

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:) Chapter 11
)
NVN Liquidation, Inc., <i>et al.</i> ,) Case No. 23-10937 (LSS)
f/k/a NOVAN, INC., ¹) (Jointly Administered)
)
Debtors.) Hearing Date:
) February 9, 2024, at 11:30 a.m. (ET)
)
) Objection Deadline:
) February 2, 2024, at 4:00 p.m. (ET)
)

MOTION OF DEBTORS FOR ENTRY OF AN ORDER PURSUANT TO 11 U.S.C. §§ 105(a) AND 554 AND FEDERAL RULE OF BANKRUPTCY PROCEDURE 6007 AUTHORIZING THE ABANDONMENT OF CERTAIN UNSELLABLE PRODUCTS SUBJECT TO CERTAIN REGULATORY OBLIGATIONS

The above-captioned debtors and debtors in possession (the “Debtors”) hereby submit this motion (the “Motion”) for entry of an order, substantially in the form attached hereto as **Exhibit A** (the “Proposed Order”), pursuant to sections 105(a) and 554 of title 11 of the United States Code, 11 U.S.C. §§ 101 *et seq.* (the “Bankruptcy Code”) and rule 6007 of the Federal Rules of Bankruptcy Procedure (the “Bankruptcy Rules”) authorizing the abandonment of the Unsellable Products (as defined below), including (i) certain intangibles associated with the Unsellable Products, including but not limited to trademarks and related contracts and contractual rights; (ii) all inventory of the Unsellable Products by whomever held and wherever held; and (iii) to the extent necessary, all regulatory obligations arising from or related to the Unsellable Products. In support of this Motion, the Debtors submit the *Declaration of John Donofrio in Support of Motion of Debtors for Entry of an Order Pursuant to 11 U.S.C. §§ 105(a) and 554 and Federal Rule of*

¹ The Debtors in these chapter 11 cases, along with the last four digitals of the Debtors’ federal tax identification number (if applicable), are: NVN Liquidation, Inc., (f/k/a Novan, Inc.) (7682) and EPI Health, LLC (9118). The corporate headquarters and the mailing address for the Debtors is P.O. Box 64, Pittsboro, NC 27312.



Bankruptcy Procedure 6007 Authorizing the Abandonment of Certain Unsellable Products Subject to Certain Regulatory Obligations (the “Declaration”), attached hereto as **Exhibit B**, and further respectfully state as follows:

JURISDICTION AND VENUE

1. The United States Bankruptcy Court for the District of Delaware (the “Court”) has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware, dated February 29, 2012. This is a core proceeding within the meaning of 28 U.S.C. § 157(b)(2).

2. Pursuant to rule 9013-1(f) of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware (the “Local Rules”), the Debtors consent to the entry of a final order with respect to this Motion if it is later determined that the Court, absent consent of the parties, cannot enter final orders or judgments consistent with Article III of the United States Constitution.

3. Venue of these chapter 11 cases (these “Chapter 11 Cases”) and this Motion in this district is proper under 28 U.S.C. §§ 1408 and 1409.

4. The statutory and legal predicates for the relief requested herein are sections 105(a) and 554 of the Bankruptcy Code and Bankruptcy Rule 6007.

BACKGROUND

A. General Background

5. On July 17, 2023 (the “Petition Date”), the Debtors each commenced a voluntary case under chapter 11 of the Bankruptcy Code in this Court. On July 28, 2023, the Office of the United States Trustee for the District of Delaware (the “U.S. Trustee”) appointed an Official Committee of Unsecured Creditors (the “Committee”) pursuant to section 1102 of the

Bankruptcy Code in these Chapter 11 Cases [D.I. 72]. No trustee or examiner has been appointed in these Chapter 11 Cases.

