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Counsel for Sentynl Therapeutics, Inc.

IN THE UNITED STATES BANKRUPTCY COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

In re:	
EIGER BIOPHARMACEUTICALS, INC., et al. ¹	Chapter 11
	Case No. 24-80040 (SGJ)
Debtors.	(Jointly Administered)

MOTION FOR ALLOWANCE OF ADMINISTRATIVE EXPENSE CLAIM OF SENTYNL THERAPEUTICS, INC.

Sentynl Therapeutics, Inc. ("Sentynl"), submits its Motion for Allowance of Administrative Expense Claim (the "Motion"), and in support thereof would respectfully show the Court as follows:

The Debtors in these chapter 11 cases, together with the last four digits of each Debtor's federal tax identification number, are: Eiger BioPharmaceuticals, Inc. (1591); EBPI Merger Inc. (9986); EB Pharma LLC (8352); Eiger BioPharmaceuticals Europe Limited (N/A); and EigerBio Europe Limited (N/A). The Debtors' service address is 2100 Ross Avenue, Dallas, Texas 75201.



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PRELIMINARY STATEMENT

- 1. On April 24, 2024, this Court approved Sentynl's purchase of Zokinvy the only known life extending treatment for progeria, a rare and fatal genetic condition for \$45,200,000.² As a condition to closing of the Zokinvy Asset Purchase Agreement,³ the parties executed and delivered the Sublicense Agreement.⁴ Debtor Eiger Biopharmaceuticals, Inc. ("Eiger Bio"), is in the process of breaching the Sublicense Agreement and effectively preventing Sentynl from manufacturing the drug and fulfilling its regulatory obligations, which could lead to Sentynl's inability to deliver Zokinvy to patients who depend on it to extend their lives. To make matters worse, the breach is for the apparent benefit of non-debtor Eiger InnoTherapeutics, Inc. ("Eiger Inno"), the purchaser of the estate's remaining Lonafarnib Assets and Lambda Assets and an entity being run by one of Eiger Bio's former founding members.⁵
- 2. As a result of Eiger Bio's post-petition breach, Sentynl is entitled to an allowed administrative expense up to the amount of the Zokinvy Purchase Price.⁶

² See Order (I) Approving the Sale of the Debtors' Zokinvy Assets, (II) Authorizing Assumption and Assignment of Certain Executory Contracts and Unexpired Leases Related Thereto, and (III) Granting Related Relief [Docket No. 162] ("Zokinvy Sale Order").

That certain Asset Purchase Agreement by and between Sentynl Therapeutics, Inc., as Purchaser, and Eiger BioPharmaceuticals, Inc., as Seller, Dated March 31, 2024, annexed as Exhibit 1 to the Zokinvy Sale Order, and as from time to time amended in accordance with the Zokinvy Sale Order or further order of this Court, including by the First Amendment to the Zokinvy Asset Purchase Agreement attached to the Zokinvy Sale Order ("Zokinvy Asset Purchase Agreement").

That certain Sublicense Agreement, dated as of the Closing Date, by and among Purchaser and the Seller, substantially in the form attached to the Zokinvy Asset Purchase Agreement as Exhibit E [filed under seal pursuant to order at Docket No. 188].

The manufacturing and regulatory issues described below arose shortly after Eiger Inno's acquisition closed on September 3, 2024 but several months after Sentynl's acquisition closed on May 3, 2024 and Sentynl initiated discussions with Lonza and IQVIA. See Notice of Closing of Lonafarnib/Lamba Sale Transaction [Docket No. 616]; Notice of Closing of Zokinvy Sale Transaction [Docket No. 214].

Separately, the Liquidating Trust has acknowledged and recognized the estate's commitment to satisfy up to an amount of \$3,161,245 in connection with the payment of a rebate claim owing to the French government. Such acknowledgment and agreement obviates the need for Sentynl to include such amount in the calculation of its administrative expense claim requested herein.

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JURISDICTION

3. The United States Bankruptcy Court for the Northern District of Texas (the "Court") has jurisdiction over this matter pursuant to 28 U.S.C. §1334 and the order of referral of the United States District Court for the Northern District of Texas. This matter is a core proceeding pursuant to 28 U.S.C. §157, and this Court may enter a final order consistent with Article II of the United States Constitution.

