and administrative expense	31,553	24,960	18,756
Total share-based compensation expense	$ 48,263	$ 39,341	$ 27,242

2022 Equity Inducement Plan

In October 2022, the Company's board of directors 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 year ended December 31, 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	2,915,362	$ 14.28		
Exercised	(172,163)	$ 13.18		$ 401.5
Forfeiture	(827,522)	$ 16.84		
Outstanding at December 31, 2024	12,127,435	$ 16.50	7.5	$ 748.5
Vested and expected to vest at December 31, 2024	12,127,435	$ 16.50	7.5	$ 748.5
Exercisable at December 31, 2024	7,610,570	$ 16.66	7.0	$ 431.2

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 years ended December 31, 2024, 2023, and 2022 was $0.4 million, $0.6 million and $1.6 million, respectively.

The total fair value of options that vested during the years ended December 31, 2024, 2023, and 2022 were $33.3 million, $29.2 million and $23.1 million, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2024, 2023, and 2022 were $9.22 per share, $13.14 per share, and $10.03 per share, respectively.

Unrecognized share-based compensation for stock options as of December 31, 2024 was $45.9 million, which is expected to be recognized over a weighted-average period of 2.1 years.

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

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	5.27 - 6.74	5.27 - 6.25	2.92 - 6.33
Expected volatility	68.27% - 70.57%	68.74% - 81.98%	65.20% - 81.68%
Risk-free interest rate	3.43% - 4.47%	3.47% - 4.67%	1.47% - 4.37%
Expected dividend yield	—	—	—

Restricted Stock Units

The following table provides a summary of restricted stock units activity under the 2021 Plan during the year ended December 31, 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	1,640,180	$ 14.35
Vested	(680,963)	$ 16.48
Forfeiture	(216,475)	$ 16.22
Unvested restricted stock units at December 31, 2024	1,774,287	$ 15.58

Unamortized share-based compensation for restricted stock units as of December 31, 2024 was $25.8 million, which is expected to be recognized over a weighted-average period of 2.7 years.

Restricted Stock Awards

The following table provides a summary of the unvested common stock awards activity during the year ended December 31, 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	(636,647)	$ 16.00
Forfeiture	(28,751)	$ 16.00
Unvested common stock as of December 31, 2024	82,281	$ 16.00

Unamortized share-based compensation for restricted stock awards as of December 31, 2024 was $0.5 million, which is expected to be recognized over a weighted-average period of 0.2 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. 407,629 shares have been issued under the ESPP as of December 31, 2024. The Company recognized $0.8 million, $0.8 million, and $0.5 million of compensation expense related to the ESPP plan for the years ended December 31, 2024, 2023, and 2022, respectively.

10. Net Loss Per Share

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

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (95,496)	$ (188,917)	$ (142,181)
Net loss per share, basic and diluted	$ (1.02)	$ (2.37)	$ (2.17)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	93,234,195	79,773,004	65,466,773

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

	As of December 31,	
	2024	2023
Stock options	12,127,435	10,068,258
Unvested common shares	82,281	747,679
Restricted stock units	1,774,287	984,920
Shares committed under ESPP	113,296	104,700
Total	14,097,299	11,905,557

11. Income Taxes

All pre-tax losses have been incurred in the United States. The total tax expense is comprised of current U.S. federal income tax expense of approximately $1.9 million and current U.S. state and local income tax expense of approximately $5.2 million.

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,		
	2024	2023	2022
Statutory rate	21.0%	21.0%	21.0%
State tax	28.9%	0.5%	0.6%
Permanent differences	(0.1)%	(0.3)%	—
Credits	19.3%	2.0%	1.7%
Change in valuation allowance	(68.5)%	(21.5)%	(22.6)%
Share-based compensation	(4.8)%	(1.7)%	(0.7)%
Uncertain tax positions	(3.9)%	—	—
Total	(8.1)%	—	—

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets		
Federal and state net operating loss carryforwards	$ 34,577	$ 38,973
Capitalized R&D Section 174 Expense	63,487	34,938
Credits	22,038	10,338
Intangible asset basis	24,206	4,034
Share-based compensation	8,892	4,775
Other	3,986	1,397
Total deferred tax assets	157,186	94,455
Total deferred tax liabilities	(1,729)	(75)
Less: valuation allowance	(155,457)	(94,380)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Valuation allowance as of beginning of year	$ 94,380	$ 53,794	$ 23,778
Increases recorded to income tax provision	61,077	40,586	30,016
Valuation allowance as of end of year	$ 155,457	$ 94,380	$ 53,794

The Company has not generated taxable income since inception with the exception of the year ended December 31, 2024. Due to its history of losses, expected future losses and lack of other positive evidence, the Company determined that it is more likely than not that its net deferred tax assets will not be realized, and therefore, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2024, 2023, and 2022. The Company increased the valuation allowance by $61.1 million, $40.6 million, and $30.0 million for the years ended December 31, 2024, 2023, and 2022, respectively.

As of December 31, 2024, the Company had federal net operating loss carryforwards, or NOLs, of $93.6 million that do not expire and federal tax credits of $25.3 million available to offset tax liabilities that begin to expire in 2038. The Company also has gross state NOLs of $169.6 million and state tax credits of $2.9 million which are available to offset state tax liabilities. The state NOLs begin to expire in 2038 and the state tax credits do not expire.

During the year ended December 31, 2024, the Company completed a Section 382 study to determine whether an ownership change per the provisions of Section 382 of the Internal Revenue Code, as well as similar state provisions, has occurred. The Company's current year utilization of net operating losses and income tax credits is not impacted by the provisions of Section 382 or 383. Utilization of its net operating loss and income tax credit carryforwards may be subject to an annual limitation due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of the net operating loss and income tax credit carryover that can be utilized annually to offset future taxable income. In general, an "ownership change" as defined by Section 382 of the Internal Revenue Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding shares of a company by certain stockholders.

In accordance with the Tax Cuts and Jobs Act of 2017, Research and Experimental, or R&E, expenses under Internal Revenue Code Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of 5 years for domestic expenses and 15 years for foreign expenses.

Uncertain Tax Positions

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table reconciles the beginning and ending amount of unrecognized tax benefits (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Balance at beginning of year	$ 2,634	$ 2,535	$ 1,141
Additions based on tax positions related to prior year	1,433	29	726
Additions based on tax positions related to current year	2,305	872	916
Reductions based on tax positions related to prior year	—	(802)	(248)
Reductions based on tax positions related to current year	—	—	—
Balance at end of year	$ 6,372	$ 2,634	$ 2,535

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2024, 2023 and 2022, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

The Company files income tax returns in the U.S. federal, California and other state tax jurisdictions. The federal and state income tax returns from December 31, 2018 to December 31, 2023 remain subject to examination.

12. 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 the year ended December 31, 2024, 2023, and 2022, the Company made matching contributions of $1.7 million, $1.3 million, and $0.8 million, respectively.

13. Segment Reporting

The Company views its operations and manages its business in one operating and one reportable segment, which includes all activities related to the identification, development and commercialization of medicines for childhood and adult diseases with equal intensity. The determination of a single operating segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker, or

CODM. The Company's CODM is its Chief Executive Officer, who reviews and evaluates net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods. Our CODM does not evaluate the operating segment using asset or liability information. The operating segment derives all net product revenues from the sales of OJEMDA in the United States through contractual arrangements with its specialty pharmacy and specialty distributor customers. All the Company's assets are located in the United States.

In addition to the significant expense categories included within net loss presented on the Company's Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
External costs:			
Third-party CRO, CMO and other third-party clinical trial costs (1)	$ 89,400	$ 71,294	$ 50,175
License upfront payments and milestones	80,000	8,000	2,500
Other research and development costs	8,949	8,465	3,598
Internal costs:			
Employee related expenses	49,353	42,762	29,345
Total research and development expenses	$ 227,702	$ 130,521	$ 85,618

(1) Costs incurred under agreements with third-party CROs, CMOs, and other third parties that conduct clinical activities on the Company's behalf.

Exhibit 10.6

SUBLEASE

THIS SUBLEASE (this "***Sublease***") is dated for reference purposes as of June 26, 2024 (the "***Effective Date***"), and is made by and between Arcus Biosciences, Inc., a Delaware corporation ("***Sublessor***"), and Day One Biopharmaceuticals, Inc., a Delaware corporation ("***Sublessee***"). Sublessor and Sublessee hereby agree as follows:

1. Recitals: This Sublease is made with reference to the fact that HCP LS Brisbane, LLC, as landlord ("***Master Lessor***"), and Sublessor, as tenant, entered into that certain Lease, dated as of December 30, 2020, as amended by that certain First Amendment to Lease Agreement (the "***First Amendment***") dated as of November 30, 2022 (as amended, the "***Master Lease***"), with respect to premises consisting of approximately 109,237 rentable square feet of space, as part of that certain Building located at 1800 Sierra Point Parkway, Brisbane, California (the "***Premises***"). A copy of the Master Lease is attached hereto as Exhibit A.

2. Subleased Premises: Sublessor hereby subleases to Sublessee, and Sublessee hereby subleases from Sublessor, a portion of the Premises consisting of approximately 18,657 rentable square feet of space located on the second floor of the Premises (hereinafter, the "***Subleased Premises***"). The Subleased Premises are more particularly depicted and described on Exhibit B attached hereto. Except to the extent that the square footage of the Premises is adjusted under the Master Lease, the square footage of the Subleased Premises shall be as set forth in this paragraph, notwithstanding any remeasurement. In connection with its use of the Subleased Premises, Sublessee shall also have the non-exclusive right to use the Common Areas (as defined in the Master Lease) and, subject to Sublessor's reasonable rules and regulations, the portions of the Premises noted as "Shared Areas" on Exhibit B (the "***Shared Areas***"), which such rules and regulations shall (a) be enforced in a non-discriminatory manner, and (b) neither materially increase Sublessee's obligations hereunder nor materially decrease Sublessee's rights hereunder.