6. Additional factual background relating to the Debtors' business, the commencement of these Chapter 11 Cases, and the current posture of these Chapter 11 Cases is set forth in the *Combined Disclosure Statement and Chapter 11 Plan of Liquidation Proposed by the Debtors* [D.I. 459] (the "Combined Disclosure Statement and Plan"), which is incorporated herein by reference.

B. The Unsellable Products

7. As described in the Combined Disclosure Statement and Plan, Cloderm is a prescription medication that is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

8. In September 2018, Debtor EPI Health, LLC ("EPI Health") acquired the rights to Cloderm by entering into that Asset Purchase Agreement between Promius Pharma, LLC and Dr. Reddy's Laboratories Inc. and EPI Health, LLC dated as of September 28, 2018 (the "Cloderm APA"). The Cloderm APA requires minimum royalty payments on the net sales of Cloderm, subject to meeting certain sales milestones.

9. As described in the Combined Disclosure Statement and Plan, Minolira is an oral prescription medication indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

10. In August 2018, EPI Health acquired the rights to Minolira by entering into that Asset Purchase Agreement between Dr. Reddy's Laboratories Ltd. and EPI Health, LLC dated as of August 20, 2018 (the "Minolira APA"). The Minolira APA requires minimum royalty payments based on the future net sales of Minolira.

11. In or around July 2022, EPI Health discontinued its promotion of Cloderm due to the introduction of competing generic drugs and a focus of resources on the sale of other of the Debtors' products. In or around June 2023, EPI Health discontinued the promotion of all other EPI commercial products, including Minolira.

12. Prior to the Petition Date, EPI Health had used two third-party logistics providers, Integrated Commercialization Solutions, Inc. (ICS) and QPharma, Inc. (collectively, the "Logistics Providers"), to store and distribute both trade products and physician samples of the Prescription Products.

13. Finally, EPI Health also has certain other current and expired legacy products that are currently in the possession of the Logistics Providers, as described in the Inventory Listing attached hereto as **Exhibit C** (collectively, the "Inventory," and with the Prescription Products, the "Unsellable Products"). The Debtors have estimated the costs to destroy the inventory is \$125,000 and that it also seeks to abandon pursuant to the Motion.

14. There are certain regulations related to the continued support of pharmaceutical products through their expiration dates. As pharmaceutical products, the Unsellable Products are subject to certain federal regulations promulgated by the U.S. Food and Drug Administration (the "FDA") and other federal laws. For example, pursuant to sections 314.80 and 211.166 of title 21 of the Code of Federal Regulations, pharmaceutical companies are required to maintain the safety, quality, and integrity of their products, including pharmacovigilance and ongoing stability testing of the products. Also, pharmaceutical companies are required to pay fees to the FDA based upon the Prescription Drug User Fee Act ("PDUFA"). Additionally, pharmaceutical companies are required to provide price reporting pursuant to section 1927(b)(3)(A) of the Social Security Act. The Debtors have estimated the costs to conduct the

expected monitoring and reporting of the Unsellable Products, through latest expiration date of product in commerce, is \$400,000 over a thirty month period.

15. Absent the ongoing support of Cloderm and Minolira, the Debtors are aware of further regulatory expectations of a total market recall of the Unsellable Products which have not yet expired. Any formal recall of the Unsellable Products would likely exceed \$500,000 and last multiple years. Additionally, with the Prescription Products (and the other Unsellable Products), the Debtors could also be subject to fees based upon PDUFA at cost of \$833,468.00.

C. Events During the Bankruptcy

16. Both prior to, and during, the Chapter 11 Cases, the Debtors conducted an extensive marketing process of their assets, including the Prescription Products, to interested parties. Additional detail concerning the marketing and sale of the Debtors' assets can be found in the *Declaration of Simon Wein in Support of Entry of Orders Authorizing Sale of Substantially All of the Debtors' Assets Free and Clear of all Encumbrances* [D.I. 273], which is incorporated herein by reference.