BACKGROUND⁷

A. Lonza Bend MSA

- 4. Bend Research, Inc., a Lonza Company ("Lonza Bend"), provides spray dried dispersion services that are critical to the manufacturing process for the Zokinvy product. The services occur in the middle of the manufacturing process and supply chain for the Zokinvy product and are thus critical to supply of the product. Sentynl does not have any previously existing relationship with Lonza Bend, nor has Sentynl identified an alternative service provider for such services.
- 5. During the negotiation of the acquisition of the Zokinvy Assets, Sentynl requested Eiger Bio to assign to Sentynl certain key manufacturing and supply agreements, such as the *Commercial Manufacturing Services and Supply Agreement with Lonza Bend, dated October 9, 2019* (the "Lonza Bend MSA"). Eiger Bio informed Sentynl on multiple occasions that Eiger Bio could not assign the Lonza Bend MSA and certain other contracts to Sentynl because Eiger Bio needed to retain them to be able to facilitate a sale of the remaining Lonafarnib Assets.

The Motion was intentionally expedited by agreement with the Liquidating Trustee. Copies of the underlying documentation and communications are available to interested parties. In advance of any hearing on the Motion, Sentynl will supplement the record with all evidentiary documentation of the facts referenced herein.

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6. Under the Sublicense Agreement, Eiger Bio agreed that certain agreements, including the Lonza Bend MSA were, "Retained Agreements," which are subject to special treatment. Importantly, Eiger Bio is obligated to use reasonable efforts not to assign the Lonza Bend Agreement in a manner that adversely affects Sentynl's rights under the Sublicense Agreement or ability to "Commercialize" Zokinvy. Additionally, Eiger Bio has represented and warranted to Sentynl that the Lonza Bend MSA, as one of the "Retained Agreements," was one of the agreements necessary for the manufacture and commercialization of Zokinvy.

- 7. In connection with Eiger Bio's proposed sale of the remaining Lonafarnib Assets to Eiger Inno, Sentynl learned that Eiger Bio agreed to assign many contracts to Eiger Inno that Eiger Bio had told Sentynl were not assignable or would not be assigned. One of those contracts was the Lonza Bend MSA. Sentynl informed Eiger Bio that it wanted those agreements assigned to Sentynl, given the prior communications from Eiger Bio that those agreements were not assignable or were not going to be assigned and given their critical importance to Sentynl's ability to manufacture and commercialize Zokinvy, but Eiger Bio and Eiger Inno refused that request.
- 8. Sentynl has sought to negotiate a new contract with Lonza Bend, using its best reasonable efforts, as contemplated by the Zokinvy Asset Purchase Agreement. Despite initial engagement and exchange of draft agreements, Lonza Bend has delayed negotiations, which Sentynl is informed and believes is likely the result of an intervention by or on behalf of Eiger Inno.
- 9. Importantly, the Lonza Bend MSA is scheduled to be formally assigned to Eiger Inno in early November 2024 (on the six month anniversary of the closing of the Zokinvy Asset

⁸ See Section 3.7 of the Sublicense Agreement.

⁹ See Sections 11.2(j) and 11.2(w) of the Sublicense Agreement.

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Purchase Agreement). The Lonza Bend MSA contains an exclusivity clause in Section 2.8 that provides Lonza Bend will not manufacture or supply the product to or for any other person other than Customer (soon to be Eiger Inno). If the Lonza Bend MSA is assigned to Eiger Inno, Sentynl is informed and believes that Eiger Inno may attempt to enforce that exclusivity clause to the detriment of Sentynl and those impacted with progeria who rely on a continuous supply of therapy.

10. If Eiger Bio proceeds with assigning the Lonza Bend MSA to Eiger Inno with the exclusivity provision in place or with any other provisions that are adverse to Sentynl, then Eiger Bio will be in breach of its covenants and obligations to Sentynl under the Zokinvy Asset Purchase Agreement.

