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

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**Form 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-35986

**Esperion Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**26-1870780**

(I.R.S. Employer  
Identification No.)

**3891 Ranchero Drive, Suite 150**

**Ann Arbor, MI 48108**

(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code:

**(734) 887-3903**

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ESPR	NASDAQ Stock Market LLC

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 1, 2020, there were 27,825,428 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

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Esperion Therapeutics, Inc.

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**Esperion Therapeutics, Inc.**  
**Condensed Balance Sheets**  
**(in thousands, except share data)**

	June 30, 2020 (unaudited)	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 298,489	\$ 166,130
Restricted cash	—	928
Short-term investments	2,247	34,651
Prepaid clinical development costs	890	6,081
Inventories	8,248	—
Other prepaid and current assets	11,497	3,924
Total current assets	321,371	211,714
Property and equipment, net	1,512	1,145
Right of use operating lease assets	6,175	1,532
Other long-term assets	1,294	56
Total assets	<u>\$ 330,352</u>	<u>\$ 214,447</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 29,690	\$ 28,856
Accrued clinical development costs	19,641	17,511
Other accrued liabilities	21,908	11,871
Revenue interest liability	9,276	5,236
Deferred revenue from collaborations	1,134	2,152
Operating lease liabilities	2,232	454
Total current liabilities	83,881	66,080
Revenue interest liability	157,015	127,308
Operating lease liabilities	3,967	1,109
Total liabilities	244,863	194,497
Commitments and contingencies (Note 5)		
<b>Stockholders' equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 120,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 27,751,655 shares issued and outstanding at June 30, 2020 and 27,497,911 shares issued and outstanding at December 31, 2019	28	27
Additional paid-in capital	734,365	715,166
Accumulated other comprehensive income	—	23
Accumulated deficit	(648,904)	(695,266)
Total stockholders' equity	85,489	19,950
Total liabilities and stockholders' equity	<u>\$ 330,352</u>	<u>\$ 214,447</u>

*See accompanying notes to the condensed financial statements.*

Esperion Therapeutics, Inc.

**Condensed Statements of Operations and Comprehensive Income (Loss)**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
<b>Revenues:</b>				
Product sales, net	\$ 609	\$ —	\$ 1,467	\$ —
Collaboration revenue	211,627	982	212,609	146,401
<b>Total Revenues</b>	<b>212,236</b>	<b>982</b>	<b>214,076</b>	<b>146,401</b>
<b>Operating expenses:</b>				
Cost of goods sold	398	—	429	—
Research and development	34,987	42,788	69,689	89,096
Selling, general and administrative	47,681	13,492	89,234	25,674
<b>Total operating expenses</b>	<b>83,066</b>	<b>56,280</b>	<b>159,352</b>	<b>114,770</b>
<b>Income (loss) from operations</b>	<b>129,170</b>	<b>(55,298)</b>	<b>54,724</b>	<b>31,631</b>
Interest expense	(4,640)	—	(8,811)	—
Other income, net	81	1,077	449	1,527
<b>Net income (loss)</b>	<b>\$ 124,611</b>	<b>\$ (54,221)</b>	<b>\$ 46,362</b>	<b>\$ 33,158</b>
Net income (loss) per common share - basic	\$ 4.50	\$ (2.01)	\$ 1.68	\$ 1.23
Net income (loss) per common share - diluted	\$ 4.32	\$ (2.01)	\$ 1.60	\$ 1.16
Weighted-average shares outstanding - basic	27,665,728	26,968,818	27,592,479	26,906,149
Weighted-average shares outstanding - diluted	28,854,445	26,968,818	28,948,058	28,518,015
<b>Other comprehensive income (loss):</b>				
Unrealized gain (loss) on investments	\$ (9)	\$ 95	\$ (23)	\$ 303
<b>Comprehensive income (loss)</b>	<b>\$ 124,602</b>	<b>\$ (54,126)</b>	<b>\$ 46,339</b>	<b>\$ 33,461</b>

See accompanying notes to the condensed financial statements.

**Esperion Therapeutics, Inc.**  
**Condensed Statements of Stockholders' Equity**  
(in thousands, except share data)  
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance December 31, 2018	26,824,859	\$ 27	\$ 677,511	\$ (598,101)	\$ (319)	\$ 79,118
Exercise of stock options	80,218	—	1,669	—	—	1,669
Vesting of restricted stock units	3,125	—	—	—	—	—
Stock-based compensation	—	—	6,636	—	—	6,636
Other comprehensive gain	—	—	—	—	208	208
Net income	—	—	—	87,379	—	87,379
Balance March 31, 2019	26,908,202	\$ 27	\$ 685,816	\$ (510,722)	\$ (111)	\$ 175,010
Exercise of stock options	115,612	—	1,887	—	—	1,887
Exercise of warrants	5,813	—	—	—	—	—
Vesting of restricted stock units	7,025	—	—	—	—	—
Stock-based compensation	—	—	6,563	—	—	6,563
Other comprehensive gain	—	—	—	—	95	95
Net loss	—	—	—	(54,221)	—	(54,221)
Balance June 30, 2019	27,036,652	\$ 27	\$ 694,266	\$ (564,943)	\$ (16)	\$ 129,334

  

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance December 31, 2019	27,497,911	\$ 27	\$ 715,166	\$ (695,266)	\$ 23	\$ 19,950
Exercise of stock options	40,133	1	1,013	—	—	1,014
Vesting of restricted stock units	10,089	—	—	—	—	—
Stock-based compensation	—	—	7,053	—	—	7,053
Other comprehensive loss	—	—	—	—	(14)	(14)
Net loss	—	—	—	(78,249)	—	(78,249)
Balance March 31, 2020	27,548,133	\$ 28	\$ 723,232	\$ (773,515)	\$ 9	\$ (50,246)
Exercise of stock options	160,024	—	3,738	—	—	3,738
Vesting of restricted stock units	43,498	—	—	—	—	—
Stock-based compensation	—	—	7,395	—	—	7,395
Other comprehensive loss	—	—	—	—	(9)	(9)
Net income	—	—	—	124,611	—	124,611
Balance June 30, 2020	27,751,655	\$ 28	\$ 734,365	\$ (648,904)	\$ —	\$ 85,489

*See accompanying notes to the condensed financial statements.*

Esperion Therapeutics, Inc.