3. Term:

A. Term. The term (the "***Term***") of this Sublease shall be for the period commencing on the earlier of (i) March 1, 2025 and (ii) the date Sublessee Substantially Completes (as defined below) its Initial Alterations (as defined below) (the "***Commencement Date***") and ending on January 3, 2032 (the "***Expiration Date***"), unless this Sublease is sooner terminated pursuant to its terms or the Master Lease sooner terminates pursuant to its terms. Notwithstanding anything herein to the contrary, in the event that Sublessee Substantially Completes its Initial Alterations at any time prior to December 1, 2024, then, the Commencement Date shall automatically be deemed to occur on December 1, 2024 and Sublessee may not conduct business in the Subleased Premises until December 1, 2024. For the avoidance of doubt, the Subleased Premises shall be deemed delivered and early access provided by Sublessor to Sublessee when Sublessor provides Sublessee keys or other means of access thereto, subject to the terms of this Sublease.

B. Early Possession. Sublessor shall permit Sublessee to enter the Subleased Premises commencing upon execution of this Sublease by Sublessor and Sublessee solely for the purpose of (i) planning construction of the Initial Alterations, (ii) conducting move-in coordination, (iii) constructing the Initial Alterations, and (iv) otherwise preparing the Subleased Premises for long-term occupancy (including, without limitation, installing its furniture, fixtures, and equipment), but, in any event, Sublessee shall not enter and occupy the Subleased Premises during such early possession period for the purpose of conducting business therein, provided (x) Master Lessor's Consent (as hereafter defined) to this Sublease has been received, (y) Sublessee has delivered to Sublessor the Security Deposit (as hereafter defined) and the Prepaid Rent (as hereafter defined), and (z) Sublessee has delivered to Sublessor evidence of all insurance required to be carried by Sublessee under this Sublease. Such occupancy shall be subject to all of the provisions of this Sublease, except that Sublessee shall not be obligated to pay Base Rent, Direct Expenses (defined below) or utilities prior

to the Commencement Date, and such early possession period shall not advance the Expiration Date of this Sublease.

4. Rent:

A. Base Rent. Sublessee shall pay to Sublessor as base rent for the Subleased Premises for each month during the Term the following amounts per month ("***Base Rent***").

Months	Monthly Base Rent
1-12*	$69,963.75
13-24*	$72,062.66
25-36*	$74,224.54
37-48*	$76,451.28
49-60*	$78,744.82
61-72	$81,107.16
73-84	$83,540.38
85-Expiration Date	$86,046.59

*So long as Sublessee is not in default under this Sublease beyond any applicable notice and cure periods, Base Rent shall be abated during (i) the first six (6) full calendar months of each of the first four (4) years of the Term and (ii) the first four (4) full calendar months of the fifth (5^{th}) year of the Term.

Base Rent and Additional Rent, as defined in Paragraph 4.B below, shall be paid on or before the first (1^{st}) day of each month. Base Rent and Additional Rent for any period during the Term hereof which is for less than one (1) month of the Term shall be a pro rata portion of the monthly installment based on a thirty (30) day month. Base Rent and Additional Rent shall be payable without notice or demand and without any deduction, offset, or abatement, in lawful money of the United States of America. Base Rent and Additional Rent shall be paid directly to Sublessor at 3928 Point Eden Way, Hayward, CA 94545, Attention: Finance/Accounts Receivable, or such other address as may be designated in writing by Sublessor, or pursuant to ACH instructions provided by Sublessor.

B. Additional Rent. All monies other than Base Rent required to be paid by Sublessor under the Master Lease as to the Subleased Premises, including, without limitation, any amounts payable by Sublessor to Master Lessor as "Direct Expenses" (as defined in Section 4.2.2 of the Master Lease) and costs of utilities under Section 6.2 of the Master Lease, as incorporated herein, shall be paid by Sublessee hereunder as and when such amounts are due under the Master Lease, as incorporated herein; provided Sublessee shall only be required to pay Direct Expenses and utilities which are allocable to the Subleased Premises (a) commencing in 2026 and continuing thereafter for the remainder of the Term, and (b) only to the extent that such Direct Expenses and utilities exceed the amount of Direct Expenses and utilities allocable to the Subleased Premises in 2025 (the "***Base Year***"). Sublessee's payment of Direct Expenses and utilities herein shall be subject to reconciliation and adjustment as between Master Lessor and Sublessor in the same manner as set forth in the provisions of the Master Lease. For the avoidance of doubt, Direct Expenses shall be paid on the first day of each month based on estimates provided by Sublessor (which shall be based on estimates provided by Master

Lessor) and subject to reconciliations provided by Sublessor (based on reconciliations provided by Master Lessor). Utilities for the Subleased Premises shall be invoiced in arrears and due on the first day of each month. Commencing in 2026 and continuing thereafter for the remainder of the Term, Sublessee shall also pay to Sublessor its pro rata share based on the square footage of the Subleased Premises to the square footage of the Premises ("***Pro Rata Share***") (which Pro Rata Share, for the avoidance of doubt, is currently equal to 17.08%), within thirty (30) days of request by Sublessor, of the cost of any utilities to the Shared Areas and Sublessor's actual, reasonable, out-of-pocket cost of performing any routine or necessary repairs or maintenance or providing other reasonable services that benefit the Subleased Premises or the Shared Areas (such as maintenance of any systems therein and janitorial service to the Subleased Premises, which Sublessor shall provide at the same level it provides to the remainder of the office portion of its Premises) to the extent they exceed the amount of such expenses in the Base Year (provided Sublessor shall not include any costs of the type described in Section 4.2.4(a)-(t) of the Master Lease), and shall pay the disproportionate cost of such amounts to the extent supplied disproportionately to Sublessee and the entire cost of such amounts to the extent supplied solely to Sublessee or due to the negligence or willful misconduct of Sublessee or its agents, employees or contractors. Sublessee shall also pay any gross receipts or rent tax payable with respect to this Sublease. All such amounts shall be deemed additional rent ("***Additional Rent***"). Base Rent and Additional Rent hereinafter collectively shall be referred to as "***Rent***". Notwithstanding the foregoing, in the event any cost or expense is incurred for Sublessee's sole benefit (including the disproportionate use of utilities) or as a result of Sublessee's request for certain services (such as after hours HVAC charges), or property taxes are increased as a result of Alterations or improvements to the Subleased Premises made by or for Sublessee (including the Initial Alterations), Sublessee shall pay the entire cost thereof within thirty (30) days of receipt of an itemized invoice therefor. For the avoidance of doubt, in no event shall Sublessee be responsible for the payment of any amounts which are attributable to Sublessor's default under the Master Lease or Sublease, which such default is not attributable to Sublessee's own default under this Sublease. In the event that Sublessee disputes the Direct Expenses or utilities billed to Sublessee hereunder, Sublessor shall be obligated, upon Sublessee's reasonable request (which, for the avoidance of doubt, shall not occur more than once in any calendar year) and, to the extent not fully reimbursed by Master Lessor, at Sublessee's cost, which shall be paid by Sublessee within thirty (30) days of demand by Sublessor, to exercise its rights under Section 4.6 of the Master Lease.

C. Payment of Seventh Month's Rent. Upon execution hereof by Sublessee, Sublessee shall pay to Sublessor the sum of Sixty-Nine Thousand Nine Hundred Sixty-Three and 75/100 Dollars ($69,963.75) (the "***Prepaid Rent***"), which shall constitute Base Rent for the seventh month of the Term, and which amount shall be applicable to and credited toward Sublessee's Base Rent payment for the seventh month of the Term.

5. Security Deposit: Upon execution hereof by Sublessee, Sublessee shall deposit with Sublessor the sum of Eighty-Six Thousand Forty-Six and 59/100 Dollars ($86,046.59) (the "***Security Deposit***"), in cash, as security for the performance by Sublessee of the terms and conditions of this Sublease. If Sublessee fails to pay Rent or other charges due hereunder beyond any applicable notice and cure period or otherwise defaults with respect to any provision of this Sublease beyond any applicable notice and cure period, then Sublessor may draw upon, use, apply or retain all or any portion of the Security Deposit for the payment of any Rent or other charge in default, for the payment of any other sum which Sublessor has become obligated to pay by reason of Sublessee's default, or to compensate Sublessor for any loss or damage which Sublessor has suffered thereby, including future rent damages under California Civil Code Section 1951.2, without prejudice to any other remedy provided herein or by law. Sublessee hereby waives the provisions of any law, now or hereafter in force, including, without limitation, California Civil Code Section 1950.7, that provides that Sublessor may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of Rent, to repair damage caused by Sublessee, or to clean the Subleased Premises, it being agreed that Sublessor, in addition, may claim those sums reasonably necessary to compensate Sublessor for any other loss or damage, foreseeable or unforeseeable, caused by the act or omission of Sublessee, including future rent damages following the termination of this Sublease. If Sublessor so uses or applies all or any portion of the Security

Deposit, then Sublessee, within ten (10) days after demand therefor, shall deposit cash with Sublessor in the amount required to restore the Security Deposit to the full amount stated above. Upon the expiration of this Sublease, if Sublessee is not in default beyond any applicable notice and cure period, Sublessor shall return to Sublessee so much of the Security Deposit as has not been applied by Sublessor pursuant to this paragraph, or which is not otherwise required to cure Sublessee's defaults within thirty (30) days following the expiration or earlier termination of this Sublease.

6. Holdover: In the event that Sublessee does not surrender the Subleased Premises by the Expiration Date in accordance with the terms of this Sublease, Sublessee shall indemnify, defend, protect and hold harmless Sublessor from and against all loss and liability resulting from Sublessee's delay in surrendering the Subleased Premises and pay Sublessor holdover rent as provided in Section 16 of the Master Lease.

7. Repairs: The parties acknowledge and agree that Sublessor has made no representations or warranties with respect to the condition of the Subleased Premises except as expressly set forth herein. Sublessor shall have no obligation whatsoever to make or pay the cost of any alterations, improvements or repairs to the Subleased Premises, including, without limitation, any improvement or repair required to comply with any law, except to the extent that the necessity of any such repairs arises out of the gross negligence or willful misconduct of Sublessor or its agents, employees, or contractors. Notwithstanding anything herein to the contrary, except to the extent damaged by Sublessee or its agents, employees or contractors, in no event shall Sublessee be responsible for maintaining and repairing the Premises (excluding the portion of the Premises consisting of the Subleased Premises) or the Shared Areas. Master Lessor shall be solely responsible for performance of any repairs required to be performed by Master Lessor under the terms of the Master Lease. With respect to work, services, repairs and restoration or the performance of other obligations required of Master Lessor under the Master Lease, Sublessor shall request the same, upon written request from Sublessee, and use reasonable efforts to obtain the same from Master Lessor, but shall not be required to engage in litigation. Notwithstanding the foregoing or any provision contained in this Sublease to the contrary, Sublessee shall not be responsible for payment or performance of any obligation arising under the Master Lease in connection with the Subleased Premises that must be performed prior to the Commencement Date of this Sublease. Sublessor shall remain obligated to pay, and shall pay prior to delinquency, all rent and other amounts required to be paid by the "Tenant" under the Master Lease to the extent required to maintain in effect the Master Lease or Sublessee's occupancy rights on the terms of this Sublease.