17. After this thorough and robust marketing process, the Debtors were unable to find a buyer for Cloderm or Minolira—even a buyer that would simply take the physical product stored at the Logistics Providers and assume the unpaid liabilities attendant to the products without any cash to the Debtors' estates. The Debtors have also proposed that Dr. Reddy's Laboratories Inc., the previous owner of Cloderm and Minolira, take back ownership of the respective products and inventories but thus far has refused to do so. Thus, Cloderm and Minolira, along with the other Unsellable Products, and the contracts and physical items associated with them, require ongoing estate resources at this point in time.

18. As the Debtors no longer sell the Unsellable Products, have been unable to find a buyer for the Unsellable Products, and, in fact, have not sold such products at any time during the Chapter 11 Cases, any such fees or expenses have no benefit to the estates and be to the detriment of all creditors. The Debtors have neither the resources nor the infrastructure to undertake a recall of the Unsaleable Products that would satisfy the regulatory or federal obligations.

D. Relevant Regulatory Issues

19. After the Petition Date, Debtors filed a notification of discontinuation of commercialization to the FDA and initiated Cloderm and Minolira to be discontinued as active sellable products from the Approved Drug Products with Therapeutic Equivalence Evaluations list (commonly referred to as the “Orange Book”) published by the FDA. The other Unsellable Products held by the Logistics Providers are legacy products that were discontinued prior to Petition Date in the normal course of business and pharmaceutical life-cycle maintenance.

E. Safety of the Unsellable Products

20. Based on the historical pharmacovigilance (drug safety) monitoring of the safety of Cloderm and Minolira, the Debtors are unaware of any imminent serious safety threats of these products to patients.

21. Additionally, the FDA maintains a public safety reporting system to allow reporting of any adverse events experienced with Cloderm and Minolira, thereby allowing action to be taken on any associated public risk related to the Unsellable Products.

F. Proposed Actions

22. The Debtors intend to notify their Logistics Providers and any third party wholesalers (the “Wholesalers”) that the Debtors are abandoning their interests in the Unsellable Products in connection with this Motion. After the approval of the relief sought in this Motion, the Logistics Providers and Wholesalers would be able to dispose of the Unsellable Products currently within their possession through their normal internal disposition procedures.

23. Finally, the Debtors will not provide any support for the Unsellable Products pursuant to 21 C.F.R. §§ 211.16, 314.80 and similar regulations. The Debtors will also forgo any FDA annual reporting, any other pharmacovigilance reporting requirements, and reporting under the Social Security Act. As noted above, a formal recall of the Unsellable Products is cost prohibitive, abandoning the Unsellable Products is in the best interests of the estates and creditors.

RELIEF REQUESTED

24. By this Motion, the Debtors request entry of the Proposed Order, substantially in the form attached hereto as Exhibit A, authorizing the abandonment of the Unsellable Products, including (i) certain intangibles associated with the Unsellable Products, including but not limited to trademarks and related contracts and contractual rights; (ii) all inventory of the Unsellable Products by whomever held and wherever held; and (iii) all regulatory obligations arising from or related to the Unsellable Products.

BASIS FOR RELIEF

25. The Debtors’ abandonment of the Unsellable Products and all rights and obligations related to such Unsellable Products is a reasonable and good faith exercise of the Debtors’ business judgment due to the Debtors’ lack of resources and the Debtors’ estates (and its

unsecured creditors) should not have to bear any burdens associated with the Unsellable Products going forward.

26. Section 554(a) of the Bankruptcy Code provides that “[a]fter notice and a hearing, the trustee may abandon any property of the estate that is burdensome to the estate of that is of inconsequential value and benefit to the estate.” 11 U.S.C. § 554(a).

27. Furthermore, section 105(a) of the Bankruptcy Code provides “the court may issue any order, process, or judgment that is necessary or appropriate to carry out provisions of this title. No provision of this title providing for the raising of an issue by a party in interest shall be construed to preclude the court from, *sua sponte*, taking any action or making any determination necessary or appropriate to enforce or implement court orders or rules, or to prevent abuse of process.” 11 U.S.C. §105(a).