**Condensed Statements of Cash Flows**  
(in thousands)  
(unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
<b>Operating activities</b>		
Net income	\$ 46,362	\$ 33,158
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	224	126
Accretion of premiums and discounts on investments	(93)	(121)
Non-cash interest expense related to the revenue interest liability	8,811	—
Stock-based compensation expense	14,448	13,199
Changes in assets and liabilities:		
Prepays and other assets	(2,382)	1,840
Deferred revenue	(1,018)	3,599
Inventories	(8,248)	—
Other long-term assets	(1,238)	—
Accounts payable	921	(16,705)
Other accrued liabilities	12,257	2,586
Net cash provided by operating activities	<u>70,044</u>	<u>37,682</u>
<b>Investing activities</b>		
Purchases of investments	(4,420)	—
Proceeds from sales/maturities of investments	36,895	72,835
Purchase of property and equipment	(776)	(423)
Net cash provided by investing activities	<u>31,699</u>	<u>72,412</u>
<b>Financing activities</b>		
Proceeds from revenue interest liability	25,000	124,649
Proceeds from exercise of common stock options	4,752	3,556
Payments on revenue interest liability	(64)	—
Net cash provided by financing activities	<u>29,688</u>	<u>128,205</u>
Net increase in cash and cash equivalents	131,431	238,299
Cash, cash equivalents and restricted cash at beginning of period	167,058	36,973
Cash, cash equivalents and restricted cash at end of period	<u>\$ 298,489</u>	<u>\$ 275,272</u>
<b>Supplemental disclosure of cash flow information:</b>		
Issuance costs from revenue interest agreement not yet paid	\$ —	\$ 240
Purchase of property and equipment not yet paid	6	285
Non cash right of use asset	(7)	26

*See accompanying notes to the condensed financial statements.*

**Esperion Therapeutics, Inc.**  
**Notes to the Condensed Financial Statements**  
**(unaudited)**

**1. The Company and Basis of Presentation**

Esperion Therapeutics, Inc. ("the Company") is the Lipid Management Company, a pharmaceutical company focused on developing and commercializing affordable, oral, once-daily, non-statin medicines for the treatment of patients with elevated low density lipoprotein cholesterol ("LDL-C"). Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering medicines that will make a substantial impact on reducing global cardiovascular disease ("CVD"); the leading cause of death around the world. NEXLETOL® (bempedoic acid) and NEXLIZET™ (bempedoic acid and ezetimibe) tablets are the first, oral, once-daily, non-statin LDL-C lowering medicines approved in the U.S. in nearly 20 years for patients with atherosclerotic cardiovascular disease ("ASCVD") or heterozygous familial hypercholesterolemia ("HeFH").

On February 21, 2020, the Company announced that the U.S. Food and Drug Administration ("FDA") approved NEXLETOL 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 effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients. NEXLETOL became commercially available on March 30, 2020.

On February 26, 2020, the Company announced that the FDA approved NEXLIZET 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 effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering fixed combination drug product ever approved. NEXLIZET became commercially available on June 4, 2020.

On January 31, 2020, the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") adopted a positive opinion for the Marketing Authorisation Applications ("MAAs") of both bempedoic acid and the bempedoic acid / ezetimibe combination tablets, recommending approval for the treatment of hypercholesterolemia and mixed dyslipidemia. On April 6, 2020, the Company announced that the European Commission ("EC") approved the NILEMDO™ (bempedoic acid) and NUSTENDI™ (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded products names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. NILEMDO is the first, oral, non-statin, LDL-C lowering medicines approved in Europe in almost two decades for indicated patients, and NUSTENDI is the first non-statin, LDL-C lowering combination medicine ever approved in Europe.

On April 17, 2020, the Company entered into a license and collaboration agreement (the "Otsuka Agreement") with Otsuka Pharmaceutical Co., Ltd. ("Otsuka"). Pursuant to the Otsuka Agreement, the Company granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan. The Company received an upfront cash payment of \$60 million in April 2020 and will receive up to an additional \$450 million in total development and sales milestones. The Company will also receive tiered royalties ranging from 15 percent to 30 percent on net sales in Japan.

On June 18, 2020, the Company entered into an amendment to the license and collaboration agreement ("LCA Amendment") with Daiichi Sankyo Europe GmbH ("DSE") dated as of January 2, 2019. In June 2020, the Company completed the transfer of the MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid the Company the second \$150 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU. Prior to the execution of the LCA Amendment, the milestone payment was due upon the first commercial sale in Europe, which is anticipated later this year. Additionally, the Company and DSE have agreed to expand the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining Regulatory Approval for such product in Turkey.

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The Company's primary activities since incorporation have been conducting research and development activities, including nonclinical, preclinical and clinical testing, performing business and financial planning, recruiting personnel, and raising capital. The Company received approval by the FDA in February 2020 to commercialize NEXLETOL and NEXLIZET in the U.S., and accordingly commenced principal operations on March 30, 2020 with the commercialization of NEXLETOL. The Company is subject to risks and uncertainties which include the need to successfully commercialize its products, research, develop, and clinically test therapeutic products; obtain regulatory approvals for its products; expand its management, commercial and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained annual operating losses since inception and expects such losses to continue over the foreseeable future. While management believes current cash resources and future cash received from the Company's net product sales, collaboration agreements with DSE and Otsuka, entered into on January 2, 2019 and April 17, 2020, respectively, and from the Revenue Interest Purchase Agreement ("RIPA") with Eiger III SA LLC ("Oberland"), an affiliate of Oberland Capital LLC, and the Purchasers named therein, entered into on June 26, 2019, will fund operations for the foreseeable future, management may continue to fund operations and advance the development of the Company's products and product candidates through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings, and permitted private and public equity offerings or through other sources.

If adequate funds are not available, the Company may not be able to continue the development of its current products or future product candidates, or to commercialize its current or future product candidates, if approved.

### **Basis of Presentation**

The accompanying condensed interim financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America ("GAAP"). In the opinion of management, the Company has made all adjustments, which include only normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods presented. Certain prior year amounts have been reclassified to conform with current year presentation. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP, but that is not required for interim reporting purposes, have been condensed or omitted. These condensed interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2019, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. The results of operations for the interim periods are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues, expenses and related disclosures. Actual results could differ from those estimates.

### **Concentration of Risk**

The Company enters into a limited number of distribution agreements with distributors and specialty pharmacies. The Company's net product sales are with these customers. As of June 30, 2020, one customer accounted for all of the Company's net trade receivables.

### **Inventories**

Inventories are stated at the lower of cost or net realizable value and recognized on a first-in, first-out ("FIFO") method. The Company uses standard cost to determine the cost basis for inventory. Inventory is capitalized based on when future economic benefit is expected to be realized. The Company began capitalizing inventory upon receiving FDA approval for NEXLETOL and NEXLIZET on February 21, 2020 and February 26, 2020, respectively. Prior to the FDA approval of NEXLETOL and NEXLIZET, expenses associated with the manufacturing of the Company's products were recorded as research and development expense.



The Company analyzes its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of sales in the period in which they are incurred.

## **Revenue Recognition**

In accordance with ASC 606, Revenue from Contracts with Customers, the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: identify the contracts with a customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when or as the entity satisfies a performance obligation. At contract inception the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. The Company derives revenue through two primary sources: collaboration revenue and product sales. Collaboration revenue consists of the collaboration payments to the Company for collaboration arrangements outside of the United States for the development, manufacturing and commercialization of the Company's product candidates by the Company's partners and product sales consists of sales of NEXLETOL and NEXLIZET.

### **a. Collaboration Revenue**

The Company has entered into an agreement related to its activities to develop, manufacture, and commercialize its product candidates. The Company earns collaboration revenue in connection with a collaboration agreement to develop and/or commercialize product candidates where the Company deems the collaborator to be the customer. Revenue is recognized when (or as) the Company satisfies performance obligations under the terms of a contract. Depending on the terms of the arrangement, the Company may defer the recognition of all or a portion of the consideration received as the performance obligations are satisfied.