8. Assignment and Subletting: Sublessee may not assign this Sublease, sublet the Subleased Premises, transfer any interest of Sublessee therein or permit any use of the Subleased Premises by another party (collectively, "***Transfer***"), without the prior written consent of Master Lessor (in accordance with the terms of the Master Lease) and Sublessor (which consent shall not be unreasonably withheld, conditioned, or delayed provided Master Lessor's consent has been obtained); provided, however, Sublessor's consent shall not be required for a transfer as described in Section 14.8 of the Master Lease. Any Transfer shall be subject to the terms of Section 14 of the Master Lease, as incorporated herein.

9. Use: Sublessee may use the Subleased Premises only for general office use consistent with first class life science projects in the City of Brisbane, including, but not limited to, administrative offices and other lawful uses reasonably related to or incidental to general office use, and in compliance with, and subject to, applicable laws and the terms of the Master Lease and this Sublease (the "***Permitted Use***"). Sublessee shall not use, store, transport or dispose of any Hazardous Materials (as defined in the Master Lease) in or about the Subleased Premises except those materials used in conjunction with general office use (e.g., printer toner, household cleaners, etc.) as expressly permitted under the Master Lease, as incorporated herein, including Section 5.3 thereof. Sublessee shall comply with all reasonable rules and regulations promulgated from time to time by Sublessor and Master Lessor so long as any such rules and regulations promulgated by Sublessor are (a) enforced in a non-discriminatory manner, and (b) neither materially increase Sublessee's obligations hereunder nor materially decrease Sublessee's rights hereunder.

10. Delivery and Acceptance: Except to the extent otherwise expressly provided in this Sublease, if Sublessor fails to timely deliver possession of the Subleased Premises to Sublessee for any reason whatsoever, then this Sublease shall not be void or voidable, nor shall Sublessor be liable to Sublessee for any loss or damage. Notwithstanding anything herein to the contrary, should Sublessor fail to deliver the Subleased Premises to Sublessee on or before the date that is three (3) business days following the later of (a) the Effective Date or (b) the date the Consent has been delivered (and such failure continues for more than two (2) business days after written notice and is not attributable to an event of Force Majeure (as such term is defined in the Master Lease) or a casualty or condemnation), then Sublessee shall have the right to terminate this Sublease by delivering written notice thereof to Sublessor prior to such delivery, whereupon Sublessor shall promptly return to Sublessee the Security Deposit and the Prepaid Rent. Except as otherwise provided in this Sublease, by taking possession of the Subleased Premises, Sublessee conclusively shall be deemed to have accepted the Subleased Premises in their as-is, then-existing condition, without any warranty whatsoever of Sublessor with respect thereto. Notwithstanding anything herein to the contrary, to Sublessor's knowledge, Sublessor represents and warrants to Sublessee that all building systems (including, without limitation, all mechanical, electrical, plumbing, roof, foundation, and exterior walls) serving the Subleased Premises are in good working order and condition as of the Effective Date.

11. Improvements: No alteration or improvements shall be made to the Subleased Premises, except in accordance with the Master Lease, and with the prior written consent of both Master Lessor (in accordance with the terms of the Master Lease) and Sublessor (which consent shall not be unreasonably withheld, conditioned, or delayed provided the consent of Master Lessor has been obtained). Subject to the foregoing, Sublessee shall construct, at its sole cost and expense, in accordance with the requirements of this Sublease and the Master Lease, the improvements described in Exhibit C, including demising the Subleased Premises from the remainder of the floor (the "***Initial Alterations***"). Sublessor shall not unreasonably withhold, condition, or delay its consent to the plans (the "***Plans***") for the Initial Alterations and, in any event, shall approve or disapprove of any such plans within five (5) business days after receipt thereof, subject to receipt of Master Lessor's consent. If Sublessor reasonably disapproves of the Plans, or any portion thereof, Sublessor shall notify Sublessee thereof and of the revisions which Sublessor reasonably requires in order to obtain Sublessor's approval. As promptly as possible thereafter, Sublessee shall submit to Sublessor revised Plans incorporating the revisions required (which revisions shall be subject to Sublessor's approval, which shall not be unreasonably withheld, conditioned, or delayed). The foregoing process shall be repeated until Sublessor finally approves all of the Plans, subject to receipt of Master Lessor's consent. Sublessor shall pay Master Lessor's fees (if any) to review such work up to $35,000.00 (the "***Review Fee Cap***"), with any additional amounts exceeding the Review Fee Cap to be payable by Sublessee. As part of its obligations hereunder, Sublessor shall use commercially reasonable efforts to coordinate with Master Lessor to promptly obtain Master Lessor's consent to any Initial Alterations or subsequent alterations, additions, or improvements. Sublessee shall use diligent, good faith, commercially reasonable efforts to complete the Initial Alterations, subject only to normal punchlist items, and obtain final governmental approval of thereof ("***Substantially Complete***") before the Commencement Date and may not occupy the Subleased Premises for the conduct of business until the demising work has been Substantially Completed. If Sublessee fails to Substantially Complete the demising work before the Commencement Date, in addition to its other remedies, Sublessor may perform such work at Sublessee's cost (the "***Self Help Right***"); provided, however, that for the avoidance of doubt, Sublessor's Self Help Right shall be limited to demising the Subleased Premises from the remainder of the Premises and not for the performance of any other portion of the Initial Alterations. Notwithstanding anything in this Sublease or the Master Lease to the contrary, Sublessee shall not be required to remove or restore upon the expiration or earlier termination of this Sublease (a) the Initial Alterations or any future alterations, additions or improvements by Sublessee except to the extent, in either case, required by Master Lessor or (b) any alteration, addition, or improvement existing as of the date the Subleased Premises are delivered to Sublessee and, to the extent that any such restoration and removal of alterations, additions or improvements existing as of the date the Subleased Premises are delivered to Sublessee is required by Master Lessor, such restoration and removal as set forth in subsections (a) and (b) above shall be performed by Sublessor at Sublessor's sole cost and expense.

12. Insurance; Waiver of Subrogation: Sublessee shall obtain and keep in full force and effect, at Sublessee's sole cost and expense, during the Term, the insurance required under Section 10 of the Master Lease. Sublessee shall name Master Lessor and Sublessor as additional insureds under its liability insurance policy. The release and waiver of subrogation set forth in Section 10.5 of the Master Lease, as incorporated herein, shall be binding on each of the parties.

13. Default: Sublessee shall be in default under this Sublease if Sublessee commits any act or omission which constitutes a default under the Master Lease, which has not been cured after delivery of written notice and passage of the applicable grace period provided in the Master Lease as modified, if at all, by the provisions of this Sublease; provided, however, that Sublessee shall not be in default of the Master Lease in the event that such default arises out of the acts or omissions of Sublessor (or its agents, employees, or contractors) that is not due to the acts or omissions of Sublessee (or its agents, employees or contractors). In the event of any default by Sublessee, Sublessor shall have all remedies provided pursuant to Sections 19.2 and 19.3 of the Master Lease and by applicable law, including damages that include the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the lessee proves could be reasonably avoided and the remedy described in California Civil Code Section 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover rent as it becomes due, if lessee has right to sublet or assign, subject only to reasonable limitations), subject to Sublessor's affirmative obligation to mitigate its damages (if any). Notwithstanding anything herein to the contrary, in the event of any default by Sublessor under this Sublease, Sublessee shall be afforded the same rights and remedies as are afforded to Sublessor following a Master Lessor default under the Master Lease, as incorporated herein (including, without limitation, those rights and remedies set forth in Section 19.5 of the Master Lease).

14. Surrender; Hazardous Materials:

A. Prior to expiration of this Sublease, Sublessee shall remove all of its trade fixtures and other articles of personal property owned by Sublessee and shall surrender the Subleased Premises to Sublessor in the condition required under the Master Lease. (For the avoidance of doubt, Sublessee shall return the Subleased Premises in as good order and condition as when Sublessee took possession of the Subleased Premises, subject to the terms of Section 11 of this Sublease and Section 15 of the Master Lease.) If the Subleased Premises are not so surrendered, then Sublessee shall be liable to Sublessor for all liabilities Sublessor incurs as a result thereof, including costs incurred by Sublessor in returning the Subleased Premises to the required condition. For the avoidance of doubt, in no event shall Sublessee be liable or responsible for removing any alterations, additions, or improvements from the Subleased Premises at the expiration or earlier termination of the Term which were present at the Subleased Premises at the time possession of the Subleased Premises was first delivered to Sublessee.

B. Under no circumstance shall Sublessee be liable for, and Sublessor shall indemnify, defend, protect and hold harmless Sublessee and Sublessee's agents, employees, and contractors from and against, all losses, costs, claims, liabilities and damages (including attorneys' and consultants' fees) arising out of any Hazardous Materials released by Sublessor or Sublessor's agents, employees, or contractors. Sublessor will provide Sublessee with any Hazardous Material reports relating to the Building that Sublessor has in its immediate possession. The provision of such reports shall be for informational purposes only, and Sublessor does not make any representation or warranty as to the correctness or completeness of any such reports. For the avoidance of doubt, Sublessee shall not be responsible for remediating (including as part of any Environmental Assessment prepared by Sublessee upon its surrender of the Subleased Premises) any Hazardous Materials that exist in the Subleased Premises as of the date the Subleased Premises are delivered to Sublessee.

15. Brokers: Sublessor and Sublessee each represents to the other that it has dealt with no real estate brokers, finders, agents or salesmen other than Newmark Cornish & Carey representing Sublessor

("***Sublessor's Broker***"), and Cushman and Wakefield, representing Sublessee ("***Sublessee's Broker***"; together with Sublessor's Broker, collectively, the "***Brokers***"), in connection with this transaction. Each party agrees to hold the other party harmless from and against all claims for brokerage commissions, finder's fees or other compen sation made by any other agent, broker, salesman or finder as a consequence of such party's actions or dealings with such agent, broker, salesman, or finder.

