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): **March 27, 2023**

Esperion Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35986**	**26-1870780**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3891 Ranchero Drive, Suite 150 **Ann Arbor, MI** (Address of principal executive offices)	**48108** (Zip Code)

Registrant's telephone number, including area code: **(734) 887-3903**

Not Applicable
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**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ESPR	NASDAQ Stock Market LLC

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

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 8.01. Other Information.

On March 27, 2023, Esperion Therapeutics, Inc. (the "Company") filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against Daiichi Sankyo Europe GmbH ("DSE") regarding the Company's right to receive a $300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the **C**holesterol **L**owering via B**e**mpedoic acid, an **A**CL-Inhibiting **R**egimen ("CLEAR") Outcomes trial demonstrating significant reductions of fatal and non-fatal myocardial infarction of 23% and non-fatal myocardial infarction of 27%.

The foregoing summary of the complaint is qualified in its entirety by reference to the full text of the complaint, a copy of which is filed with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Complaint in Esperion Therapeutics, Inc. v. Daiichi Sankyo Europe GmbH, Case No. 1:23-cv-02568
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

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

Date: March 27, 2023

Esperion Therapeutics, Inc.

By: /s/ Sheldon L. Koenig
Sheldon L. Koenig
President and Chief Executive Officer

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC. Plaintiff, v. DAIICHI SANKYO EUROPE GMBH., Defendant.	Civil Action No:

COMPLAINT

1. Plaintiff Esperion Therapeutics, Inc. ("Esperion") brings this Complaint for declaratory judgment against Daiichi Sankyo Europe GmbH ("DSE") regarding its right to a Regulatory Milestone Payment, as defined in the License and Collaboration Agreement between Esperion and DSE, dated January 2, 2019 (the "Agreement"). A redacted copy of which is attached hereto as Exhibit A[1].

2. This dispute arises out of one of DSE's payment obligations under the Agreement—the Regulatory Milestone Payment.

3. Esperion is entitled to a Regulatory Milestone Payment from DSE on the occurrence of an event, termed Regulatory Milestone Event in the Agreement: Regulatory Approval in the DSE Territory[2] that includes "cardiovascular risk reduction" in the label that correlates with the relative risk reduction rate equal or greater than 15%. Ex. A at Section 9.2.

[1] Capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Agreement.
[2] The DSE Territory means "Andorra, Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy (incl. Vatican City), Latvia,

4. The amount of the Regulatory Milestone Payment that Esperion is entitled to upon achievement of this Regulatory Milestone Event depends on the relative cardiovascular risk reduction rate as demonstrated by the results of a recently completed global cardiovascular outcomes trial, known as Cholesterol Lowering via bempedoic acid, an ACL-inhibiting Regimen (CLEAR) Outcomes (the “CLEAR Outcome Study”).

5. This Complaint seeks a declaratory judgment from this Court to settle a legal dispute that exists between Esperion and DSE regarding how the phrase “cardiovascular risk” is to be defined as it is used in the relevant section of the Agreement.

PARTIES

6. Esperion is a pharmaceutical company incorporated in Delaware and has its principal place of business at 3891 Ranchero Drive, Suite 150, Ann Arbor, Michigan 48108. Esperion is focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients struggling with elevated low-density lipoprotein cholesterol (“LDL-C”).

7. Upon information and belief, Defendant Daiichi Sankyo Europe GmbH is a limited liability company in Germany with its principal place of business in Munich, Germany. Daiichi Sankyo Europe GmbH is a wholly owned affiliate of Daiichi Sankyo Co., Ltd., headquartered in Tokyo, Japan.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) because this is a dispute between citizens of a State and citizens of a foreign state and the amount in controversy exceeds $75,000, exclusive of interest and costs.

Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovenia, Slovakia, Spain, Sweden, Switzerland and United Kingdom” and Turkey. Ex. A at Section 1.35 and 1st Amendment to the Agreement, dated June 18, 2020.