The collaboration agreements may require the Company to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In an agreement involving multiple goods or services promised to be transferred to a customer, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation.

The terms of the agreement typically include consideration to be provided to the Company in the form of non-refundable up-front payments, development milestones, sales milestones, and royalties on sales of products within a respective territory. The Company recognizes regulatory and approval milestones consideration when it is probable that a future reversal is unlikely to occur. For sales based milestones and royalties based on sales of product in a territory, the Company applies the sales-based royalty exception in ASC 606-10-55-65 to all of these milestones and royalties.

At the inception of the contract, the transaction price reflects the amount of consideration the Company expects to be entitled to in exchange for transferring promised goods or services to its customer. In the arrangement where the Company satisfies performance obligation(s) during the regulatory phase over time, the Company recognizes collaboration revenue typically using an input method on the basis of regulatory costs incurred relative to the total expected cost which determines the extent of progress toward completion. The Company reviews the estimate of the transaction price and the total expected cost each period and makes revisions to such estimates as necessary. Under contracted supply agreements with collaborators, the Company may manufacture and supply quantities of active pharmaceutical ingredient ("API") or bulk tablets reasonably required by collaboration partners for the development or sale of licensed products in their respective territory. The Company recognizes revenue when the collaboration partner has obtained control of the API or bulk tablets. The Company records the costs related to the supply agreement in cost of goods sold on the condensed statements of operations and comprehensive income (loss).

Under the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. The Company receives royalties from the commercialization of such products, and records its share of the variable consideration, representing a percentage of net product sales, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborator. The collaborator will provide the Company with estimates of its royalties for such quarter; these estimates are reconciled to actual results in the subsequent quarter, and the royalty is adjusted accordingly, as necessary.

**b. Product Sales, Net**

On February 21, 2020, the Company announced that the FDA approved NEXLETOL 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. On February 26, 2020, the Company announced that the FDA approved NEXLIZET 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. On March 30, 2020, NEXLETOL was commercially available in the U.S. through prescription and on June 4, 2020, NEXLIZET was commercially available in the U.S. through prescription. Net product sales totaled \$0.6 million and \$1.5 million for the three and six months ended June 30, 2020, respectively.

The Company sells NEXLETOL and NEXLIZET to wholesalers in the U.S and, in accordance with ASC 606, recognizes revenue at the point in time when the customer is deemed to have obtained control of the product. The customer is deemed to have obtained control of the product at the time of physical receipt of the product at the customers' distribution facilities, or free on board ("FOB") destination, the terms of which are designated in the contract.

Product sales are recorded at the net selling price, which includes estimates of variable consideration for which reserves are established for (a) rebates and chargebacks, (b) co-pay assistance programs, (c) distribution fees, (d) product returns, and (e) other discounts. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the applicable contract. The amount of variable consideration may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Given the early stage of the Company's commercial operations it has provided constraint of its variable consideration due to its potential consumption trends. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Liabilities for co-pay assistance, expected product returns, rebates, and distributor fees are classified as "Other accrued liabilities" in the condensed balance sheets. Discounts, such as prompt pay discounts, and chargebacks are recorded as a reduction to trade accounts receivable, which is included in "Other prepaid and current assets" in the condensed balance sheets.

*Forms of Variable Consideration*

*Rebates and Chargebacks:* The Company estimates reductions to product sales for Public Health Service Institutions, such as Medicaid, Medicare and Veterans' Administration ("VA") programs, as well as certain other qualifying federal and state government programs, and other group purchasing organizations. The Company estimates these reductions based upon the Company's contracts with government agencies and other organizations, statutorily defined discounts and estimated payor mix. These organizations purchase directly from the Company's wholesalers at a discount and the wholesalers charge the Company back the difference between the wholesaler price and the discounted price. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter. The Company's reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

*Co-pay assistance:* Eligible patients who have commercial insurance may receive assistance from the Company to reduce the patient's out of pocket costs. The Company will buy down the difference between the amount of the eligible patient's co-pay when the drug is purchased at the pharmacy at a determined price. Liabilities for co-pay assistance are calculated by actual program participation from third-party administrators.

*Distribution Fees:* The Company has written contracts with its customers that include terms for distribution fees and costs for inventory management. The Company estimates and records distribution fees due to its customers based on gross sales.

*Product Returns:* The Company generally offers a right of return based on the product's expiration date and certain spoilage and damaged instances. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of product sales in the period the related product sales is recognized. The Company's estimates for expected returns are based primarily on an ongoing analysis of sales information and visibility into the inventory remaining in the distribution channel.

*Discounts:* The Company provides product discounts, such as prompt pay discounts, to its customers. The Company estimates cash discounts based on terms in negotiated contracts and the Company's expectations regarding future payment patterns.

### **Recently Implemented Accounting Pronouncements**

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13 which requires financial instruments to be recognized at an estimate of current expected credit losses. As part of the ASU, financial assets measured at amortized cost will be presented at the net amount expected to be collected. In addition, companies will recognize an allowance for credit losses on available-for-sale investments rather than reducing the amortized cost in an other-than-temporary impairment. The Company has chosen the practical expedient to exclude accrued interest from both the fair value and the amortized cost basis of available-for-sale debt securities in identifying and measuring an impairment. The Company adopted the standard on January 1, 2020. The adoption of this standard did not have a material impact on the Company's balance sheets, statements of operations or statements of cash flows.

In August 2018, the FASB issued ASU 2018-15 which includes provisions to clarify customer's accounting for implementation costs incurred in a cloud computing arrangement. Under the updated guidance, a customer in a cloud computing arrangement that is a service contract should follow the internal-use software guidance to determine how to account for costs incurred in implementation. The updated guidance also requires certain classification on the balance sheets, statements of operations and statements of cash flows as well as additional quantitative and qualitative disclosures. The Company adopted the standard effective January 1, 2020 and has chosen to adopt the standard prospectively. Implementation costs for cloud computing arrangements are capitalized in "Other prepaid and current assets" on the Company's balance sheets. The adoption of this standard did not have a material impact to the Company's balance sheets, statements of operations or statements of cash flows.

There have been no other material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

### **3. Collaborations with Third Parties**

#### **DSE Agreement Terms**

On January 2, 2019, the Company entered into a license and collaboration agreement with DSE. Pursuant to the agreement, the Company granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablets in the European Economic Area and Switzerland ("DSE Territory"). DSE will be responsible for commercialization in the DSE Territory. The Company remains responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory.

Pursuant to the agreement, the consideration consists of a \$150.0 million upfront cash payment as well as \$150.0 million cash payment to the Company upon first commercial sales in the DSE Territory. The Company also is responsible to supply DSE with certain manufacturing supply of the API or bulk tablets. The Company is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the marketing authorisation in the European Union for the CV risk reduction label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments related to total net sales achievements for DSE in the DSE Territory. Finally, the Company will receive tiered fifteen percent (15%) to twenty-five percent (25%) royalties on net DSE Territory sales.