28. Section 554 of the Bankruptcy Code provides that a debtor may ordinarily abandon property that is burdensome to the estate. *In re Exide Holdings, Inc.*, 2021 WL 3145612, at *8 (D. Del. July 26, 2021). The abandonment power embodied in section 554 enables the trustee (or a debtor) to rid the estate of burdensome or worthless assets. *In re Quanta Resources Corp.*, 739 F.2d 912, 915 (3d. Cir. 1984). Abandonment speeds the administration of the estate and serves the creditors’ interest in expeditiously obtaining a fair amount on settlement of their claims. *Id.*

29. More specifically, when deciding whether property may be abandoned under §554, a court will defer to a trustee/debtor’s judgment upon finding that the trustee/debtor made: (1) a business judgment; (2) in good faith; (3) upon some reasonable basis; and (4) within the trustee’s scope of authority. *In re APP Winddown, LLC*, No. 16-12551, 2019 Bankr. LEXIS 3790, at *7, (Bankr. D. Del. Dec. 16, 2019); *In re Syntax-Brilliant Corp.*, No. 08-11407 (KJC), 2018 Bankr. LEXIS 2116, at *15 (Bankr. D. Del. July 18, 2018). A trustee may abandon property

in which no equity or value remains. See *In re Pilz Compact Disc, Inc.*, 229 B.R. 630, 645 (Bankr. E.D. Pa. 1999) (authorizing abandonment of inventory that was not useful to the estate).

30. The right to abandon property is nearly absolute. See *Midlantic Nat'l Bank v. New Jersey Dep't of Env't'l Protection*, 474 U.S. 494, 507 (1986). However, there is a “narrow exception to that power . . . as a bankruptcy court cannot authorize an abandonment without formulating conditions that will adequately protect the public’s health and safety.” *Exide Holdings*, 2021 WL 3145612, at *8 citing *Midlantic*, 474 U.S. at 502, 507 and n.9 (internal citations omitted). “Courts have read this exception narrowly” *In re Unidigital Inc.*, 262 B.R. 283, 286 (Bankr. D. Del. 2001) and “[c]ases which have interpreted *Midlantic* focus largely on imminent and identifiable harm.” *In re Venoco, LLC*, 572 B.R. 105 (Bankr. D. Del. 2017). See also *Unidigital Inc.*, 262 B.R. at 288 (holding that debtor could abandon 30,000-pound industrial printer containing possible hazardous materials because of no imminent or identifiable harm; *In re Mahoney-Troast Const. Co.*, 189 B.R. 57, 61 (Bankr. D.N.J. 1995) (holding that movement of 200 tons of gasoline-contaminated soil was not an imminent threat to public because there was no danger of it migrating onto adjacent property).

31. The Debtors have attempted to sell the rights to the Prescription Products, and otherwise dispose of the Unsellable Products, on multiple occasions without success. The inability of the Debtors to sell the Prescription products demonstrates that the intangibles of the Prescription Products, such as trademarks and the contracts associated with each Prescription Product, provide no value to the Debtors’ estates. Likewise, the physical inventory of the Unsellable Products (including the Prescription Products) does not provide any value to the Debtors’ estates and, in fact, would require estate resources to remain compliant with federal and state laws. While the Debtors have identified the proper wind down and regulatory expectations

concerning the Unsellable Products, to continue to store and provide reporting services for the Unsellable Products is a drain on estate assets.

32. Furthermore, the “narrow exception” to the near absolute right of the Debtors to abandon property does not apply in this case. For this exception to apply, there would need to be an “imminent and identifiable harm.”