16. Notices: Unless at least five (5) days' prior written notice is given in the manner set forth in this paragraph, the address of each party for all purposes connected with this Sublease shall be the applicable address set forth below its signature at the end of this Sublease. All notices, demands or communications in connection with this Sublease shall be (a) personally delivered; or (b) properly addressed and (i) submitted to an overnight courier service, charges prepaid, or (ii) deposited in the mail (certified, return receipt requested, and postage prepaid). Notices shall be deemed delivered upon receipt, if personally delivered, one (1) business day after being submitted to an overnight courier service and three (3) business days after mailing, if mailed as set forth above. All notices given to Master Lessor under the Master Lease shall be considered received only when delivered in accordance with the Master Lease.

17. Miscellaneous: Sublessor has not had an inspection of the Premises performed by a Certified Access Specialist as described in California Civil Code § 1938. A Certified Access Specialist (CASp) can inspect the Subleased Premises and determine whether the Subleased Premises complies with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the Subleased Premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the Subleased Premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Subleased Premises. Capitalized terms used but not defined in this Sublease shall have the meanings ascribed to such terms in the Master Lease.

18. Other Sublease Terms:

A. Incorporation by Reference. Except as set forth below, the terms and conditions of this Sublease shall include all of the terms of the Master Lease and such terms are incorporated into this Sublease as if fully set forth herein, except that: (i) each reference in such incorporated sections to "Lease" shall be deemed a reference to "Sublease"; (ii) each reference to the "Premises", "Lease Term" and "Base Rent" shall be deemed a reference to the "Subleased Premises", "Term" and "Base Rent" under this Sublease, respectively; (iii) each reference to "Landlord" and "Tenant" shall be deemed a reference to "Sublessor" and "Sublessee", respectively, except as otherwise expressly set forth herein; (iv) with respect to work, services, repairs, restoration, insurance, indemnities, representations, warranties or the performance of any other obligation of Master Lessor under the Master Lease, the sole obligation of Sublessor shall be to request the same in writing from Master Lessor as and when requested to do so by Sublessee, and to use Sublessor's reasonable efforts (without requiring Sublessor to spend more than a nominal sum) to obtain Master Lessor's performance; (v) with respect to any obligation of Sublessee to be performed under this Sublease, wherever the Master Lease grants to Sublessor a specified number of days to perform its obligations under the Master Lease, except as otherwise provided herein, Sublessee shall have three (3) fewer days to perform the obligation, including, without limitation, curing any defaults (which period shall be reduced by only one (1) day if Sublessor has five (5) days (or less) to perform); (vi) with respect to any approval required to be obtained from the "Landlord" under the Master Lease, such consent must be obtained from both Master Lessor and Sublessor, and the approval of Sublessor may be withheld if Master Lessor's consent is not obtained (provided, however, that if the consent of Master Lessor has been obtained, then Sublessor's approval shall not be unreasonably withheld, conditioned, or delayed); (vii) in any case where the "Landlord" reserves or is granted the right to manage, supervise, control, repair, alter, regulate the use of, enter or use the Premises or any areas beneath, above or adjacent thereto,

perform any actions or cure any failures, such reservation or right shall be deemed to be for the benefit of both Master Lessor and Sublessor; (viii) in any case where "Tenant" is to indemnify, release or waive claims against "Landlord", such indemnity, release or waiver shall be deemed to cover, and run from Sublessee to, both Master Lessor and Sublessor (except to the extent any such claims, losses, liabilities, or damages giving rise to such indemnification, release, or waiver were caused by or attributable to the gross negligence or willful misconduct of Sublessor (or its agents, employees or contractors)); (ix) in any case where "Tenant" is to execute and/or deliver certain documents or notices to "Landlord", such obligation shall be deemed to run from Sublessee to both Master Lessor and Sublessor; (x) all payments shall be made to Sublessor; (xi) Sublessee shall pay all consent and review fees set forth in the Master Lease to each of Master Lessor and Sublessor and any caps shall apply separately to Master Lessor and Sublessor (provided, however, that for the avoidance of doubt, in no event shall Sublessee shall be responsible for any fees or costs incurred by Master Lessor in connection with Master Lessor's review and consent to this Sublease); and (xii) Sublessor's obligations under Section 4 are limited to forwarding statements and refunds provided by Master Lessor, and Sublessee shall have no right to dispute or audit such statements. Except as expressly provided in Paragraph 4(A) above, under no circumstances shall rent abate under this Sublease except to the extent that rent correspondingly abates under the Master Lease as to the Subleased Premises.

Notwithstanding the foregoing, the following provisions of the Master Lease shall not be incorporated herein: Summary of Basic Lease Information, Sections 1.1.1, 1.1.2 (the first sentence only), 1.1.3 (the last sentence only), 1.2, 2.1 (except the first, third and fourth sentences), 2.2, 3, 4.6, 5.1, 5.3.1.1 (the last sentence only), 5.3.1.4.3, 6.5, 6.6, 7.3, 8.5 (the last four sentences only), 14.3 (the penultimate sentence and the parentheticals in the second sentence only), 14.4 (the last three sentences), 14.8, 18 (the first and third sentences only), 21, 23.1 (before the semicolon in the first sentence and the last two sentences only), 29.18 and 29.24, Exhibits A, B, F, G and H and the First Amendment. In addition, notwithstanding subpart (iii) above, (a) references in the following provisions to "Landlord" shall mean Master Lessor only: Sections 1.1.2(iv), 1.1.3, 4.2.4, 4.3, 6.1 (the first sentence only and the first clause in the last sentence only), 7.2, 8.4 (the last reference in the first sentence), 10.2, 11.1 (the second and third sentences only), 11.2 (except the last instance), 13 (the first sentence), 15.2 (the last reference of the first sentence only), 29.26 (the first sentence) and 29.29.1; (b) references in the following provisions to "Landlord" shall mean Master Lessor and Sublessor: Sections 4.5, 10.3.4, 10.4, 17, 24 (the third sentence only) and 26.2; (c) references to the "Permitted Use" shall mean the use permitted under Section 9 above; (d) Tenant's Share shall mean 17.08% based on the current rentable square footage of the Premises and the Subleased Premises; (e) in Section 14.3, Sublessee shall pay Sublessor the entire premium payable to Master Lessor under the Master Lease, plus fifty percent (50%) of any remaining Transfer Premium (provided, however, that for the avoidance of doubt, the costs of Sublessee's improvements and alterations made to the Subleased Premises to effect the Transfer shall be expressly deducted from the Transfer Premium); and (f) the reference in Section 8.1 $100,000 shall be to $50,000.

B. Assumption of Obligations. This Sublease is and at all times shall be subject and subordinate to the Master Lease and the rights of Master Lessor thereunder. Sublessee hereby expressly assumes and agrees: (i) to comply with all provisions of the Master Lease which are incorporated hereunder; and (ii) to perform all the obligations on the part of the "Tenant" to be performed under the terms of the Master Lease during the Term of this Sublease that are incorporated hereunder. In the event the Master Lease is terminated for any reason whatsoever, this Sublease shall terminate simultaneously with such termination (unless Master Lessor or a successor tenant agrees to permit Sublessee to continue to occupy the Subleased Premises on the terms of this Sublease for the remainder of the Term), without any liability of Sublessor to Sublessee. In the event of a conflict between the provisions of this Sublease and the Master Lease, as between Sublessor and Sublessee, the provisions of this Sublease shall control. In the event of a conflict between the express provisions of this Sublease and the provisions of the Master Lease, as incorporated herein, the express provisions of this Sublease shall prevail. Except as otherwise provided in this Sublease, Sublessee shall have

all other rights, privileges, options, reservations and remedies granted or allowed to or held by Sublessor under the Master Lease, as incorporated herein.

19. Conditions Precedent: This Sublease and Sublessor's and Sublessee's obligations hereunder are conditioned upon the written consent of Master Lessor (the "***Consent***"). Each party shall use commercially reasonable efforts to obtain such Consent, including by promptly signing Master Lessor's commercially reasonable consent form (subject to each party's reasonable review thereof). If Sublessor fails to obtain Master Lessor's consent within thirty (30) days after execution of this Sublease by Sublessor, then Sublessor or Sublessee may terminate this Sublease by giving the other party written notice thereof prior to the date such consent is received, and Sublessor shall return to Sublessee its payment of the Prepaid Rent and the Security Deposit.

20. Termination; Recapture; No Relocation: Notwithstanding anything to the contrary herein, Sublessee acknowledges that, under the Master Lease, both Master Lessor and Sublessor have certain termination and recapture rights, including, without limitation, in Sections 11, 13 and 14.4. Nothing herein shall prohibit Master Lessor or Sublessor from exercising any such rights in accordance with the terms of the Master Lease and neither Master Lessor nor Sublessor shall have any liability to Sublessee as a result thereof. In the event Master Lessor or Sublessor exercise any such termination or recapture rights as to all of the Subleased Premises, this Sublease shall terminate without any liability to Master Lessor or Sublessor. Notwithstanding anything herein to the contrary, in no event shall Sublessor be permitted to relocate the Subleased Premises to another location during the Term.

21. Inducement Recapture: Any agreement for free or abated rent or other charges, or for the giving or paying by Sublessor to or for Sublessee of any cash or other bonus, inducement or consideration for Sublessee's entering into this Sublease, all of which concessions are hereinafter referred to as "***Inducement Provisions***", shall be deemed conditioned upon Sublessee's full and faithful performance of all of the terms, covenants and conditions of this Sublease. Upon a default by Sublessee beyond applicable notice and cure periods, any such Inducement Provision shall automatically be deemed deleted from this Sublease and no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Sublessor under such an Inducement Provision shall be immediately due and payable by Sublessee to Sublessor, notwithstanding any subsequent cure of said default by Sublessee.