9. This Court has personal jurisdiction over DSE because DSE is a party to the License and Collaboration Agreement by and between DSE and Esperion, dated as of January 2, 2019, in which DSE agreed to "submit[] to the jurisdiction of the courts sitting in New York City, New York, for the purpose of any dispute arising between the Parties in connection with this Agreement." Ex. A at Section 14.4; see also 28 U.S.C. § 1391(b); N.Y. G.O.L. § 5-1402.

10. Venue is proper in this District because DSE has consented to this matter being adjudicated in New York. 28 U.S.C. § 1391.

FACTS

11. Esperion, founded in 2008, is a pharmaceutical company focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients struggling with elevated LDL-C.

12. Elevated LDL-C is well-accepted as a significant risk factor for cardiovascular disease. A consequence of elevated LDL-C is atherosclerosis, which is a disease characterized by the deposition of excess LDL and other similar lipid-containing particles in the walls of arteries. This process leads to the formation of atherosclerotic plaque lesions in the artery walls. Depending upon their location, continued progression of atherosclerotic plaques can lead to heart attacks, strokes and peripheral artery disease.

13. Two patient populations with a high unmet medical need arising from particularly severe elevation of LDL-C are those suffering from (i) atherosclerotic cardiovascular disease ("ASCVD"), which is a slow, progressive disease characterized by the hardening and narrowing of arterial walls; and (ii) heterozygous familial hypercholesterolemia ("HeFH"), which is a genetic condition characterized by impaired cholesterol metabolism and clinically elevated blood cholesterol.

14. Esperion currently has two marketed products approved in the United States and Europe for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

15. NEXLETOL® contains bempedoic acid and was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

16. NEXLIZET® contains bempedoic acid and ezetimibe and was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

The License and Collaboration Agreement With DSE

17. On January 2, 2019, Esperion entered into the Agreement. Pursuant to the Agreement, Esperion granted DSE exclusive commercialization rights to products containing bempedoic acid—which would include NEXLETOL® and NEXLIZET® (branded in Europe as NILEMDO® and NUSTENDI®)—in the European Economic Area and Switzerland, defined in the Agreement as the DSE Territory.

18. In consideration for such exclusive commercialization rights, the Agreement requires, among other things, DSE to make certain payments to Esperion if various conditions are met. See Ex. A at Section 9. One such payment is the Regulatory Milestone Payment. Ex. A at 9.2.

19. Under the Agreement, Esperion is entitled to the Regulatory Milestone Payment if two conditions, together comprising a Regulatory Milestone Event, are met: (1) Grant of Regulatory Approval in the DSE Territory of a Licensed Product; and (2) such Regulatory Approval “includes cardiovascular risk reduction in the label that correlates with the relative risk

reduction rate" equal or greater than 15%, which itself is contractually tied to the results of the CLEAR Outcome Study. Ex. A at Section 9.2.

20. If Regulatory Approval is granted and the CLEAR Outcome Study demonstrates a cardiovascular risk reduction rate equal to or greater than 15% and less than 20%, Esperion is entitled to a Regulatory Milestone Payment of $200,000,000. Ex. A at Section 9.2

21. If Regulatory Approval is granted and the CLEAR Outcome Study demonstrates a cardiovascular risk reduction rate equal to or greater than 20%, Esperion is entitled to a Regulatory Milestone Payment of $300,000,000. Ex. A at Section 9.2.

22. Section 9.2 of the Agreement specifically provides as follows:

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	**$200,000,000**
Equal to or greater than 20%	**$300,000,000**

CLEAR Outcome Study

23. Esperion recently completed the CLEAR Outcome Study. The study was designed to evaluate whether treatment with bempedoic acid reduced the risk of cardiovascular events in patients who are statin averse and who have cardiovascular disease or are at high risk for cardiovascular disease.

24. The Clear Outcome Study demonstrated the effect of bempedoic acid on different types of adverse cardiovascular events and provided efficacy data for several endpoints, including (1) MACE-4, a composite of four major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization); (2) MACE-3, a composite of three major adverse cardiovascular events (cardiovascular death, nonfatal myocardial

infarction, or nonfatal stroke); (3) fatal and nonfatal myocardial infarction; (4) coronary revascularization; (5) fatal and nonfatal stroke; (6) cardiovascular death; and (7) all-cause mortality.