33. The Debtors are not aware of either an imminent or an identifiable harm when the Prescription Products are administered according to label recommendations. Likewise, the Debtors are not aware of the abandonment of the Unsellable Products creating an imminent and identifiable harm. First, the Debtors, through the Logistics Providers, sell the Unsellable Products to the Wholesalers and pharmacies (the “Direct Purchase Pharmacies”). The Debtors can readily identify the Logistics Providers, Wholesalers and Direct Purchase Pharmacies and provide notice of the Debtors’ abandonment of such Unsellable Products, enabling the Logistics Providers, Wholesalers and Direct Purchase Pharmacies to destroy the Unsellable Products they have in their possession or take any other and further actions the Logistics Providers and Wholesalers reasonably believe they need to make in accordance with applicable laws and regulations.

34. Second, as noted above, the FDA maintains a safety monitoring system to allow the public (patients, family of patients, healthcare workers) to report any adverse effects of pharmaceutical products and thereby allow the FDA to take action should any public risk be identified.

35. Thirdly, the Debtors are unaware of any systemic issues or chronic adverse reactions associated with the use of the Unsellable Products.

36. Lastly, all regulation requirements have been maintained for the Unsellable Products since the Petition Date and have not been sold to customers since June of 2023. Also,

the unsellable products have not been supported by patient assistance programs since June of 2023. Based on the above, the levels of inventory are lower and provide lower risk if abandoned at the Petition Date.

37. In sum, due to the lack of resources of the estate to provide the regulatory and safety support, the abandonment of the Unsellable Products is in the best interest of the Debtors' estates and creditors in these Chapter 11 Cases. As such, the Debtors request that the Court enter an order authorizing the abandonment of the Unsellable Products.

NOTICE

38. The Debtors will provide notice of this Motion to: (a) the U.S. Trustee; (b) counsel to the Committee; (c) the Securities and Exchange Commission; (d) the Internal Revenue Service; (e) the United States Department of Justice; (f) the Office of the United States Attorney for the District of Delaware; (g) the FDA; (h) the Social Security Administration, (i) the Logistics Providers, (j) the Wholesalers; (k) the Direct Purchase Pharmacies; and (l) any other party entitled to notice pursuant to Bankruptcy Rule 2002. The Debtors submit that, in light of the nature of the relief requested, no other or further notice need be provided.

CONCLUSION

WHEREFORE, for the reasons set forth herein, the Debtors respectfully request that the Court (a) enter the Proposed Order substantially in the form attached hereto as **Exhibit A** and (b) grant such other and further relief as is just and proper.

Dated: January 19, 2024
Wilmington, Delaware

Respectfully submitted,

/s/ Daniel B Butz

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Derek C. Abbott (No. 3376)

Daniel B. Butz (No. 4227)

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**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:)	
)	Chapter 11
NVN Liquidation, Inc., <i>et al.</i> ,)	
f/k/a NOVAN, INC., ¹)	Case No. 23-10937 (LSS)
)	
Debtors.)	(Jointly Administered)
)	
)	<u>Hearing Date:</u>
)	February 9, 2024, at 11:30 a.m. (ET)
)	
)	<u>Objection Deadline:</u>
)	February 2, 2024, at 4:00 p.m. (ET)

NOTICE OF MOTION AND HEARING

PLEASE TAKE NOTICE that, on January 19, 2024, the above-captioned debtors and debtors in possession (collectively, the “Debtors”) filed the *Motion of Debtors for Entry of an Order Pursuant to 11 U.S.C. §§ 105(a) and 554 and Federal Rule of Bankruptcy Procedure 6007 Authorizing the Abandonment of Certain Unsellable Products Subject to Certain Regulatory Obligations* (the “Motion”) with the United States Bankruptcy Court for the District of Delaware (the “Court”).

PLEASE TAKE FURTHER NOTICE that any responses or objections to approval of the relief requested in the Motion must (a) be in writing; (b) be filed with the Clerk of the Court, 824 Market Street, 3rd Floor, Wilmington, Delaware 19801, on or before **February 2, 2024, at 4:00 p.m. (ET)** (the “Objection Deadline”); and (c) served so as to be received on or before the Objection Deadline by the undersigned counsel to the Debtors.