22. Parking and Signage; Amenities; Access: Sublessee shall have the right to park in 53 parking spaces in the on-site parking lot and garage that serves the Building, on an unreserved basis, as provided in Section 28 of the Master Lease, as incorporated herein. Subject to Master Lessor's and Sublessor's consent (which consent shall not be unreasonably withheld, conditioned, or delayed provided the consent of Master Lessor has been obtained) and Section 23 of the Master Lease, and provided the same do not unreasonably reduce or diminish Sublessor's ability to install its own signs, Sublessee shall have the right, at its sole cost, to install its name and/or logo or any of its affiliates' names and/or logos on (i) signage within the Subleased Premises, (ii) Building entrance signage and lobby identification signage in the Building, and (iii) to the extent space is available without reducing any existing signage (and subject to Master Lessor's prior approval), identification signage on the monument sign serving the Building. Notwithstanding anything herein to the contrary, Sublessee shall be afforded the same amenities with respect to the Building as are afforded to Sublessor under the Master Lease, at no additional cost or expense except to the extent charged by Master Lessor (such as for food in a café). To the extent that Master Lessor's consent is required for such amenities, Sublessor shall request such identification cards, consents, etc. as are necessary to provide such amenities access to Sublessee, which shall be at Sublessee's sole cost. Subject to the terms of the Master Lease and Master Lessor's rights, Sublessee shall be afforded access to the Building and the Subleased Premises on a 24 hours per day, 7 days per week, 365 days per year basis.

23. Sublessor Representations and Warranties: Sublessor represents and warrants to Sublessee, and covenants and agrees with Sublessee that: (i) it is the holder of the interest of the "Tenant" under the Master Lease with respect to the Subleased Premises and such interest has not previously been assigned, transferred or sublet, (ii) the Master Lease is in full force and effect, (iii) Sublessor has no actual knowledge of any default by it under the Master Lease and Sublessor has not received any notices of default from Master Lessor which have not been cured, (iv) to Sublessor's actual knowledge, Master Lessor is not in default under the Master Lease, (v) Exhibit A annexed hereto contains a true, correct and complete copy of the Master Lease, and (vi) it shall not amend the Master Lease in any manner that will materially increase any obligation of Sublessee or materially decrease any rights of Sublessee without Sublessee's prior written consent; provided, however, that for the avoidance of doubt in no event shall any such amendment have the effect of increasing Sublessee's rental obligations owed under this Sublease.

24. Counterparts. This Sublease may be executed in any number of counterparts, all of which are considered one and the same original notwithstanding that all parties hereto have not signed the same counterpart. Signatures of this Sublease which are transmitted by either or both electronic or telephonic means (including, without limitation, facsimile and email) constitute valid delivery and are valid and binding for all purposes. If the signature of any party on this Sublease is not an original, but is a digital, mechanical, or electronic signature or reproduction, then the same shall be as enforceable, valid and binding as, and the legal equivalent to, an authentic and traditional ink-on-paper original wet signature penned manually by its signatory. The parties (i) intend to be bound by the signatures (whether original or electronic) on any document sent by electronic mail, (ii) are aware that the other party will rely on such signatures, and (iii) hereby waive any defenses to the enforcement of the terms of this Sublease based on the foregoing forms of signature.

25. Miscellaneous. This Sublease shall not be amended or modified except in a writing signed by each of the parties affected by such amendment or modification. The drafting and negotiation of this Sublease has been participated in by each of the parties. For all purposes, this Sublease shall be deemed to have been drafted jointly by the parties. This Sublease shall be construed and enforced in accordance with the substantive laws of the State of California without reference to its conflicts of laws provisions. Paragraph captions used herein are solely for the convenience of the reader and do not limit or define the provisions hereof.

[Remainder of Page Intentionally Left Blank]

Exhibit 10.6

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

SUBLESSOR: SUBLESSEE:

ARCUS BIOSCIENCES, INC., a Delaware corporation DAY ONE BIOPHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Bob Goeltz By: /s/ Charles York

Name: Bob Goeltz Name: Charles York

Its: CFO Its: COO / CFO

Address: Arcus Biosciences, Inc.
3928 Point Eden Way
Hayward, CA 94545
Attn: Legal

Address for Notices:
Before the Commencement Date:
2000 Sierra Point Parkway, Suite 501
Brisbane, CA 94005

After the Commencement Date:

The Subleased Premises

Exhibit 10.6

EXHIBIT A

MASTER LEASE

[To Be Attached]

Exhibit 10.6

EXHIBIT B

SUBLEASED PREMISES AND SHARED AREAS

Exhibit 10.6

EXHIBIT C

INITIAL ALTERATIONS

1.0 PURPOSE

Day One Biopharmaceuticals, Inc. (the "Company," "we," "us" or "our") is committed to promoting high standards of honest and ethical business conduct and compliance with laws, rules and regulations. Because stock is an important part of the Company's compensation program, our Board of Directors ("Board") has adopted this Insider Trading Policy ("Policy") governing the purchase, sale and other dispositions of the Company's securities by the individuals and entities covered by this Policy to promote compliance with insider trading laws, rules and regulations, as well as applicable stock exchange listing standards.

Insider trading happens when someone who is in possession of material nonpublic information ("MNPI") trades securities on the basis of that information or discloses MNPI to someone else who trades on the basis of that information.

If you are considering trading our stock or other securities, please keep these three key points in mind:

- Never buy or sell our securities based on MNPI;
- Keep all MNPI confidential, including from your family and friends; and
- When in doubt about whether you have MNPI, ask before trading.

You are responsible for understanding and following this Policy and for the consequences of any actions you may take. Our Chief Compliance Officer or Chief Financial Officer will assist with implementing, interpreting and enforcing this Policy, pre-clearing trading activities of certain people, and pre-approving any Rule 10b5-1 Plans (plans that permit insiders to sell Company securities on a pre-determined schedule that the insider does not control, discussed more fully later in this Policy).

2.0 SCOPE

This Policy applies to our employees, contractors, consultants and Board members, as well as to their immediate family members, people sharing their households and anyone subject to their influence or control. It also applies to entities such as venture capital funds, partnerships, trusts and corporations that are associated or affiliated with our employees, contractors or consultants and Board members. An "immediate family member" under this Policy means any child, stepchild, parent, stepparent, spouse, domestic partner, sibling, mother-in-law, father-in- law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of a person security holder, and includes any person (other than a tenant or employee) sharing the household of that person. We will refer to all of these individuals and entities in this Policy collectively as "Insiders." Notwithstanding the foregoing, this Policy shall not apply to any venture capital fund or other entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) other than for an Employee, officer or directors own account if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws.

Additional trading restrictions in this Policy apply to our officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), and directors (together with the officers, the "Section 16 Insiders") and to the individuals listed on Exhibit A ("Designated Insiders") who are not Section 16 Insiders but who have regular access to MNPI in the normal course of their job. The list of Designated Insiders may be modified by our Chief Compliance Officer or Chief Financial Officer.

If you are aware of MNPI when your employment or service relationship with the Company ends, you still may not trade our securities until that MNPI has become public or is no longer material.

Additionally, the Company will not transact in its securities unless in compliance with U.S. securities laws.

The primary purpose of this Policy is to prevent people who are in possession of MNPI from trading in our stock or other securities on the basis of that MNPI or disclosing MNPI to someone else who trades on the basis of that information.

“Material information” is information about the Company, positive or negative, that a reasonable stockholder would consider important in making a decision to purchase or sell the Company’s securities. Material information can be positive or negative and can relate to virtually any aspect of the Company’s business or its securities.

Examples of material information may include:

- financial information (especially cash balance, burn and runway);
- significant regulatory communications;
- timing and achievement of major development milestones;
- results of studies and trials;
- entry into a new commercial agreement or termination of an existing commercial agreement;
- mergers or acquisitions;
- important pipeline expansion;
- significant cybersecurity incidents or data breaches;
- significant new litigation or regulatory inquires or developments in existing litigation or inquires;
- significant developments in borrowings, or financings or capital investments;
- significant changes in corporate strategy;
- restatements of historical financial statements;
- stock offerings or stock splits; and
- changes in senior executive management or our Board.

This list is illustrative only and is not intended to provide a comprehensive list of circumstances that could result in material information. Determination of what may constitute material information will depend upon the facts and circumstances in each particular situation.

“Nonpublic” means that the confidential information has not yet been shared broadly outside the Company. Please remember as well that we may possess confidential information relating to or belonging to our collaborators, partners or other third parties and that it is equally important that we treat this information with the same care with which we treat our own information. If you are not sure whether information is considered public, you should either consult with our Chief Compliance Officer or Chief Financial Officer or assume that the information is nonpublic and treat it as confidential.

This Policy applies to all transactions involving our securities, including common stock, restricted stock units (“RSUs”), options and warrants to purchase common stock and any other debt or equity securities the Company may issue from time to time, such as bonds, preferred stock, convertible notes, as well as to derivative securities relating to the Company’s securities, whether or not issued by the Company, such as exchange-traded options.

3.0 DELEGATION OF ACTIVITIES

Responsible roles identified in this policy may delegate an activity to a qualified delegate but retain accountability for the outcome.

4.0 DEFINITIONS AND KEY TERMS

Refer to *GUI-004* Day One Glossary

5.0 POLICY

5.1 Prohibited Activities and Other Restrictions

5.1.1 Insider Restrictions

The following is a list of prohibited activities for all Insiders:

- Trade our securities while in possession of any MNPI (other than pursuant to a 10b5-1 Plan entered into in accordance with this Policy).
- Trade our securities outside of a Trading Window or during a Blackout Period designated by our Chief Compliance Officer or Chief Financial Officer (other than pursuant to a 10b5-1 Plan entered into in accordance with this Policy). See the definition of "***Trading Window***" "***Blackout Period***" below.
- Unless approved in advance by our Chief Compliance Officer or Chief Financial Officer, make a gift, charitable contribution or other transfer without consideration, of our securities during a period when the Insider cannot trade.
- Share MNPI with any outside person, unless required by your job and such person is under NDA, or as authorized by our Chief Compliance Officer or Chief Financial Officer; provided that a director may disclose such information to his or her affiliates so long as such affiliates have established their own insider trading controls and procedures in compliance with applicable securities laws. For further clarity, a director that is originally sponsored, nominated or designated by a third party person or entity (the "***Sponsoring Party***") may share MNPI with their respective Sponsoring Party whether or not such Sponsoring Party is an affiliate of the director.
- Give trading advice about the Company, unless the advice is to tell someone not to trade our securities because the trade would violate this Policy or the law; provided that a director may provide such advice to his or her affiliates so long as such affiliates have established their own insider trading controls and procedures in compliance with applicable securities laws.
- Other than the exercise of equity awards issued by us, engage in transactions involving options or other derivative securities on our stock, such as puts and calls, whether on an exchange or in any other market.
- Engage in hedging or monetization transactions involving our securities, such as zero cost collars and forward sale contracts, or contribute our securities to exchange funds in a manner that could be interpreted as hedging in our stock.