The agreement calls for both parties to participate in a Joint Collaboration Committee (the "DSE JCC"). The DSE JCC is comprised of executive management from each company and the Company will lead in all aspects related to development and DSE will lead in all aspects related to commercialization in the DSE Territory.

### *Agreement Terms Amendment*

On June 18, 2020, the Company entered into an amendment to the license and collaboration agreement with DSE, dated as of January 2, 2019. In June, the Company completed the transfer of the MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid the Company the second \$150.0 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU, as previously agreed. Additionally, the Company and DSE have agreed to expand the DSE Territory, or the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining regulatory approval for such products in Turkey.

### *Collaboration Revenue*

The Company considered the guidance under ASC 606 and concluded that the agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$150.0 million should be included in the transaction price and related to the following performance obligations under the agreement: 1) the license to the Company's intellectual property and 2) the obligation to provide ongoing regulatory and development activities. The Company used the adjusted market assessment approach in determining the standalone selling price of the Company's intellectual property and the expected cost plus margin approach in determining the standalone selling price of the Company's obligation to provide ongoing regulatory and development activities. In the three and six months ended June 30, 2019, the Company recognized \$1.0 million and \$146.4 million of collaboration revenue, respectively. In the three and six months ended June 30, 2020, the Company recognized approximately \$0.7 million and \$1.6 million, respectively, related to the on-going performance obligation for the ongoing regulatory efforts related to the MAA in the DSE Territory, which was transferred to DSE in June 2020.

In addition, in the three and six months ended June 30, 2020, the Company recognized the \$150.0 million milestone as collaboration revenue based on the successful transfer of the NUSTENDI MAA. In the three and six months ended June 30, 2020, the Company recognized collaboration revenue of \$1.0 million related to the sales of bulk tablets of NILEMDO and NUSTENDI to DSE pursuant to the Supply Agreement that was executed with DSE.

All remaining future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606 due to the fact that such amounts hinge on development activities, regulatory approvals and sales-based milestones. Additionally, the Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

### **Otsuka Agreement Terms**

On April 17, 2020, the Company entered into the Otsuka Agreement with Otsuka. Pursuant to the Otsuka Agreement, the Company granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan.

Pursuant to the agreement, the consideration consists of a \$60.0 million upfront cash payment and the Company will be eligible to receive additional payments of up to \$450.0 million if certain regulatory and commercial milestones are achieved by Otsuka. The potential future milestone payments include up to \$20.0 million upon first JNDA submissions in the Otsuka Territory, up to \$70.0 million upon the first NHI Price Listing for NEXLETOL in the Otsuka Territory, and up to \$50.0 million upon the achievement of the primary major adverse cardiovascular events ("MACE") in the CLEAR Outcomes study and the CV risk reduction rate on the U.S. label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments up to \$310.0 million related to total net sales achievements for Otsuka in Japan. Finally, the Company will receive tiered fifteen percent (15%) to thirty percent (30%) royalties on net sales in Japan.

The agreement calls for both parties to participate in a Joint Collaboration Committee (the "Otsuka JCC"). The Otsuka JCC is comprised of executive management from each company and Otsuka will lead in all aspects related to development and commercialization in the Otsuka Territory.

### Collaboration Revenue

The Company considered the guidance under ASC 606 and concluded that the agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$60.0 million should be included in the transaction price and related to the performance obligation under the agreement to the license to the Company's intellectual property. In the three and six months ended June 30, 2020, the Company recognized \$60.0 million of collaboration revenue related to the \$60.0 million upfront payment.

All future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606 due to the fact that such amounts hinge on development activities, regulatory approvals and sales-based milestones. Additionally, the Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

The Company has not yet recognized any revenue for milestone payments as the related regulatory and commercial milestones have not yet been achieved.

### 4. Inventories

Inventories as of June 30, 2020 and December 31, 2019 consist of the following (in thousands):

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Raw materials	\$ 4,961	\$ —
Work in process	2,869	—
Finished goods	418	—
	<u>\$ 8,248</u>	<u>\$ —</u>

The Company has entered into a contract manufacturing agreement with a third party commercial manufacturing organization for the production of certain inventory supplies of NEXLETOL and NEXLIZET. The agreement has an initial term of three years and will renew automatically for successive periods of one year each unless terminated by either party. Under the agreement the Company is obligated to purchase minimum order commitments on a rolling twelve-month period for the batches of inventory supplies produced.

### 5. Commitments and Contingencies

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that the Company and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving the Company's lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, the Company filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted the Company's motion to dismiss with prejudice and entered judgment in the Company's favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, the Company filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit denied the Company's petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, the Company filed an answer to the amended complaint, and on March 28, 2019, the Company filed its amended answer to the amended complaint. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

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On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015, regarding the Company’s lead product candidate’s path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. On February 8, 2019, the Company and defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit, and the Company filed a reply brief on May 15, 2019. On November 6, 2019, the court held a hearing on the motion to dismiss. On February 13, 2020, the court granted the motion to dismiss with prejudice and entered judgment in the Company’s favor. On March 16, 2020, the plaintiff filed a notice of appeal to the Supreme Court of Delaware. On June 1, 2020, the plaintiff filed his opening brief on appeal to the Supreme Court of Delaware. On July 1, 2020, the Company and the defendants filed an answering brief. The lawsuit seeks, among other things, any damages sustained by the Company as a result of the defendants’ alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, restitution from the defendants, and attorneys’ fees and costs. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

There have been no other material changes to the Company’s contractual obligations and commitments and contingencies outside the ordinary course of business from those previously disclosed in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 other than the Revenue Interest Purchase Agreement disclosed in Note 8 “Liability Related to the Revenue Interest Purchase Agreement.”

**6. Investments**

The following table summarizes the Company’s cash equivalents and short-term investments:

	June 30, 2020			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
	(in thousands)			
<b>Cash equivalents:</b>				
Money market funds	\$287,632	\$ —	\$ —	\$ 287,632
<b>Short-term investments:</b>				
Commercial paper	2,247	—	—	2,247
<b>Total</b>	<b>\$289,879</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 289,879</b>
	December 31, 2019			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
	(in thousands)			
<b>Cash equivalents:</b>				
Money market funds	\$ 20,970	\$ —	\$ —	\$ 20,970
U.S. treasury notes	2,497	—	—	2,497
Commercial paper	4,494	—	—	4,494
<b>Short-term investments:</b>				
Certificates of deposit	245	—	—	245
U.S treasury notes	29,155	23	—	29,178
Commercial paper	5,228	—	—	5,228
<b>Total</b>	<b>\$ 62,589</b>	<b>\$ 23</b>	<b>\$ —</b>	<b>\$ 62,612</b>

At June 30, 2020, remaining contractual maturities of investments classified as current on the balance sheets were less than 12 months.

During the three and six months ended June 30, 2020, other income, net in the statements of operations includes interest income on investments of \$0.1 million and \$0.5 million, respectively, and income for the accretion of premiums and discounts on investments of less than \$0.1 million and \$0.1 million, respectively. During the three and six months ended June 30, 2019, other income, net in the statements of operations includes interest income on investments of \$1.0 million and \$1.4 million, respectively, and income for the accretion of premiums and discounts on investments of less than \$0.1 million and \$0.1 million, respectively.

