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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 23, 2024

DAY ONE BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40431**	**83-2415215**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Sierra Point Parkway, Suite 501
Brisbane, California **94005**
(Address of principal executive offices) **(Zip Code)**

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On July 23, 2024, Day One Biopharmaceuticals, Inc. (the "Company") and Ipsen Pharma SAS ("Ipsen") entered into an Exclusive License Agreement (the "License Agreement") pursuant to which the Company will license to Ipsen, on an exclusive basis, the right to commercialize tovorafenib outside the United States. All capitalized terms herein have the definitions assigned to them in the License Agreement unless otherwise defined herein.

In consideration for the rights and licenses granted by the Company to Ipsen in the License Agreement, Ipsen will pay the Company (i) an upfront license fee in the amount of approximately $71 million within thirty days after the effective date of the License Agreement and (ii) Ipsen Biopharmaceuticals, Inc. (USA) (the "Investor"), a fully-owned Affiliate of Ipsen, agreed to purchase shares of the Company's common stock (the "Company Share Issuance") for $40 million, at a price per share representing a 17% premium to the volume weighted average price ("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 (the "Revenue Release") and the ten consecutive trading days following the Revenue Release, in accordance with the terms set forth in a certain investment agreement by and between the Company and the Investor dated July 23, 2024 (the "Investment Agreement") and attached as Schedule 6.2 to the License Agreement.

The Company is also eligible to receive up to approximately $350 million in additional launch and sales milestone payments as well as tiered, double-digit royalty payments starting at mid-teens percentage on annual net sales of OJEMDA, subject to certain adjustments specified in the License Agreement.

The royalty payment obligations under the License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of OJEMDA in the applicable country. Following the two-year anniversary of the effective date of the License Agreement, Ipsen may terminate the License Agreement for convenience with six months' prior written notice or for certain other specified reasons. The Company may terminate the License Agreement if Ipsen or any of its Affiliates challenge the validity of any patents controlled by the Company that are licensed under the License Agreement. Both Ipsen and the Company may terminate the License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the License Agreement or (ii) the other party's bankruptcy event.

The above description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024.

Item 3.02. Unregistered Sales of Equity Securities

The description of the Investment Agreement and the Company Share Issuance thereunder set forth in Item 1.01 above is incorporated by reference into this Item 3.02. The Company Share Issuance is being made in a private placement that is exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 7.01. Regulation FD Disclosure

On July 25, 2024, the Company issued a press release announcing the entry into the License Agreement with Ipsen, a copy of which is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, regarding the License Agreement, dated July 25, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

DAY ONE BIOPHARMACEUTICALS, INC.

Date: July 25, 2024

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

Press release

Intended for international media and investor audiences only

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

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

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

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

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

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

Ipsen's deep heritage and expertise in oncology means we can accelerate the delivery of this innovation as teams focus on regulatory activities outside the U.S. pLGG is the most common brain tumor diagnosed in children, with patients suffering profound tumor- and treatment-associated morbidities that can impact their life trajectory.[i] Depending on the tumor's size, location and growth rate, pLGG can present with a variety of symptoms including vision, hearing and speech problems, neurological symptoms, premature puberty, physical changes and generalized symptoms such as balance problems, fatigue and nausea.[v] Mortality is relatively rare, however due to the chronic nature of pLGG and potential morbidity associated with treatment, the disease can significantly affect the development, cognition, education and overall quality of life of affected children, whilst negatively impacting the mental health of parents and caregivers.[vi,vii]

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

ENDS

About Ipsen

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

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

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

About Day One Biopharmaceuticals

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

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

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

About tovorafenib

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

Tovorafenib is under evaluation as a therapy for patients aged 6 months to 25 years with pLGG harboring BRAF fusion or rearrangement, or BRAF V600 mutation requiring front-line treatment (Phase III FIREFLY-2/LOGGIC). It is also being studied in combination with the MEK inhibitor pimasertib for adolescent and adult patient populations with recurrent or progressive solid tumors with MAPK pathway alterations (FIRELIGHT-1).