- Engage in short sales of our securities, meaning a sale of securities that you do not own, including short sales "against the box".
- Use or pledge our securities as collateral in a margin account or as collateral for a loan unless the pledge has been approved by our Chief Compliance Officer or Chief Financial Officer.
- Distribute our securities to limited partners, general partners or stockholders of any entity outside of a Trading Window or during a Blackout Period, unless those limited partners, general partners or stockholders have agreed in writing to hold the securities until the next Trading Window.
- Engage in any of the above activities for securities you own in any other company if you have MNPI about that company obtained in the course of your service to the Company.

5.1.2 Additional Restrictions Applicable to Section 16 Insiders and Designated Insiders

All of the restrictions noted above for Insiders and elsewhere in this Policy also apply to our Section 16 Insiders and Designated Insiders.

Prior to trading our securities other than pursuant to a 10b5-1 Plan, Section 16 Officers and Designated Insiders must obtain pre- approval from our Chief Compliance Officer or Chief Financial Officer (or in the case of the Chief Compliance Officer or Chief Financial Officer, the Chief Executive Officer) by: (a) providing written notification of the amount and nature of the proposed trade, (b) certifying no earlier than two business days prior to the proposed trade that you have no MNPI and, to your knowledge, you will have no MNPI as of the proposed trade, and (c) receiving email confirmation from our Chief Compliance Officer or Chief Financial Officer approving the trade, which approval can be granted or denied at the Chief Compliance Officer's or Chief Financial Officer's discretion. You may satisfy (a) and (b) by emailing the required information and certification to our Chief Compliance Officer or Chief Financial Officer and must notify our Chief Compliance Officer or Chief Financial Officer promptly via email of any changes to the certification in (b) prior to the proposed trade.

5.1.3 Exceptions to Prohibited Activities

The trading restrictions of this Policy do not apply to the following:

- *401(k) Plan*. Investing 401(k) plan contributions in a company stock fund in accordance with the terms of our 401(k) plan. However, any changes in your investment election regarding the Company's securities are subject to trading restrictions under this Policy.
- *ESPP*. Purchasing our stock through periodic, automatic payroll contributions under our Employee Stock Purchase Plan. Employees, other than Section 16 Insiders or Designated Insiders, may make changes in elections under the ESPP outside of a Trading Window or during a Blackout Period. Section 16 Insiders or Designated Insiders may not make any decrease in their elections under, or withdraw from, the ESPP outside of a Trading Window or during a Blackout Period. Moreover, any sales of stock acquired under the ESPP are subject to trading restrictions under this Policy.

- *Options*. Exercising stock options granted under our equity incentive plans for cash or by delivering to the Company previously owned Company stock or through a net exercise of a stock option that is permitted by the Company's equity incentive plan and that does not involve a sales of shares in the open market. Payment of taxes in connection with exercising stock options granted under our equity incentive plans pursuant to net settlement arrangements approved by the Company for the payment of taxes upon the exercise of stock options and that does not involve a sale of shares in the open market. However, the sale of any shares issued on the exercise of Company- granted stock options, as well as any cashless exercise of Company-granted stock options in which stock is sold on the open market to pay the exercise price or taxes (i.e., "same-day sales") are subject to trading restrictions under this Policy.
- *RSUs*. The settlement of RSUs pursuant to a net settlement or a "sale to cover" for non-discretionary, automatic tax withholdings initiated and approved by the Company for the payment of taxes upon the vesting of RSUs.

5.1.4 Other Legal Restrictions

The trading prohibitions of this Policy are not the only stock-trading rules and regulations you need to follow. You should be aware of additional prohibitions and restrictions set by contract or by federal and state securities laws and regulations (e.g., contractual restrictions on the resale of securities, rules on short swing trading by Section 16 Insiders, compliance with Rule 144 under the Securities Act of 1933, as amended, and others). Any Insider who is uncertain whether other prohibitions or restrictions apply should ask our Chief Compliance Officer or Chief Financial Officer.

5.2 When Trading is Allowed

5.2.1 Blackout Periods

You can only Trade in a Trading Window. Other than pursuant to an approved 10b5-1 Plan, Insiders are allowed to trade our securities only during a trading window period, which opens after the close of trading on the next full trading day following the widespread public release of our quarterly or year end operating results, and closes at the close of trading on the last day of the month of the then current quarter (the "***Trading Window***"). If the last day of the month falls on a weekend or U.S. federal holiday, the Blackout Period will begin after the closing of trading on the immediately preceding business day. For example, if we publicly announce our quarterly financial results after the close of trading on a Monday (or before trading begins on a Tuesday), then the first time an Insider can trade our securities is after the close of market on Tuesday (effectively at the opening of the market on Wednesday for regular trading). However, if we announce quarterly financial results after trading begins on that Tuesday, then the first time the Insider can trade is after the close of market on Wednesday (effectively at the opening of the market on Thursday for regular trading).

Even During a Trading Window, You Are Not Allowed to Trade While in Possession of MNPI. Even during a Trading Window, you still may not trade our securities if you possess MNPI at that time. An Insider who possesses MNPI during a Trading Window may only trade our securities after the close of trading on the next full trading day following our widespread public release of that MNPI.

You Cannot Trade During a Blackout Period. Even during a Trading Window, our Chief Compliance Officer or Chief Financial Officer, at his or her discretion, may designate special trading Blackout Periods that apply to specific individuals or groups of people (including all Insiders) for as long as our Chief Compliance Officer or Chief Financial Officer determines. No Insider subject to a Blackout Period may trade our securities during any such Blackout Period. Additionally, no Insider subject to a Blackout Period may tell anyone (other than an advisor authorized to effectuate trades on such Insider's behalf) not subject to the Blackout Period that a Blackout Period has been designated or that one previously was in place because that also is confidential information that cannot be disclosed internally or externally; provided that each of the Chief Compliance Officer and Chief Financial Officer may, at his or her discretion, disclose the existence of a Blackout Period to third parties not subject to the Blackout Period.

5.2.2 Permitted Trades Under 10b5-1 Plans

We allow Insiders to trade in our securities while in possession of MNPI, outside of a Trading Window or during a Blackout Period, only pursuant to a "10b5-1 Plan."

What Is a 10b5-1 Plan? A 10b5-1 Plan is a written plan for selling or purchasing a predetermined number of shares that is entered into while an Insider is not in possession of MNPI as contemplated in Rule 10b5-1.

*How Do I Adopt a 10b5-1 Plan? W*e have engaged a broker to administer our 10b5-1 Plans, and any 10b5-1 Plan that you adopt must be adopted through that broker unless otherwise approved by our Chief Compliance Officer or Chief Financial Officer. If you are interested in setting up a 10b5-1 Plan, you should consult with our Chief Compliance Officer or Chief Financial Officer and make sure that:

- The 10b5-1 Plan complies with the requirements of Rule 10b5-1 under the Exchange Act and this Policy.
- You have certified to our Chief Compliance Officer or Chief Financial Officer in writing, no earlier than two business days prior to the date that the 10b5-1 Plan is formally adopted (and shall not have withdrawn such certification prior to such adoption), that as of such date and as of the adoption date of the 10b5-1 Plan, (i) you are not and, to your knowledge, will not be, aware of MNPI, (ii) all trades to be made pursuant to the 10b5-1 Plan will be in accordance with applicable SEC rules, (iii) you are adopting the 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Section 10(b) of the Exchange Act and Rule 10b-5 of the Exchange Act, and (iv) you will act in good faith with respect to the 10b5-1 Plan throughout its duration. This certification may be made in an email to our Chief Compliance Officer or Chief Financial Officer. You must notify the Chief Compliance Officer or Chief Financial Officer promptly via email and withdraw the certification if any changes of circumstances prior to the adoption date of the 10b5-1 Plan have or will render such certification to be inaccurate as of that time.
- The first trade under the 10b5-1 Plan does not occur (i) for a Section 16 Insider: until the later of (A) ninety (90) days after adoption of the 10b5-1 Plan and (B) two (2) business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the 10b5-1 Plan was adopted that discloses the Company's financial results (but not to exceed 120 days following the adoption of the 10b5-1 Plan); and (ii) for persons other than Section 16 Insiders: at least thirty (30) days after adoption of the 10b5-1 Plan, in each case, for 30 days following our Chief Compliance Officer's or Chief Financial Officer's approval of the 10b5-1 Plan. These waiting periods are collectively referred to as the "***Cooling- Off Period***."

- The 10b5-1 Plan is not a single-trade 10b5-1 Plan adopted during the 12-month period immediately following the person's adoption of another single-trade 10b5-1 Plan, subject to the exceptions noted in Rule 10b5-1, which are provided for you in the Appendix.
- The 10b5-1 Plan is adopted during a Trading Window and not during any Blackout Period.

An individual may have no more than one 10b5-1 Plan adopted at any point in time (i.e., multiple concurrent or overlapping plans are prohibited), subject to the exceptions noted in Rule 10b5-1, which are provided for you in the Appendix. One of these exceptions is for plans authorizing certain "sell-to-cover" transactions.

Approval of a 10b5-1 Plan by our Chief Compliance Officer or Chief Financial Officer and/or acknowledgment of a 10b5-1 Plan by the Company shall not be considered a determination by us or our Chief Compliance Officer or Chief Financial Officer that the 10b5-1 Plan satisfies the requirements of Rule 10b5-1.

How Do I Modify a 10b5-1 Plan? Once you have an approved 10b5-1 Plan in place, you will need approval from our Chief Compliance Officer or Chief Financial Officer to make certain changes to it. Modifying or changing the amount, price or timing of the purchase or sale of our securities underlying the 10b5-1 Plan (or a modification or change to a written formula or algorithm, or computer program that affects the amount, price or timing of the purchase or sale of such securities) (any such modification or change, a "***Plan Modification***") will be deemed to be the same as terminating your existing 10b5-1 Plan and entering into a new 10b5-1 Plan. As a result, the approval process for a Plan Modification is the same as the approval process for initially adopting a 10b5-1 Plan, including being subject to a new Cooling-Off Period. We discourage you from making multiple Plan Modifications, as that may give the appearance that you are trading on MNPI under the guise of that plan. Plan Modifications can only be made during a Trading Window and not during any Blackout Period and can be made only when you are not in possession of MNPI. For other modifications to a 10b5-1 Plan, you must notify our Chief Compliance Officer or Chief Financial Officer of such modification in writing at least two business days prior to the modification and such modification must be approved by the Chief Compliance Officer or Chief Financial Officer.