PLEASE TAKE FURTHER NOTICE THAT A HEARING ON THE MOTION WILL BE HELD ON FEBRUARY 9, 2024, AT 11:30 A.M. (ET) BEFORE THE HONORABLE LAURIE SELBER SILVERSTEIN AT THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE, 824 MARKET STREET, 6th FLOOR, COURTROOM #2, WILMINGTON, DELAWARE 19801.

PLEASE TAKE FURTHER NOTICE THAT ONLY OBJECTIONS MADE IN WRITING AND TIMELY FILED AND RECEIVED IN ACCORDANCE WITH THE PROCEDURES ABOVE WILL BE CONSIDERED BY THE COURT AT SUCH HEARING.

¹ The Debtors in these chapter 11 cases, along with the last four digitals of the Debtors’ federal tax identification number (if applicable), are: NVN Liquidation, Inc., (f/k/a Novan, Inc.) (7682) and EPI Health, LLC (9118). The corporate headquarters and the mailing address for the Debtors is P.O. Box 64, Pittsboro, NC 27312.

IF YOU FAIL TO RESPOND IN ACCORDANCE WITH THIS NOTICE, THE COURT MAY GRANT THE RELIEF REQUESTED IN THE MOTION WITHOUT FURTHER NOTICE OR HEARING.

Dated: January 19, 2024
Wilmington, Delaware

Respectfully submitted,

/s/ Daniel B. Butz

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Derek C. Abbott (No. 3376)

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*Counsel to the Debtors and
Debtors in Possession*

EXHIBIT A

Proposed Order

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

NVN Liquidation, Inc., *et al.*,
f/k/a NOVAN, INC.,¹

Debtors.

Chapter 11

Case No. 23-10937 (LSS)

Re: D.I. __

**ORDER PURSUANT TO 11 U.S.C. §§ 105(a) AND 554 AND
FEDERAL RULE OF BANKRUPTCY PROCEDURE 6007
AUTHORIZING THE ABANDONMENT OF CERTAIN UNSELLABLE
PRODUCTS SUBJECT TO CERTAIN REGULATORY OBLIGATIONS**

Upon consideration of the motion (the “Motion”)² of the Debtors for entry of an order (this “Order”) authorizing the abandonment of certain of the debtors’ property; and this Court having jurisdiction to consider the Motion pursuant to 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware, dated February 29, 2012; and this Court being able to issue a final order consistent with Article III of the United States Constitution; and venue of these Chapter 11 Cases and the Motion in this district being proper pursuant to 28 U.S.C. §§ 1408 and 1409; and this matter being a core proceeding pursuant to 28 U.S.C. § 157(b); and this Court having found that proper and adequate notice of the Motion and the relief requested therein has been provided in accordance with the Bankruptcy Rules and the Local Rules, and that, except as otherwise ordered herein, no other or further notice is necessary; and objections (if any) to the Motion having been withdrawn, resolved

¹ The Debtors in these chapter 11 cases, along with the last four digitals of the Debtors’ federal tax identification number (if applicable), are: NVN Liquidation, Inc., (f/k/a Novan, Inc.) (7682) and EPI Health, LLC (9118). The corporate headquarters and the mailing address for the Debtors is P.O. Box 64, Pittsboro, NC 27312.

² Capitalized terms not otherwise defined herein are to be given the meanings ascribed to them in the Motion.

or overruled on the merits; and a hearing having been held to consider the relief requested in the Motion and upon the record of the hearing and all of the proceedings had before this Court; and this Court having found and determined that the relief sought in the Motion is in the best interests of the Debtors, their estates, their creditors and all other parties-in-interest; and that the legal and factual bases set forth in the Motion establish just cause for the relief granted herein; and after due deliberation and sufficient cause appearing therefor;

IT IS HEREBY ORDERED THAT:

1. The Motion is GRANTED.
2. The Debtors are authorized to abandon the Unsellable Products as described in the Motion.
3. The Debtors are authorized and empowered to execute and deliver such documents, and to take and perform all actions necessary to implement and effectuate the relief granted in this Order.
4. This Court shall retain jurisdiction over any matter or dispute arising from or relating to the implementation of this Order.