25. On March 4, 2023, the Company announced the full results from the CLEAR Outcome Study.

CLEAR Outcome Study Demonstrates Reduction of Cardiovascular Risk by Over 20%

26. The CLEAR Outcome Study demonstrated that the risk of nonfatal myocardial infarction—heart attacks—was significantly lower for a patient taking bempedoic acid, as compared to a placebo, by 27%.[3]

27. Because the Clear Outcome Study demonstrated a reduction of cardiovascular risk by over 20%—specifically, a reduction in nonfatal heart attacks—Esperion believes that it will be entitled to receive a $300 million milestone payment from DSE upon Regulatory Approval with the inclusion of cardiovascular risk reduction in the label.[4] Esperion communiated this to DSE on March 8, 2023.

28. DSE disagrees. DSE believes (and has communicated to Esperion) that DSE will never be required to pay Esperion any Regulatory Milestone Payment even if Esperion received Regulatory Approval because the CLEAR Outcome Study did not show the MACE-4 composite risk reduction to be over 15%.

29. DSE's position—that Section 9.2 of the Agreement requires the CLEAR Outcome Study to show the MACE-4 composite risk reduction to be over 15% in order for the second

[3] The results of the CLEAR Outcome Study were published in the New England Journal of Medicine. See Bempedoic Acid and Cardiovascular Outcomes in Statin-Intolerant Patients | NEJM.
[4] The CLEAR Outcome Study also demonstrated a cardiovascular risk reduction rate of 23% for the composite of nonfatal and fatal myocardial infarction that independently would entitle Esperion to a Regulatory Milestone Payment of $300,000,000, as well as cardiovascular risk reductions rates equal to or above 15% for several other endpoints that independently would entitle Esperion to a Regulatory Milestone Payment of $200,000,00, including fatal and nonfatalstroke (15%), coronary revascularization (19%), and MACE-3 (15%).

Condition of the Regulatory Milestone Event to be achieved—is inconsistent with the plain and unambiguous language of the Agreement.

30. In order for Esperion to achieve the second condition of the Regulatory Milestone Event, Section 9.2 requires only, in the plainest language possible, a “cardiovascular risk reduction” of 15% or greater “as a result of the CLEAR Outcome Study” to be included in the label upon Regulatory Approval.

31. Section 9.2 of the Agreement does not even mention MACE-4.

32. On the other hand, one of the many cardiovascular risks that confront the population is the risk of myocardial infarction, commonly known as ***a heart attack***.

Esperion Suffers Economic Harm from DSE’s Position

33. Consistent with its obligations as a public company, on March 15, 2023, Esperion publicly disclosed that it “has had communications with Daiichi Sankyo Europe (DSE) regarding potential milestone payments in which DSE has conveyed that it disagrees with the Company’s assessment that the CLEAR Outcomes data would support the Company’s right to receive any milestone payments upon inclusion of certain required cardiovascular risk reduction data in the EU label, because the CLEAR Outcomes study showed a 12.98% reduction in MACE-4, the primary endpoint of the trial.” See March 15, 2023 Form 8-K.

34. On March 15, 2023, prior to issuing the disclosure, Esperion’s stock price was $3.99. When the market opened the day following the disclosure on March 16, 2023, Esperion’s stock price immediately fell to $1.49.

35. Additionally, since DSE has taken its March 14, 2023 position that Esperion will never be entitled to a Regulatory Milestone Payment, it has been materially more difficult for Esperion to raise the capital necessary for the continued operation of its business.

36. DSE's incorrect position regarding Section 9.2 has caused ongoing harm to Esperion, and also risks the continued development and distribution of a significant and valuable medicine that could help millions of people around the world.

CAUSES OF ACTION

COUNT I
Declaratory Judgement

37. Esperion repeats and re-alleges each and every allegation set forth in Paragraphs 1 through 36 above as if fully set forth herein.