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive income (loss) to other income in the statements of operations during the three and six months ended June 30, 2020 and 2019.

In the three and six months ended June 30, 2020, there were no allowances for credit losses and all unrealized gains (losses) for available-for-sale securities were recognized in accumulated other comprehensive income. As of June 30, 2020, the Company had no accrued interest receivables.

## 7. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value is defined as “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.” Fair value measurements are defined on a three level hierarchy:

- Level 1 inputs: Quoted prices for identical assets or liabilities in active markets;
- Level 2 inputs: Observable inputs other than Level 1 prices, such as quoted market prices for similar assets or liabilities or other inputs that are observable or can be corroborated by market data; and
- Level 3 inputs: Unobservable inputs that are supported by little or no market activity and require the reporting entity to develop assumptions that market participants would use when pricing the asset or liability.

The following table presents the Company’s financial assets that have been measured at fair value on a recurring basis:

Description	Total	Level 1	Level 2	Level 3
		(in thousands)		
<b>June 30, 2020</b>				
Assets:				
Money market funds	\$ 287,632	\$ 287,632	\$ —	\$ —
Investments:				
Commercial paper	2,247	—	2,247	—
Total assets at fair value	\$ 289,879	\$ 287,632	\$ 2,247	\$ —
<b>December 31, 2019</b>				
Assets:				
Money market funds	\$ 20,970	\$ 20,970	\$ —	\$ —
Investments:				
Certificates of deposit	245	245	—	—
U.S. treasury notes	31,675	31,675	—	—
Commercial paper	9,722	—	9,722	—
Total assets at fair value	\$ 62,612	\$ 52,890	\$ 9,722	\$ —

There were no transfers between Levels 1, 2 or 3 during the three and six months ended June 30, 2020 and 2019.

## 8. Liability Related to the Revenue Interest Purchase Agreement

On June 26, 2019, the Company entered into a RIPA with Oberland, as agent for purchasers party thereto (the “Purchasers”), and the Purchasers named therein, to obtain financing in respect to the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets and other working capital needs. Pursuant to the RIPA, the Company received \$125.0 million at closing, less certain issuance costs. The Company is also entitled to receive up to approximately \$75.0 million in



subsequent installments subject to the terms and conditions set forth in the RIPA: (i) \$25.0 million upon certain regulatory approval of its product candidates and (ii) \$50.0 million, at the Company's option, upon reaching \$100.0 million trailing worldwide six-month net sales any time prior to December 31, 2021 (the "Third Payment"). In March 2020, the Company received \$25.0 million from Oberland upon receiving regulatory approval of NEXLETOL.

As consideration for such payments, the Purchasers have a right to receive certain revenue interests (the "Revenue Interests") from the Company based upon net sales of the Company's certain products which will be tiered payments initially ranging from 2.5% to 7.5% of the Company's net sales in the covered territory (the "Covered Territory"); provided that (a) if annual net sales equal or exceed \$350.0 million by December 31, 2021 (the "Sales Threshold"), the initially tiered revenue interest rate will be decreased to a single rate of 2.5% of the Company's net sales in the Covered Territory, beginning on January 1, 2022, and (b) if annual net sales equal or exceed the Sales Threshold and if the Purchasers receive 100% of their invested capital by December 31, 2024, the revenue interest rate will be decreased to a single rate of 0.4% of the Company's net sales in the Covered Territory beginning on January 1, 2025. If the Third Payment is drawn down by the Company, the applicable royalty rates will increase by one-third. The Covered Territory is the United States, but is subject to expand to include the world-wide net sales if the Company's annual U.S. net sales are less than \$350.0 million for the year ended December 31, 2021. The U.S. net sales milestone thresholds are not to be taken as financial guidance. The Purchasers' rights to receive the Revenue Interests shall terminate on the date on which the Purchasers have received Revenue Interests payments of 195% of the then aggregate purchase price (the "Cumulative Purchaser Payments") paid to the Company, unless the RIPA is terminated earlier.

Under the RIPA, the Company has an option (the "Call Option") to terminate the RIPA and repurchase future Revenue Interests at any time upon advance written notice. Additionally, the Purchasers have an option (the "Put Option") to terminate the RIPA and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect or a change of control. If the Put Option is exercised prior to the first anniversary of the closing date by the Purchasers (except pursuant to a change of control), the required repurchase price will be 120% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests). In all other cases, if the Put Option or the Call Option are exercised, the required repurchase price will be 175% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests), if such option is exercised prior to the third anniversary of the closing date, and 195% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests), if such option is exercised thereafter.

In addition, the RIPA contains various representations and warranties, information rights, non-financial covenants, indemnification obligations and other provisions that are customary for a transaction of this nature.

In connection with the arrangement, as of June 30, 2020, the Company has recorded a liability, referred to as the "Revenue interest liability" in the condensed balance sheets, of \$166.3 million, net of \$0.5 million of capitalized issuance costs in connection with the RIPA. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method.

A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded approximately \$4.6 million and \$8.8 million in interest expense related to this arrangement for the three and six months ended June 30, 2020, respectively.

The Company received \$125.0 million in exchange for entering into the RIPA and \$25.0 million in March 2020 upon receiving regulatory approval of NEXLETOL. The effective annual imputed interest rate is 10.1%. The Company incurred \$0.6 million of issuance costs in connection with the RIPA, which will be amortized to interest expense over the estimated term of the RIPA. Payments made to Oberland as a result of the Company's net sales will reduce the revenue interest liability.



The following table summarizes the revenue interest liability activity during the six months ended June 30, 2020:

	(in thousands)
Revenue interest liability at December 31, 2019	\$ 132,544
Oberland funding for regulatory approval of NEXLETOL	25,000
Interest expense recognized	8,811
Revenue Interests payments	(64)
Revenue interest liability at June 30, 2020	<u>\$ 166,291</u>

## 9. Other Accrued Liabilities

Other accrued liabilities consist of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued compensation	\$ 10,868	\$ 7,818
Accrued professional fees	5,864	3,842
Accrued inventory	1,771	—
Accrued other	3,405	211
Total other accrued liabilities	<u>\$ 21,908</u>	<u>\$ 11,871</u>

## 10. Stock Compensation

### *Employee Stock Purchase Plan*

In April 2020, the board of directors approved the Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan (the "ESPP") which was approved by the Company's shareholders on May 28, 2020. The ESPP allows eligible employees to authorize payroll deductions of up to 10% of their base salary or wages up to \$25,000 annually to be applied toward the purchase of shares of the Company's common stock on the last trading day of the offering period. Participating employees will purchase shares of the Company's common stock at a discount of up to 15% on the lesser of the closing price of the Company's common stock on the NASDAQ Global Select Market (i) on the first trading day of the offering period or (ii) the last day of any offering period. Offering periods under the ESPP will generally be in six month increments, commencing on September 1 and March 1 of each calendar year with the administrator having the right to establish different offering periods.