EXHIBIT B

Declaration

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

NVN Liquidation, Inc., *et al.*,
f/k/a NOVAN, INC.,¹

Debtors.

Chapter 11

Case No. 23-10937 (LSS)

(Jointly Administered)

**DECLARATION OF JOHN DONOFRIO IN SUPPORT OF MOTION OF DEBTORS
FOR ENTRY OF AN ORDER PURSUANT TO 11 U.S.C. §§ 105(A) AND 554 AND
FEDERAL RULE OF BANKRUPTCY PROCEDURE 6007 AUTHORIZING THE
ABANDONMENT OF CERTAIN UNSELLABLE PRODUCTS SUBJECT TO CERTAIN
REGULATORY OBLIGATIONS**

I, John Donofrio, declare as follows:

1. I am Chief Operating Officer of NVN Liquidation, inc. f/k/a/ Novan, Inc. and former President of EPI Health, LLC (collectively, the “Debtors”). I submit this declaration (this “Declaration”) in support of the *Motion of Debtors for Entry of an Order Pursuant to 11 U.S.C. §§ 105(a) and 554 and Federal Rule of Bankruptcy Procedure 6007 Authorizing the Abandonment of Certain Unsellable Products Subject to Certain Regulatory Obligations* (the “Motion”), filed contemporaneously herewith.²

2. I am over the age of 18 years and authorized to submit this Declaration on behalf of the Debtors. Except as otherwise indicated, all facts set forth in this Declaration are based upon my personal knowledge, my discussions with members of the Debtors’ Board of Directors and other members of the management team, and the Debtors’ advisors, my review of relevant

¹ The Debtors in these chapter 11 cases, along with the last four digitals of the Debtors’ federal tax identification number (if applicable), are: NVN Liquidation, Inc., (f/k/a Novan, Inc.) (7682) and EPI Health, LLC (9118). The corporate headquarters and the mailing address for the Debtors is P.O. Box 64, Pittsboro, NC 27312.

² Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Motion.

documents and information concerning the Debtors' operations, or my opinions based upon my experience and knowledge. If called as a witness, I could and would testify competently to the facts set forth in this Declaration.

3. In September 2018, Debtor EPI Health, LLC ("EPI Health") acquired the rights to Cloderm by entering into that Asset Purchase Agreement between Promius Pharma, LLC and Dr. Reddy's Laboratories Inc. and EPI Health, LLC dated as of September 28, 2018 (the "Cloderm APA"). The Cloderm APA requires minimum royalty payments on the net sales of Cloderm, subject to meeting certain sales milestones.

4. In August 2018, EPI Health acquired the rights to Minolira by entering into that Asset Purchase Agreement between Dr. Reddy's Laboratories Ltd. and EPI Health, LLC dated as of August 20, 2018 (the "Minolira APA"). The Minolira APA requires minimum royalty payments based on the future net sales of Minolira.

5. In or around July 2022, EPI Health discontinued its promotion of Cloderm due to the introduction of competing generic drugs and a focus of resources on the sale of other of the Debtors' products. In or around June 2023, EPI Health discontinued the promotion of all other EPI commercial products, including Minolira.

6. Prior to the Petition Date, EPI Health had used two third-party logistics providers, Integrated Commercialization Solutions, Inc. (ICS) and QPharma, Inc. (collectively, the "Logistics Providers"), to store and distribute both trade products and physician samples of the Prescription Products.