B. Regulatory Obligations

- 11. Zokinvy's status as a commercial progeria therapeutic, approved by the FDA, MHRA, EMA, Japan, and Israel, places significant and important regulatory filing obligations on Sentynl, including the operation and maintenance of the global safety database, and periodic reporting obligations under such as Development Safety Update Reports ("<u>DSUR</u>"), the next of which is due to regulatory authorities on November 29, 2024.
- 12. Pursuant to the Zokinvy Asset Purchase Agreement and the Sublicense Agreement, Sentynl has acquired and/or licensed from Eiger Bio all data and "Regulatory Information" necessary for Sentynl to commercialize Zokinvy.
- 13. To aid in the process of transferring from Eiger Bio to Sentynl the data from the global safety database and ensure that the upcoming DSUR filing is timely made, the Liquidating Trustee engaged Rich Franco as a consultant to coordinate among Eiger Bio, Eiger Inno and Sentynl for the preparation of the upcoming DSUR filing and other related coordination efforts. Eiger Bio, Eiger Inno, and Sentynl met on October 15, 2024 to allocate responsibilities for certain

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safety data elements of the DSUR to representatives of the three companies. Mr. Franco agreed to receive and compile data elements from each group for the next DSUR.

- 14. The next morning, Mr. Franco communicated to Sentynl that he was unable to fulfill those responsibilities because Leen Kawas, Managing General Partner of an investor in Eiger Inno, complained to the Liquidating Trustee and demanded that Eiger Inno be in charge of pharmacovigilance matters, such as the DSUR, because Eiger Inno had assumed contracts with IQVIA, which is a third party that has provided services related to the maintenance and use of the global safety database for Zokinvy. This demand was made even though the marketing authorization of Zokinvy from the European Union had not formally transferred yet from Eiger Bio to Sentynl, and so Eiger Bio was technically responsible for the filing at the time. The marketing authorization of Zokinvy has since transferred to Sentynl and as a result Sentynl is now the official holder of marketing authorization of Zokinvy from the European Union and has the corresponding regulatory obligations. However, due to what Sentynl is informed and believes to be Eiger Inno's problematic engagement to date, Sentynl will not be able to meet its upcoming regulatory obligations unless Eiger Inno cooperates with Sentynl and Eiger Bio as previously proposed and Eiger Inno does not attempt to prevent IQVIA from transferring the applicable data from the global safety database to Sentynl. As discussed above, Sentynl acquired rights to that data and "Regulatory Information," and it should be transferred to Sentynl under the terms of the Zokinvy Asset Purchase Agreement.
- 15. Additionally, Eiger Bio has failed to fulfill obligations under the transaction documents in regard to safety databases and pharmacovigilance. For example, Eiger Bio is obligated to transfer to Sentynl all relevant information sufficient for Sentynl to comply with its obligations to regulatory authorities and investigators regarding adverse events that have been

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observed during any clinical trials conducted with the Licensed Progeria Product or Licensed Product prior to the Effective Date. The agreements also invest Sentynl with the responsibility for maintaining a safety database for the Licensed Progeria Product. ¹⁰ The parties are also obligated to enter into a separate written pharmacovigilance agreement with respect to the Licensed Progeria Products and other Licensed Products to enable the parties to fulfill their respective regulatory reporting obligations. Finally, Eiger Bio is obligated to perform specific transition activity services related to pharmacovigilance scheduled for the benefit of Sentynl.

BASIS FOR RELIEF

- 16. Section 503(b)(1)(A) of the Bankruptcy Code provides, in relevant part, that "[a]fter notice and a hearing, there shall be allowed administrative expenses, other than claims allowed under Section 502(f) of this title, including . . . the actual, necessary costs and expenses of preserving the estate" The claimant seeking administrative expenses bears the burden of proof. *Toma Steel Supply, Inc. v. TransAmerican Nat. Gas Corp. (In re TransAmerican Nat. Gas Corp.)*, 978 F.2d 1409, 1416 (5th Cir. 1992).
- 17. "[T]o qualify as an 'actual and necessary cost' under section 503(b)(1)(A), a claim against the estate must have arisen post-petition and as a result of actions taken by the trustee [or debtor-in-possession] that benefitted the estate." *Matter of Whistler Energy II, L.L.C.*, 931 F.3d 432, 441 (5th Cir. 2019) (quoting *Total Minatome Corp. v. Jack/Wade Drilling, Inc. (In re Jack/Wade Drilling, Inc.)*, 258 F.3d 385, 387 (5th Cir. 2001)). The benefit does not, however, "have to be substantial" to qualify. *See In re Women First Healthcare, Inc.*, 332 B.R. 115, 121 (Bankr. D. Del. 2005).