The following table summarizes the activity relating to the Company's options to purchase common stock for the six months ended June 30, 2020:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value  (in thousands)
Outstanding at December 31, 2019	4,677,929	\$ 39.31	6.82	\$ 109,054
Granted	234,940	\$ 61.14		
Forfeited or expired	(134,945)	\$ 56.38		
Exercised	(200,157)	\$ 23.74		
Outstanding at June 30, 2020	<u>4,577,767</u>	\$ 40.61	6.10	\$ 72,396

The following table summarizes information about the Company's stock option plan as of June 30, 2020:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value  (in thousands)
Vested and expected to vest at June 30, 2020	4,577,767	\$ 40.61	6.10	\$ 72,396
Exercisable at June 30, 2020	3,195,452	\$ 35.88	5.12	\$ 65,786

Stock-based compensation related to stock options was \$5.5 million and \$11.1 million for the three and six months ended June 30, 2020, respectively, including \$0.3 million and \$0.5 million for the three and six months ended June 30, 2020, respectively, that were capitalized into inventory, and \$6.2 million and \$12.6 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, there was \$44.0 million of unrecognized stock-based compensation expense related to unvested options, which will be recognized over a weighted-average period of 2.4 years.

The following table summarizes the activity relating to the Company's RSUs for the six months ended June 30, 2020:

	Number of RSUs	Weighted-Average Fair Value Per Share
Outstanding and unvested at December 31, 2019	245,966	\$ 44.45
Granted	322,167	\$ 52.82
Forfeited	(28,921)	\$ 44.70
Vested	(53,587)	\$ 51.98
Outstanding and unvested at June 30, 2020	485,625	\$ 49.16

Stock-based compensation related to RSUs was approximately \$1.8 million and \$3.3 million for the three and six months ended June 30, 2020, respectively, including \$0.1 million and \$0.1 million for the three and six months ended June 30, 2020, respectively, that were capitalized into inventory, and \$0.4 million and \$0.6 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, there was \$21.5 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of 3.2 years.

## 11. Leases

The Company has operating leases primarily related to the Company's principal executive office, automobile leases and other IT related equipment. The lease for the principal executive office has a lease term of 5 years and the automobile leases and IT equipment leases primarily have a term of 3 years. During the six months ended June 30, 2020, the right of use operating lease assets and operating lease liabilities recognized on the condensed balance sheet increased by \$4.6 million and \$4.6 million from December 31, 2019, respectively, due to the addition of automobile leases and IT equipment associated with the onboarding of the Company's commercial salesforce to support the commercialization of NEXLETOL and NEXLIZET. During the three and six months ended June 30, 2020, the Company recognized \$0.6 million and \$0.8 million, respectively, of operating lease costs, recognized on the condensed statements of operations, and paid cash for the amounts included in the measurement of lease liabilities of \$0.6 million and \$0.8 million, respectively, which were included in operating cash flows on the condensed statements of cash flows. During the three and six months ended June 30, 2019, the Company recognized less than \$0.1 million and \$0.1 million, respectively, of operating lease costs, recognized on the condensed statements of operations, and paid cash for the amounts included in the measurement of lease liabilities of less than \$0.1 million and \$0.1 million, respectively, which were included in operating cash flows on the condensed statements of cash flows. At June 30, 2020, the weighted-average remaining lease term of operating leases was 2.7 years and the weighted average discount rate was 3.6%. There were no right-of-use assets obtained in exchange for lease obligations in the six months ended June 30, 2020 or 2019. The Company had no additional operating and finance leases that have not yet commenced as of June 30, 2020 or 2019.

The following table summarizes the Company's future maturities of operating lease liabilities as of June 30, 2020:

	(in thousands)
2020 (remaining)	\$ 1,209
2021	2,380
2022	2,333
2023	584
2024	—
Total lease payments	6,506
Less imputed interest	307
Total	<u>\$ 6,199</u>

## 12. Income Taxes

There was no provision for income taxes for the three and six months ended June 30, 2020 and 2019, because the Company has incurred annual operating losses since inception. At June 30, 2020, the Company continues to conclude that it is not more likely than not that the Company will realize the benefit of its deferred tax assets due to its history of losses. Accordingly, a full valuation allowance has been applied against the net deferred tax assets.

## 13. Net Income (Loss) Per Common Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net income per share is computed by dividing net income by the weighted-average number of common stock equivalents outstanding for the period, including shares that potentially could be dilutive if they were exercised during the period, determined using the treasury-stock method. For purposes of this calculation, stock options and unvested RSUs are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table summarizes the calculation of basic and diluted net income (loss) per share:

	For the three months ended,		For the six months ended,	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Net income (loss) (in thousands)	\$ 124,611	\$ (54,221)	\$ 46,362	\$ 33,158
Weighted average common shares outstanding - basic	27,665,728	26,968,818	27,592,479	26,906,149
Effect of dilutive shares:				
Warrants for common stock	—	—	—	4,230
Common shares under option	1,139,280	—	1,291,353	1,607,093
Unvested RSUs	49,437	—	64,226	543
Dilutive shares	1,188,717	—	1,355,579	1,611,866
Weighted average common shares outstanding - diluted	<u>28,854,445</u>	<u>26,968,818</u>	<u>28,948,058</u>	<u>28,518,015</u>
Net income (loss) per common share - basic	\$ 4.50	\$ (2.01)	\$ 1.68	\$ 1.23
Net income (loss) per common share - diluted	\$ 4.32	\$ (2.01)	\$ 1.60	\$ 1.16

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The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net income (loss) per share due to their anti-dilutive effect:

	<u>For the three months ended,</u>		<u>For the six months ended,</u>	
	<u>June 30,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>	<u>June 30,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>
Common shares under option	2,427,074	5,322,686	2,391,374	2,511,692
Unvested RSUs	295,423	83,778	190,565	77,653
Total potential dilutive shares	<u>2,722,497</u>	<u>5,406,464</u>	<u>2,581,939</u>	<u>2,589,345</u>

#### 14. Statements of Cash Flows

The following table provides a reconciliation of cash and cash equivalents and restricted cash presented on the condensed balance sheets to the same amounts presented on the condensed statements of cash flows on June 30, 2020 and 2019 and December 31, 2019 and 2018 (in thousands):

	<u>June 30,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash and cash equivalents	\$ 298,489	\$ 274,344	\$ 166,130	\$ 36,973
Restricted cash	—	928	928	—
Total cash and cash equivalents and restricted cash shown on the condensed statements of cash flows	<u>\$ 298,489</u>	<u>\$ 275,272</u>	<u>\$ 167,058</u>	<u>\$ 36,973</u>

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our annual report on Form 10-K for the fiscal year ended December 31, 2019 and other filings that we make with the Securities and Exchange Commission.

### Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are based on our management's belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events, including our clinical development and commercialization plans, or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, including in relation to the clinical development, commercialization plans, or approval of expanded indications for bempedoic acid and the bempedoic acid / ezetimibe combination tablets to be materially different from any future results, performance or achievements, including in relation to the clinical development, commercialization plans, or approval of expanded indications for bempedoic acid and the bempedoic acid / ezetimibe combination tablets, and the impact of COVID-19 on our business, clinical activities and commercial development plans, expressed or implied by these forward-looking statements.