How Do I Terminate a 10b5-1 Plan? Once you have an approved 10b5-1 Plan in place, you will need approval from our Chief Compliance Officer or Chief Financial Officer to terminate it.

5.2.3 Other Trading Arrangements

Insiders are not allowed to enter into "non-Rule 10b5-1 trading arrangements" (as defined in Regulation S-K Item 408(c)) unless otherwise approved in advance by the Chief Compliance Officer or Chief Financial Officer.

5.3 Consequences for Violating Insider Trading Laws

The consequences of violating the insider trading laws can be severe. People who violate insider trading laws may be required to disgorge profits made or losses avoided by trading, pay the loss suffered by the persons who purchased securities from or sold securities to the insider tippee, pay civil fines of up to three times the profit made or loss avoided, pay a criminal penalty of up to $5 million for individuals and $25 million for entities and serve a prison term of up to 20 years. In addition, individual directors, officers and other supervisory personnel may also be required to pay major civil or criminal penalties for failure to take appropriate steps to prevent insider trading by those under their supervision, influence or control.

5.4 Consequences of Violating This Policy

We may impose discipline on anyone violating this Policy, up to and including termination of employment, and we may issue stop transfer orders to our transfer agent to prevent any attempted trades that would violate this Policy.

5.5 Administration

The Chief Compliance Officer or Chief Financial Officer will administer and interpret this Policy and enforce compliance as needed. The Chief Compliance Officer or Chief Financial Officer may consult with the Company's outside legal counsel as needed. The Chief Compliance Officer or Chief Financial Officer may designate other individuals to perform the Chief Compliance Officer's or Chief Financial Officer's duties under this Policy.

Neither the Company nor the Chief Compliance Officer nor the Chief Financial Officer will be liable for any act made under this Policy. Neither the Company nor the Chief Compliance Officer nor the Chief Financial Officer is responsible for any failure to approve a trade or for imposing any Blackout Period.

5.6 Reporting Violations

Any Insider who violates this Policy or any federal or state laws governing insider trading or tipping, or who knows of any such violation by any other Insider, must report the violation immediately to our Chief Compliance Officer. If you want to submit a concern or complaint regarding a possible violation of this Policy anonymously, you should follow the procedures outlined in our Whistleblower Policy (*POL-016*). Anyone who violates this Policy may be subject to disciplinary measures, which may include termination of employment.

5.7 Changes to This Policy

Our Board reserves the right in its sole discretion to modify or grant waivers to this Policy. Any amendments or waiver may be publicly disclosed if required by applicable laws, rules and regulations. For the avoidance of doubt, unless explicitly stated by the Board, any waiver, amendment or modification of the Policy by the Board shall not be considered a waiver of the Company's Code of Business Conduct and Ethics (*CODE-001*).

5.8 Trading by The Company

We will not transact in our securities unless in compliance with applicable U.S. securities laws, rules and regulations and applicable Nasdaq listing standards.

6.0 REFERENCES

Document ID	Document Title
CODE-001	Code of Business Conduct & Ethics
GUI-004	Day One Glossary
POL-016	Whistleblower Policy

7.0 APPENDICES

Exhibit A: Designated Insiders

Appendix : Exceptions to the Multiple, Overlapping 10b5-1 Plan Restriction

Exhibit 19.1

EXHIBIT A: Designated Insiders

All full-time employees

Appendix

Exceptions to the Multiple, Overlapping 10b5-1 Plan Restriction

Such exceptions are:

- An eligible "sell-to-cover" 10b5-1 Plan where such plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales. For the avoidance of doubt, this exception does not extend to sales incident to the exercise of option awards.

- A series of separate contracts with different broker-dealers or other agents acting on behalf of the person (other than the Company) to execute trades thereunder may be treated as a single 10b5-1 Plan, provided that the individual constituent contracts with each broker-dealer or other agent, when taken together as a whole, meet all of the applicable conditions of and remain collectively subject to the provisions of Rule 10b5-1, including that a modification of any individual contract acts as modification of the whole 10b5-1 Plan, as defined in Rule 10b5-1(c)(1)(iv). The substitution of a broker-dealer or other agent acting on behalf of the person (other than the Company) for another broker-dealer that is executing trades pursuant to a 10b5-1 Plan shall not be a "Plan Modification" as long as the purchase or sales instructions applicable to the substitute and substituted broker are identical with respect to the prices of securities to be purchased or sold, dates of the purchases or sales to be executed, and amount of securities to be purchased or sold.

- One later-commencing 10b5-1 Plan for purchases or sales of any securities of the Company on the open market under which trading is not authorized to begin until after all trades under the earlier-commencing 10b5-1 Plan are completed or expired without execution. However, if the earlier commencing 10b5-1 Plan does not end naturally pursuant to its existing terms without action by the 10b5-1 Plan participant, the first trade under such later-commencing 10b5-1 Plan must be scheduled after the "Effective Cooling-Off Period," or the Cooling-Off Period that would be applicable to the later-commencing 10b5-1 Plan if the date of adoption of the later-commencing 10b5-1 Plan were deemed to be the date of termination of the earlier-commencing 10b5-1 Plan.

Exceptions to the Single-Trade 10b5-1 Plan Restriction

There is an exception for eligible "sell-to-cover" 10b5-1 Plans where the plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales.

8.0 REVISION HISTORY

Version	Effective Date	Change History
04	Current	Added Appendices
03	25 May 2024	Added Trading Window definition and updated Section 5.2.1
02	04 Mar 2024	Transposed to company policy template
01	17 Feb 2023	New Document Policy was approved by the Board on 17 Feb 2023.

Exhibit 21.1

Subsidiaries of Day One Biopharmaceuticals, Inc.

None.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-256521, 333-263343, 333-268071, 333-269727, and 333-276372) and Registration Statements on Form S-3 (Nos. 333-265346 and 333-274521) of Day One Biopharmaceuticals, Inc. of our report dated February 26, 2024 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Dallas, Texas
February 25, 2025

Exhibit 23.2

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-8 Nos. 333-284210, 333-256521, 333-263343, 333-268071, 333-269727 and 333-276372) pertaining to the 2021 Equity Incentive Plan, 2021 Employee Stock Purchase Plan and 2022 Equity Inducement Plan of Day One Biopharmaceuticals, Inc., and

(2) Registration Statements (Form S-3 Nos. 333-281822, 333-265346 and 333-274521) of Day One Biopharmaceuticals, Inc.

of our report dated March 6, 2023, with respect to the financial statements of Day One Biopharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California
February 25, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeremy Bender, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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.

February 25, 2025	/s/ Jeremy Bender, Ph.D., M.B.A.
Date	Jeremy Bender, Ph.D., M.B.A. Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles York II, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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.

February 25, 2025	/s/ Charles York II, M.B.A.
Date	Charles York II, M.B.A.. Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(Subsection (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officers of Day One Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), do hereby certify that, to the best of our knowledge:

1. The Annual Report on Form 10-K for the year ended December 31, 2024 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Act of 1934; and

2. The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 25, 2025	/s/ Jeremy Bender, Ph.D., M.B.A.
Date	Jeremy Bender, Ph.D., M.B.A. Chief Executive Officer (Principal Executive Officer)
February 25, 2025	/s/ Charles York II, M.B.A.
Date	Charles York II, M.B.A.. Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 97.1

DAY ONE BIOPHARMACEUTICALS, INC.

COMPENSATION RECOVERY POLICY

(Adopted December 5, 2023)

The Board has determined that it is in the best interests of the Company and its stockholders to adopt this Policy enabling the Company to recover from specified current and former Company executives certain incentive-based compensation in the event of an accounting restatement resulting from material noncompliance with any financial reporting requirements under the federal securities laws. Capitalized terms are defined in Section 14.

This Policy is designed to comply with Rule 10D-1 of the Exchange Act and shall become effective on the Effective Date and shall apply to Incentive-Based Compensation Received by Covered Persons on or after the Listing Rule Effective Date.

1. Administration

This Policy shall be administered by the Administrator. The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Administrator may retain, at the Company's expense, outside legal counsel and such compensation, tax or other consultants as it may determine are advisable for purposes of administering this Policy.

2. Covered Persons and Applicable Compensation

This Policy applies to any Incentive-Based Compensation Received by a person (a) after beginning service as a Covered Person; (b) who served as a Covered Person at any time during the performance period for that Incentive-Based Compensation; and (c) was a Covered Person during the Clawback Period.

However, recovery is not required under this Policy with respect to:

i. Incentive-Based Compensation Received prior to an individual becoming a Covered Person, even if the individual served as a Covered Person during the Clawback Period.

ii. Incentive-Based Compensation Received prior to the Listing Rule Effective Date.

iii. Incentive-Based Compensation Received prior to the Clawback Period.

iv. Incentive-Based Compensation Received while the Company did not have a class of listed securities on a national securities exchange or a national securities association, including the Exchange.

The Administrator will not consider the Covered Person's responsibility or fault or lack thereof in enforcing this Policy with respect to recoupment under the Final Rules.

3. Triggering Event

Subject to and in accordance with the provisions of this Policy, if there is a Triggering Event, the Administrator shall require a Covered Person to reimburse or forfeit to the Company the Recoupment Amount applicable to such Covered Person. A Company's obligation to recover the Recoupment Amount is not dependent on if or when the restated financial statements are filed.

4. Calculation of Recoupment Amount

The Recoupment Amount will be calculated in accordance with the Final Rules, illustrative, non-exclusive examples of which are provided in the Calculation Guidelines attached hereto as Exhibit B.

5. Method of Recoupment

Subject to compliance with the Final Rules and applicable law, the Administrator will determine, in its sole discretion, the method for recouping the Recoupment Amount hereunder which may include, without limitation:

i. Requiring reimbursement or forfeiture of the pre-tax amount of cash Incentive-Based Compensation previously paid;

ii. Offsetting the Recoupment Amount from any compensation otherwise owed by the Company to the Covered Person, including without limitation, any prior cash incentive payments, executive retirement benefits, wages, equity grants or other amounts payable by the Company to the Covered Person in the future;

iii. Seeking recovery of any gain realized on the vesting, exercise, settlement, cash sale, transfer, or other disposition of any equity-based awards; and/or

iv. Taking any other remedial and recovery action permitted by law, as determined by the Administrator.