7. EPI Health also has certain other current and expired legacy products that are currently in the possession of the Logistics Providers, as described in the Inventory Listing attached to the Motion (collectively, the "Inventory," and with the Prescription Products, the

“Unsellable Products”). The Debtors have estimated the costs to destroy the inventory is \$125,000 and that it also seeks to abandon pursuant to the Motion.

8. I am aware that there are certain regulations related to the continued support of pharmaceutical products through their expiration dates. I am aware that, as pharmaceutical products, the Unsellable Products are subject to certain federal regulations promulgated by the U.S. Food and Drug Administration (the “FDA”) and other federal laws. For example, pursuant to sections 314.80 and 211.166 of title 21 of the Code of Federal Regulations, I am aware that pharmaceutical companies are required to maintain the safety, quality, and integrity of their products, including pharmacovigilance and ongoing stability testing of the products. Also, I am aware that pharmaceutical companies are required to pay fees to the FDA based upon the Prescription Drug User Fee Act (“PDUFA”). Additionally, I am aware that pharmaceutical companies are required to provide price reporting pursuant to section 1927(b)(3)(A) of the Social Security Act.

9. The Debtors have estimated the costs to conduct the expected monitoring and reporting of the Unsellable Products, through latest expiration date of product in commerce, is \$400,000 over a thirty month period.

10. Absent the ongoing support of Cloderm and Minolira, I am aware of further regulatory expectations of a total market recall of the Unsellable Products which have not yet expired. I believe that any formal recall of the Unsellable Products would likely exceed \$500,000 and last multiple years. Additionally, I am aware that the Prescription Products (and the other Unsellable Products), the Debtors could also be subject to fees based upon PDUFA at cost of \$833,468.00.

11. I am aware that the Debtors were unable to find a buyer for Cloderm or Minolira—even a buyer that would simply take the physical product stored at the Logistics Providers and assume the unpaid liabilities attendant to the products without any cash to the Debtors’ estates. I am aware that the Debtors have also proposed that Dr. Reddy’s Laboratories Inc., the previous owner of Cloderm and Minolira, take back ownership of the respective products and inventories but thus far has refused to do so.

12. I am aware that, after the Petition Date, Debtors filed a notification of discontinuation of commercialization to the FDA and initiated Cloderm and Minolira to be discontinued as active sellable products from the Approved Drug Products with Therapeutic Equivalence Evaluations list (commonly referred to as the “Orange Book”) published by the FDA. I am aware that the other Unsellable Products held by the Logistics Providers are legacy products that were discontinued prior to Petition Date in the normal course of business and pharmaceutical life-cycle maintenance.

13. Based upon the historical pharmacovigilance (drug safety) monitoring of the safety of Cloderm and Minolira, the Debtors are unaware of any imminent serious safety threats of these products to patients.

Based upon the foregoing, pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 19th day of January 2024.

/s/ John Donofrio
John Donofrio
Chief Operating Officer
NVN Liquidation, Inc. f/k/a Novan, Inc.

EXHIBIT C

Inventory Listing

Exhibit C**Integrated Commercialization Solutions, Inc. (ICS)**

Description	NDC	Stock Units
Minolira 105MG Tabs 30 Count	71403010130	11,825
Minolira 135MG Tabs 30 Count	71403010230	19,059
Rhofade 1% Cream 30g GM Tube	7140300330	72,637
Wynzora Cream 60 GM Tube	73499000101	10,713
Sitavig 50MG 2 Count	71403004902	121,243
Cloderm Cream 45 GM Tube	71403080445	23,267
Bionect 100GM Cream .20% Each	68712000704	99
Bensal HP 30G Tube 3-6% Each	63801010701	26,035

Qpharma, Inc.

Description	NDC	Stock Units
Cloderm 2g Sample Tube	71403-804-23	106,764
Minolira 135mg Tablet, 5 Count Sample Bottle	71403-102-05	2,696
Wynzora Cream 5g Sample Tube	73499-001-03	42,850
Misc. Marketing Materials and Promotional Items	N/A	N/A