Forward-looking statements are often identified by the use of words such as, but not limited to, "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other similar terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and that could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those referred to or discussed in or incorporated by reference into the section titled "Risk Factors" included in Item 1A of Part II of this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this report represent our views as of the date of this quarterly report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

We use the terms "we," "us," "our," or the "Company" in this report to refer to Esperion Therapeutics, Inc.

### Overview

#### Corporate Overview

We are the Lipid Management Company, a pharmaceutical company focused on developing and commercializing affordable, oral, once-daily, non-statin medicines for the treatment of patients with elevated low density lipoprotein cholesterol, or LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering medicines that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. NEXLETOL® (bempedoic acid) and NEXLIZET™ (bempedoic acid and ezetimibe) tablets are the first, oral, once-daily, non-statin LDL-C lowering medicines approved in the U.S. in nearly 20 years for patients with atherosclerotic cardiovascular disease, or ASCVD, or heterozygous familial hypercholesterolemia, or HeFH.

On February 21, 2020, we announced that the U.S. Food and Drug Administration, or FDA, approved NEXLETOL 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 effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients. NEXLETOL became commercially available on March 30, 2020.

On February 26, 2020, we announced that the FDA approved NEXLIZET 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 effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering fixed combination drug product ever approved. NEXLIZET became commercially available on June 4, 2020.

On January 31, 2020, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, adopted a positive opinion for the Marketing Authorisation Applications, or MAAs, of both bempedoic acid and the bempedoic acid / ezetimibe combination tablets, recommending approval for the treatment of hypercholesterolemia and mixed dyslipidemia. On April 6, 2020, we announced that the European Commission, or EC, approved NILEMDO™ (bempedoic acid) and NUSTENDI™ (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded products names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. NILEMDO is the first, oral, non-statin, LDL-C lowering medicines approved in Europe in almost two decades for indicated patients, and NUSTENDI is the first non-statin, LDL-C lowering combination medicine ever approved in Europe.

On April 17, 2020, we entered into a license and collaboration agreement, or the Otsuka Agreement, with Otsuka Pharmaceutical Co., Ltd., or Otsuka. Pursuant to the Otsuka Agreement, we granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan. We estimate this amount to total up to \$100 million over the next few years. We received an upfront cash payment of \$60 million in April 2020 and will receive up to an additional \$450 million in total development and sales milestones. We will also receive tiered royalties ranging from 15 percent to 30 percent on net sales in Japan.

On June 18, 2020, we entered into an amendment to the license and collaboration agreement, or LCA Amendment, with Daiichi Sankyo Europe GmbH, or DSE, dated as of January 2, 2019. In June 2020, we completed the transfer of the MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid us the second \$150 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU, which is anticipated later this year. Prior to the execution of the LCA Amendment, the milestone payment was due upon the first commercial sale in Europe, which is anticipated later this year. Additionally, we and DSE have agreed to expand the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining Regulatory Approval for such product in Turkey.

We were incorporated in Delaware in January 2008 and commenced our operations in April 2008. Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid and the bempedoic acid / ezetimibe combination tablets. In February 2020, the FDA approved NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020. We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock, the incurrence of indebtedness, through collaborations with third parties and revenue interest purchase agreements, and we have incurred losses in each year since our inception.

During the three and six months ended June 30, 2020, our net income was \$124.6 million and \$46.4 million, respectively, primarily due to revenue generated from our collaboration agreements with DSE and Otsuka. In the three and six months ended June 30, 2019, the collaboration agreement with DSE provided \$1.0 million and \$146.4 million in revenue, respectively, driving a net loss of \$54.2 million in the three months ended June 30, 2019 and net income of \$33.2 million in the six months ended June 30, 2019. All of our prior net losses resulted from costs incurred in connection with research and development programs and general and administrative costs associated with our operations. We expect to incur significant expenses and operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

- commercializing NEXLETOL and NEXLIZET tablets in the U.S.; and
- completing the clinical development activities for the CLEAR global cardiovascular outcomes trial, or CVOT.

Accordingly, we may need additional financing to support our continuing operations and further the development of our products. We may seek to fund our operations and further development activities through collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings, permitted public or private equity offerings or through other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy or continue operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

### **Product Overview**

NEXLETOL is a first-in-class ATP Citrate Lyase, or ACL, inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. NEXLETOL 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.

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. Phase 3 data demonstrated NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. NEXLIZET 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.

NILEMDO is a first-in-class ACL inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. NILEMDO was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin or statin with other lipid-lowering therapies in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies as an adjunct to diet in adult patients who are statin-intolerant, or for whom a statin is contraindicated.

NUSTENDI contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. NUSTENDI was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or as an adjunct to diet in adult patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

During the six months ended June 30, 2020, we incurred \$33.6 million in expenses related to our CLEAR Outcomes CVOT and other ongoing clinical studies.

During the six months ended June 30, 2019, we incurred \$56.9 million in expenses related to our CLEAR Outcomes CVOT, our open-label extension study, and our 1002FDC-058 study.

### **Ongoing Clinical Studies**

#### *Global Cardiovascular Outcomes Trial—CLEAR Outcomes*

CLEAR Outcomes is a Phase 3, event driven, randomized, multicenter, double-blind, placebo-controlled clinical study designed to evaluate whether treatment of bempedoic acid reduces the risk of cardiovascular events in patients with statin intolerance who have cardiovascular disease or are at high risk for cardiovascular disease. The primary endpoint of the study is the effect of bempedoic acid on major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as "four-component MACE"). CLEAR Outcomes is designed to provide 90 percent power to detect an approximately 15 percent relative risk reduction in the primary endpoint in the bempedoic acid treatment group as compared to the placebo group and is expected to complete with a minimum of 1,620 patients experiencing the primary endpoint.

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The study over-enrolled with 14,032 patients with hypercholesterolemia and high cardiovascular disease risk at over 1,400 sites in 32 countries. Eligible patients at high risk (LDL-C >100 mg/dL in primary prevention) for cardiovascular disease or with cardiovascular disease (LDL-C between 100 mg/dL to 190 mg/dL in secondary prevention) and who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered statin averse, were randomized to receive bempedoic acid 180 mg once-daily or placebo. The expected average baseline LDL-C level in all patients is between 135 mg/dL and 140 mg/dL.

CLEAR Outcomes will conclude once the predetermined number of MACE endpoints occur. We initiated CLEAR Outcomes in December 2016 and completed enrollment in August 2019. The expected average treatment duration will be 3.75 years with a minimum treatment duration of approximately 2.25 years. Based on estimated cardiovascular event rates, we expect to meet the target number of events in the second half of 2022. The study is intended to support our submissions for a CV risk reduction indication in the U.S., Europe and other territories.