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

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

About FIREFLY-1

FIREFLY-1 is evaluating tovorafenib as once-weekly monotherapy in patients aged 6 months to 25 years with relapsed or progressive pLGG harboring a known activating BRAF alteration. The trial is being conducted in collaboration with the Pacific Pediatric Neuro-Oncology Consortium. The pivotal and ongoing Phase II FIREFLY-1 study[v] evaluated the safety and efficacy of tovorafenib in 137 relapsed or refractory BRAF-altered pLGG patients, who had received at least one line of prior therapy, across two study arms. Arm 1 (n=77) was used for the efficacy analyses and Arm 2 provided safety data for an additional 60 patients, initiated to enable access to tovorafenib once Arm 1 had fully recruited.[ii,iii] The primary endpoint in Arm 1 of best overall response rate (ORR), determined by independent radiology review committee (IRC) and based on Response Assessment in Neuro-Oncology High-Grade Glioma (RANO-HGG) criteria, achieved ORR of 67% and median time to response (TTR) of 3 months. At the time of data cutoff on 5 June 2023 there was a median duration of response (DOR) of 16.6 months. The secondary endpoint of best ORR by IRC according to Response Assessment in Pediatric Neuro-Oncology Low-Grade Glioma (RAPNO LGG) criteria was 51% with a median DOR of 13.8 months and median TTR of 5.3 months. Among 137 patients (arms 1 and 2), the most common all-grade treatment-related adverse events (TRAEs) were hair color changes (76%), elevated creatine phosphokinase (56%) and anemia (49%). Grade ≥3 TRAEs occurred in 42% of patients with elevated creatine phosphokinase (12%) and anemia (10%) as the most common. Nine (7%) patients had TRAEs leading to discontinuation of tovorafenib.[vi] Additional information about FIREFLY-1 may be found at ClinicalTrials.gov, using Identifier NCT04775485.

About Pediatric Low-Grade Glioma

Pediatric low-grade glioma (pLGG) is the most common brain tumor with an estimated US incidence of 1,100 and Europe incidence of 700 children per year who are eligible for front-line systemic therapy.[i,viii] BRAF is the gene most commonly altered in pLGG, which include two primary types of BRAF alterations – a BRAF gene fusion and BRAF point mutation. These BRAF alterations account for >50% of pLGG cases worldwide and until now there were no approved treatments for people with pLGG driven by BRAF fusions.[i,vi]

Pediatric low-grade gliomas can be chronic and relentless, with patients suffering profound side effects from both the tumor and the treatment, which may include chemotherapy and radiation. These side effects can impact their life over the long term, and may include muscle weakness, loss of vision, and difficulty speaking. This type of tumor has a high risk of progression, and many children with pLGG require long-term treatment. While most children with pLGG survive their cancer, children who do not achieve a complete resection following surgery may face years of increasingly aggressive treatment.

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Disclaimers and/or Forward-Looking Statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's latest Universal Registration Document, available on ipsen.com.

Day One Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One's entry into the exclusive global licensing agreement with Ipsen, Day One's plans to develop cancer therapies, expectations from current clinical trials, and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One's ability to develop, obtain regulatory approval for or commercialize any product candidate, Day One's ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, geopolitical conflicts and the sufficiency of Day One's cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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[i] Ryall S, et al. *Acta Neuropathol Commun*. 2020;8(1):30.

[ii] FDA grants accelerated approval to tovorafenib for patients with relapsed or refractory BRAF-altered pediatric low-grade glioma | FDA (last accessed July 2024)

[iii] Day One Press Release. April 2024. Available here: Day One's OJEMDA™ (tovorafenib) Receives US FDA Accelerated Approval for Relapsed or Refractory BRAF-altered Pediatric Low-Grade Glioma (pLGG), the Most Common Form of Childhood Brain Tumor | Day One Biopharmaceuticals, Inc. (last accessed July 2024)

[iv] Sholl LM. *Precis Cancer Med*. 2020;3:26

[v] Dana-Farber Cancer Institute. Childhood low-grade gliomas. https://www.dana-farber.org/cancer-care/types/childhood-low-grade-gliomas Last accessed: July 2024

[vi] Traunwieser T, et al. *Neurooncol Adv.* 2020;2(1):vdaa094.

[vii] Armstrong GT, et al. *Neuro Oncol.* 2011;13(2):223-234.

[viii] Estimates of annual incidence and prevalence for addressable patient population in E.U. 4 + U.K. are based on Ipsen calculations from publicly available data (Eurostat, <25yo population; Global Burden of Disease 2019; Desandes et al. Incidence and survival of children with central nervous system primitive tumors in the French National Registry of Childhood Solid Tumors. Neuro Oncol. 2014 Jul;16(7):975-83. doi: 10.1093/neuonc/not309; Qaddoumi et al. Outcome and prognostic features in pediatric gliomas: a review of 6212 cases from the Surveillance, Epidemiology, and End Results database. Cancer. 2009 Dec 15;115(24):5761-70. doi: 10.1002/cncr.24663)