6. Arbitration

To the fullest extent permitted by law, any disputes under this Policy shall be submitted to mandatory binding arbitration (the "***Arbitrable Claims***"), governed by the Federal Arbitration Act (the "***FAA***"). Further, to the fullest extent permitted by law, no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in the Covered Person's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding.

SUBJECT TO THE ABOVE PROVISO, ANY RIGHTS THAT A COVERED PERSON MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS ARE WAIVED. ANY

RIGHTS THAT A COVERED PERSON MAY HAVE TO PURSUE OR PARTICIPATE IN A CLASS OR COLLECTIVE ACTION PERTAINING TO ANY CLAIMS BETWEEN A COVERED PERSON AND THE COMPANY ARE WAIVED.

The Covered Person is not restricted from filing administrative claims that may be brought before any government agency where, as a matter of law, the Covered Person's ability to file such claims may not be restricted. However, to the fullest extent permitted by law, arbitration shall be the exclusive remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Brisbane, California through JAMS before a single neutral arbitrator, in accordance with the JAMS Comprehensive Arbitration Rules and Procedures then in effect, provided however, that the FAA, including its procedural provisions for compelling arbitration, shall govern and apply to this Arbitration provision. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. If, for any reason, any term of this Arbitration provision is held to be invalid or unenforceable, all other valid terms and conditions herein shall be severable in nature and remain fully enforceable.

7. Recovery Process; Impracticability

Actions by the Administrator to recover the Recoupment Amount will be reasonably prompt.

The Administrator must cause the Company to recover the Recoupment Amount unless the Administrator shall have previously determined that recovery is impracticable and one of the following conditions is met:

i. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; before concluding that it would be impracticable to recover any Recoupment Amount based on expense of enforcement, the Company must make a reasonable attempt to recover such Recoupment Amount, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;

ii. Recovery would violate home country law where that law was adopted prior to November 28, 2022; before concluding that it would be impracticable to recover any Recoupment Amount based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

iii. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

8. Non-Exclusivity

The Administrator intends that this Policy will be applied to the fullest extent of the law. Without limitation to any broader or alternate clawback authorized in any written document with a Covered Person, (i) the Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy, and (ii) this Policy will nonetheless apply to Incentive-Based Compensation as required by the Final Rules, whether or not specifically referenced in those arrangements. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other clawback policy of the Company as then in effect, or any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies or regulations available or applicable to the Company (including SOX 304). If recovery is required under both SOX 304 and this Policy, any amounts recovered pursuant to SOX 304 may, in the Administrator's discretion, be credited toward the amount recovered under this Policy, or vice versa.

9. No Indemnification

The Company shall not indemnify any Covered Persons against (i) the loss of any Recoupment Amount or any adverse tax consequences associated with any Recoupment Amount or any recoupment hereunder, or (ii) any claims relating to the Company enforcement of its rights under this Policy. For the avoidance of doubt, this prohibition on indemnification will also prohibit the Company from reimbursing or paying any premium or payment of any third-party insurance policy to fund potential recovery obligations obtained by the Covered Person directly. No Covered Person will seek or retain any such prohibited indemnification or reimbursement.

Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recovery of any Recoupment Amount and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

10. Covered Person Acknowledgement and Agreement

All Covered Persons subject to this Policy must acknowledge their understanding of, and agreement to comply with, the Policy by executing the certification attached hereto as Exhibit A. **Notwithstanding the foregoing, this Policy will apply to Covered Persons whether or not any such person executes such certification.**

11. Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators or other legal representatives and shall inure to the benefit of any successor to the Company.

12. Interpretation of Policy

To the extent there is any ambiguity between this Policy and the Final Rules, this Policy shall be interpreted so that it complies with the Final Rules. If any provision of this Policy, or the application of such provision to any Covered Person or circumstance, shall be held invalid, the remainder of this Policy, or the application of such provision to Covered Persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

In the event any provision of this Policy is inconsistent with any requirement of any Final Rules, the Administrator, in its sole discretion, shall amend and administer this Policy and bring it into compliance with such rules.

Any determination under this Policy by the Administrator shall be conclusive and binding on the applicable Covered Person. Determinations of the Administrator need not be uniform with respect to Covered Persons or from one payment or grant to another.

13. Amendments; Termination

The Administrator may make any amendments to this Policy as required under applicable law, the Final Rules, and all other applicable rules and regulations, or as otherwise determined by the Administrator in its sole discretion.

The Administrator may terminate this Policy at any time.

14. Definitions

"***Administrator***" means the Compensation Committee of the Board, or in the absence of a committee of independent directors responsible for executive compensation decisions, a majority of the independent directors serving on the Board.

"***Board***" means the Board of Directors of the Company.

"***Clawback Measurement Date***" is the earlier to occur of:

i. The date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described in this Policy; or

ii. The date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described in this Policy.

"***Clawback Period***" means the Company's three (3) completed fiscal years immediately prior to the Clawback Measurement Date and any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year (that results from a change in the Company's fiscal year) within or immediately following such three (3)-year period; provided that any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of 9 to 12 months will be deemed a completed fiscal year.

"***Company***" means Day One Biopharmaceuticals, Inc., a Delaware corporation, or any successor corporation.

"***Covered Person***" means any Executive Officer (as defined in the Final Rules), including, but not limited to, those persons who are or have been determined to be "officers" of the Company within the meaning of Section 16 of Rule 16a-1(f) of the rules promulgated under the Exchange Act, and "executive officers" of the Company within the meaning of Item 401(b) of Regulation S-K, Rule 3b-7 promulgated under the Exchange Act, and Rule 405 promulgated under the Securities Act of 1933, as amended; provided that the Administrator may identify additional employees who shall be treated as Covered Persons for the purposes of this Policy with prospective effect, in accordance with the Final Rules.

"***Effective Date***" means December 5, 2023, the date the Policy was adopted by the Board (or an authorized committee thereof).

"***Exchange***" means the Nasdaq Global Select Market or any other national securities exchange or national securities association in the United States on which the Company has listed its securities for trading.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Final Rules***" means the final rules promulgated by the SEC under Section 954 of the Dodd-Frank Act, Rule 10D-1 and Exchange listing standards, each as may be amended from time to time.

"***Financial Reporting Measure***" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and TSR are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC.

"***Incentive-Based Compensation***" means compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure. [Examples of "Incentive-Based Compensation" include, but are not limited to: non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and SARs that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or

in part on satisfying a Financial Reporting Measure goal. "Incentive-Based Compensation" excludes, for example, time-based awards such as stock options or restricted stock units that are granted or vest *solely* upon completion of a service period; awards based on non-financial strategic or operating metrics such as the consummation of a merger or achievement of non-financial business goals; service-based retention bonuses; discretionary compensation; and salary.]

"***Listing Rule Effective Date***" means October 2, 2023.

"***Policy***" means this Compensation Recovery Policy.

Incentive-Based Compensation is deemed "***Received***" in the Company's fiscal period during which the relevant Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, irrespective of whether the payment or grant occurs on a later date or if there are additional vesting or payment requirements, such as time-based vesting or certification or approval by the Compensation Committee or Board, that have not yet been satisfied.

"***Recoupment Amount***" means the amount of Incentive-Based Compensation Received by the Covered Person based on the financial statements prior to the restatement that exceeds the amount such Covered Person would have received had the Incentive-Based Compensation been determined based on the financial restatement, computed without regard to any taxes paid (*i.e.*, gross of taxes withheld).

"***SARs***" means stock appreciation rights.

"***SEC***" means the U.S. Securities and Exchange Commission.

"***SOX 304***" means Section 304 of the Sarbanes-Oxley Act of 2002.

"***Triggering Event***" means any event in which the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***TSR***" means total stockholder return.

EXHIBIT A

Certification

I certify that:

1. I have read and understand the Company's Compensation Recovery Policy (the "***Policy***"). I understand that the Company's General Counsel is available to answer any questions I have regarding the Policy.

2. I understand that the Policy applies to all of my existing and future compensation-related agreements with the Company with respect to Incentive-Based Compensation Received after the Listing Rule Effective Date, whether or not explicitly stated therein.

3. I agree that notwithstanding the Company's certificate of incorporation, bylaws, and any agreement I have with the Company, including any indemnity agreement I have with the Company, I will not be entitled to, and will not seek indemnification from the Company for, any amounts recovered or recoverable by the Company in accordance with the Policy.

4. I understand and agree that in the event of a conflict between the Policy and the foregoing agreements and understandings on the one hand, and any prior, existing or future agreement, arrangement or understanding, whether oral or written, with respect to the subject matter of the Policy and this Certification, on the other hand, the terms of the Policy and this Certification shall control, and the terms of this Certification shall supersede any provision of such an agreement, arrangement or understanding to the extent of such conflict with respect to the subject matter of the Policy and this Certification; provided that, in accordance with Section 8 of the Policy, nothing herein limits any other remedies or rights of recoupment that may be available to the Company.

5. I agree to abide by the terms of the Policy, including, without limitation, by returning any Recoupment Amount to the Company to the extent required by, and in a manner permitted by, the Policy.

Signature: _____

Name: _____

Title: _____

Date: _____

EXHIBIT B

Calculation Guidelines

The Recoupment Amount will be calculated in accordance with the Final Rules as determined by the Administrator, illustrative, non-exclusive examples of which are provided in the Calculation Guidelines below:

i. For cash awards not paid from bonus pools, the erroneously awarded compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was received and the amount that should have been received applying the restated Financial Reporting Measure.

ii. For cash awards paid from bonus pools, the erroneously awarded compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

iii. For equity awards, if the shares, options, restricted stock units, or SARs are still held at the time of recovery, the erroneously awarded compensation is the number of such securities received in excess of the number that should have been received applying the restated Financial Reporting Measure (or the value of that excess number). If the options or SARs have been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the excess options or SARs (or the value thereof). If the underlying shares have been sold, the Company may recoup proceeds received from the sale of shares.

iv. For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

a. The amount must be based on a reasonable estimate of the effect of the accounting restatement on the stock price or TSR upon which the Incentive-Based Compensation was Received; and

b. The Company must maintain documentation of the determination of that reasonable estimate and the Company must provide such documentation to the Exchange in all cases.