See Section 5.3(c) and Schedule 5.3(c) of the Sublicense Agreement.

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- 18. Breach of a post-petition agreement may give rise to an administrative expense claim. See In re Finevest Foods, Inc., 159 B.R. 972, 981 (Bankr. M.D. Fla. 1993) ("The Court finds that debtor breached the warranty contained in § 4.1.7(a) of the asset purchase agreement and that claimant is entitled to an administrative expense claim in the amount of \$306,223.00."); In re Wildwood Villages, LLC, 2022 Bankr. LEXIS 1466 (Bankr. M.D. Fla. Jan. 21, 2022) (debtor developer's post-petition breach of a covenant to provide recreational facilities gave rise to an administrative claim).
- 19. "The claimant bears the burden of proving by a preponderance of the evidence that its claim qualifies as an administrative expense." *In re Krisu Hosp., LLC*, No. 19-20347-rlj11, 2021 Bankr. LEXIS 788, at *10 (Bankr. N.D. Tex. Mar. 26, 2021) (quoting *In re Acis Cap. Mgmt., L.P.*, 604 B.R. 484, 517 (N.D. Tex. 2019)).
- 20. Here, there can be no credible argument that Eiger Bio's (1) forthcoming assignment of the Lonza Bend MSA to Eiger Inno and (2) acquiescence to Eiger Inno's control of regulatory matters, do not adversely and materially affect Sentynl's rights under the Sublicense Agreement and its ability to commercialize Zokinvy and fulfill its regulatory obligations. Such actions constitute material breaches of the Zokinvy Asset Purchase Agreement and Sublicence Agreement by Eiger Bio and are compensable as an administrative expense. Because these breaches frustrate the entire purpose of the Zokinvy Asset Purchase Agreement and Sublicense Agreement and continued production and therefore commercialization of Zokinvy, the most important goal of this entire bankruptcy case to ensure patients with progeria can continue to receive treatment, Sentynl should be allowed an administrative expense in an amount up to the Zokinvy Purchase Price.

RESERVATION OF RIGHTS

21. In filing this Motion, Sentynl does not waive any claims it may have against Eiger Inno.

CONCLUSION

WHEREFORE, Sentynl respectfully requests that this Court enter an order, substantially in the form attached hereto as **Exhibit A**, allowing Sentynl an administrative expense claim against the Debtors' respective estates for in the amount up to the full \$45,200,000 paid under the Zokinvy Asset Purchase Agreement and such other and further relief as is just and necessary.

Dated: November 1, 2024 Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

By: /s/ L. James Dickinson

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Certificate of Service

I certify that on November 1, 2024, I caused a copy of the foregoing document to be served by the Electronic Case Filing System for the United States Bankruptcy Court for the Northern District of Texas.

/s/ L. James Dickinson
L. James Dickinson

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EXHIBIT A

Proposed Order

IN THE UNITED STATES BANKRUPTCY COURT FOR THE NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

In re:	
EIGER BIOPHARMACEUTICALS, INC., et al. 1	Chapter 11
	Case No. 24-80040 (SGJ)
Debtors.	(Jointly Administered)

ORDER GRANTING MOTION FOR ALLOWANCE OF ADMINISTRATIVE EXPENSE CLAIM OF SENTYNL THERAPEUTICS, INC.

Upon consideration of the *Motion for Allowance and Payment of Administrative Expense Claim of Sentynl Therapeutics, Inc.* (the "Motion") and after due deliberation and sufficient cause appearing therefor, it is hereby:

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The Debtors in these chapter 11 cases, together with the last four digits of each Debtor's federal tax identification number, are: Eiger BioPharmaceuticals, Inc. (1591); EBPI Merger Inc. (9986); EB Pharma LLC (8352); Eiger BioPharmaceuticals Europe Limited (N/A); and EigerBio Europe Limited (N/A). The Debtors' service address is 2100 Ross Avenue, Dallas, Texas 75201.

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ORDERED that Sentynl is hereby allowed a chapter 11 administrative expense claim pursuant to 11 U.S.C. § 503 for material breaches of the Zokinvy Asset Purchase Agreement and Sublicence Agreement in the total amount of \$45,200,000; and it is further

ORDERED that this Court shall retain jurisdiction over any and all matters arising from or related to the implementation or interpretation of this Order.

END OF ORDER