38. DSE has stated that even if Esperion receives Regulatory Approval in the DSE Territory, it will not pay Esperion the Regulatory Milestone Payment to which it would be entitled under the Agreement.

39. DSE's position is that it is impossible for Esperion to achieve the Regulatory Milestone Event even if Esperion received Regulatory Approval because the CLEAR Outcome Study did not show MACE-4 risk reduction equal to or greater than 15%.

40. However, DSE's position is wrong. Under Section 9.2 of the Agreement, in order to achieve one of the conditions of the Regulatory Milestone Event, the CLEAR Outcome Study need only show a "cardiovascular risk reduction" of 15% or greater, which is not limited to MACE-4, as DSE claims.

41. The CLEAR Outcome Study demonstrated a cardiovascular risk reduction of over 15%.

42. Specifically, the CLEAR Outcome Study showed a reduction rate of 27% for nonfatal myocardial infarction (heart attacks) in patients using bempedoic acid.

43. Upon public disclosure of DSE's position regarding the impossibility of Esperion meeting one condition of the Regulatory Milestone Event, Esperion suffered immediate economic

harm. Esperion's stock price fell by over 50%, dropping from $3.99 to $1.49 after such disclosure. Since the disclosure, Esperion continues to suffer harm as it had become materially more difficult to raise the capital necessary for the continued operation of its business.

CLAIM FOR RELIEF

WHEREFORE, Esperion requests that this Court issue a declaratory judgment against Defendant in favor of Plaintiff and enter an order:

a. Declaring that "cardiovascular risk reduction" as stated in Section 9.2 of the Agreement is not limited to MACE-4 results;

b. Declaring that "cardiovascular risk reduction" as stated in Section 9.2 of the Agreement includes risk reduction of nonfatal myocardial infarction (heart attacks); and

c. Declaring that Esperion's CLEAR Outcome Study demonstrated a cardiovascular risk reduction of over 20%.

Dated: March 27, 2023

Respectfully submitted,

ESPERION THERAPEUTICS, INC.,
By its attorneys,
/s/ Jordan D. Weiss
Jordan D. Weiss
Emily S. Unger (pro hac vice forthcoming)
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800
JWeiss@goodwinlaw.com
EUnger@goodwinlaw.com

EXHIBIT A

LICENSE AND COLLABORATION AGREEMENT

by and between

DAIICHI SANKYO EUROPE GMBH

and

ESPERION THERAPEUTICS, INC.

JANUARY 2, 2019

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

1.35. **"DSE Territory"** means Andorra, Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy (incl. Vatican City), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovenia, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

9.2. **Regulatory Milestone Payment.** Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within thirty (30) days following receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	**$200,000,000**
Equal to or greater than 20%	**$300,000,000**

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

14.3. **Governing Law.** The Agreement shall be construed and the respective rights of the Parties determined in accordance with the substantive Laws of the State of New York, notwithstanding any provisions of New York Law or any other Law governing conflicts of laws to the contrary.

14.4. **Jurisdiction.** Each Party by its execution hereof, (a) hereby irrevocably submits to the jurisdiction of the courts sitting in New York City, New York, for the purpose of any dispute arising between the Parties in connection with this Agreement (each, an "**Action**"), except as otherwise expressly provided in this Agreement; (b) hereby waives, to the extent not prohibited by applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such Action, any claim that (i) it is not subject personally to the jurisdiction of the above-named court, (ii) its property is exempt or immune from attachment or execution, (iii) any such Action brought in the above-named court should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than the above-named court, or should be stayed by reason of the pendency of some other proceeding in any other court other than the above-named court, or (iv) this Agreement or the subject matter hereof may not be enforced in or by such court; and (c) hereby agrees not to commence any such Action other than before the above-named court. Notwithstanding the previous sentence a Party may commence any Action in a court other than the above-named court solely for the purpose of enforcing an order or judgment issued by the above-named court.

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

Redacted

DSE Legal Department

Redacted