### ***The COVID-19 Pandemic***

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, or COVID-19, as a pandemic, which continues to spread throughout the United States and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19. We are monitoring the global outbreak and spread of COVID-19 and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a work-from-home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, the patients we serve and other business partners in light of COVID-19. Given the fluidity of the COVID-19 pandemic however, we do not yet know the full extent of the potential impact of COVID-19 on our business operations. The ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, among others. Accordingly, we are unable to reliably estimate the extent to which our business, financial condition and results of operations will or has been affected, including any impacts on product sales or research and development expense. To date, we have not experienced any interruption of our supply of drug products needed to support our ongoing clinical study and product sales. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19. We will continue to work diligently with our partners and stakeholders to continue supporting patient access to our approved medicines, advancing our product under regulatory review as well as in our clinical studies to the extent safe to do so for patients, caregivers and healthcare practitioners, and ensuring the continuity of our manufacturing and supply chain. For additional information related to the potential impact of COVID-19 on our business, please read Part II-Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q.

### **Financial Operations Overview**

#### ***Product sales, net***

Product sales, net is related to our sales of NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020

#### ***Collaboration revenue***

Collaboration revenue is related to our collaboration agreements with DSE and Otsuka. Collaboration revenue in the three and six months ended June 30, 2020, was primarily related to the \$150.0 million milestone from the MAA transfer to DSE and the \$60.0 million from the upfront payment with Otsuka. In the three and six months ended June 30, 2019, collaboration revenue was primarily related to the initial recognition of the \$150.0 million upfront payment from our collaboration agreement with DSE.



### ***Cost of goods sold***

Cost of goods sold is related to our net product sales of NEXLETOL and NEXLIZET and the cost of goods sold from our supply agreements with collaboration partners. Prior to the FDA approval of NEXLETOL and NEXLIZET, expenses associated with the manufacturing of our products were recorded as research and development expense.

### ***Research and Development Expenses***

Since our inception, we have focused our resources on our research and development activities, including conducting nonclinical, preclinical and clinical studies. Our research and development expenses consist primarily of costs incurred in connection with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets, which include:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical and clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials and commercial product manufacturing supply prior to product approval, including the procurement of ezetimibe in our continued development of our bempedoic acid / ezetimibe combination tablet;
- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;
- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. To date, substantially all of our research and development work has been related to bempedoic acid and the bempedoic acid / ezetimibe combination tablets. Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies. We do not allocate acquiring and manufacturing clinical study materials, salaries, stock-based compensation, employee benefits or other indirect costs related to our research and development function to specific programs.

We will continue to incur research and development expenses in the foreseeable future as they relate to our ongoing CLEAR Outcomes CVOT and any other development programs or additional indications we choose to pursue. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablets. The duration, costs and timing associated with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval outside the U.S. and Europe. For example, if a regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development or post-commercialization clinical studies of bempedoic acid or the bempedoic acid / ezetimibe combination tablets, we could be required to expend significant additional financial resources and time on the completion of clinical development or post-commercialization clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablets.

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses primarily consist of salaries and related costs for personnel, including stock-based compensation, associated with our sales, executive, accounting and finance, commercial, operational and other administrative functions. Other general and administrative expenses include selling expenses, facility-related costs, communication expenses and professional fees for legal, patent prosecution, protection and review, consulting and accounting services.

We anticipate that our selling, general and administrative expenses will increase in the future in connection with the commercialization of NEXLETOL and NEXLIZET, increases in our headcount, expansion of our information technology infrastructure, and increased expenses associated with being a public company and complying with exchange listing and Securities and Exchange Commission, or SEC, requirements. These increases will likely include higher legal, compliance, accounting and investor and public relations expenses.

**Interest Expense**

Interest expense is related to our Revenue Interest Purchase Agreement, or RIPA, with Eiger III SA LLC, or Oberland, an affiliate of Oberland Capital.

**Other Income, Net**

Other income, net, primarily relates to interest income and the accretion or amortization of premiums and discounts earned on our cash, cash equivalents and investment securities.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis, including those related to our collaboration agreements and revenue interest liability. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no other material changes to the significant accounting policies previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. As we continue through fiscal year 2020, we expect that net product sales will become a critical accounting estimate.

**Results of Operations**

**Comparison of the Three Months Ended June 30, 2020 and 2019**

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019:

	<b>Three Months Ended June 30,</b>		
	<b>2020</b>	<b>2019</b>	<b>Change</b>
	<b>(unaudited, in thousands)</b>		
<b>Revenue:</b>			
Product sales, net	\$ 609	\$ —	\$ 609
Collaboration revenue	211,627	982	210,645
<b>Operating Expenses:</b>			
Cost of goods sold	398	—	398
Research and development	34,987	42,788	(7,801)
Selling, general and administrative	47,681	13,492	34,189
<b>Income (loss) from operations</b>	<b>129,170</b>	<b>(55,298)</b>	<b>184,468</b>
Interest expense	(4,640)	—	(4,640)
Other income, net	81	1,077	(996)
<b>Net income (loss)</b>	<b>\$ 124,611</b>	<b>\$ (54,221)</b>	<b>\$ 178,832</b>

**Product sales, net**

Product sales, net for the three months ended June 30, 2020 was \$0.6 million relating to our sales of NEXLETOL and NEXLIZET. NEXLIZET was commercially available in the U.S. on June 4, 2020.

***Collaboration Revenue***

Collaboration revenue recognized for the three months ended June 30, 2020 was \$211.6 million compared to \$1.0 million for the three months ended June 30, 2019, an increase of \$210.6 million. The increase in collaboration revenue was primarily related to the \$60.0 million upfront payment from the collaboration with Otsuka and \$150.0 million of collaboration revenue from DSE related to the MAA transfer milestone.

***Cost of goods sold***

Cost of goods sold for the three months ended June 30, 2020 was \$0.4 million, primarily related to cost of goods sold from our supply agreements with collaboration partners and our net product sales of NEXLETOL and NEXLIZET. NEXLIZET was commercially available in the U.S. on June 4, 2020.

***Research and development expenses***

Research and development expenses for the three months ended June 30, 2020, were \$35.0 million, compared to \$42.8 million for the three months ended June 30, 2019, a decrease of \$7.8 million. The decrease in research and development expenses was primarily attributable to a decline in costs related to the completion of enrollment of our CLEAR CVOT, which was fully enrolled during the third quarter of 2019.

***Selling, general and administrative expenses***

Selling, general and administrative expenses for the three months ended June 30, 2020, were \$47.7 million, compared to \$13.5 million for the three months ended June 30, 2019, an increase of \$34.2 million. The increase in selling, general and administrative expenses was primarily attributable to costs to support the commercialization of NEXLETOL and NEXLIZET in the U.S., increases in our headcount resulting from the buildout of our approximately 300-member customer-facing team, stock-based compensation expense, and other costs to support our growth.

***Interest Expense***

Interest expense for the three months ended June 30, 2020, was \$4.6 million. Interest expense was related to our RIPA with Oberland, which was entered into on June 26, 2019.

***Other income, net***

Other income, net for the three months ended June 30, 2020, was \$0.1 million, compared to \$1.1 million for the three months ended June 30, 2019, a decrease of \$1.0 million. The decrease is related to lower interest income on our investments due to lower interest rates.

**Comparison of the Six Months Ended June 30, 2020 and 2019**

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019:

	<b>Six Months Ended June 30,</b>		<b>Change</b>
	<b>2020</b>	<b>2019</b>	
	<b>(unaudited, in thousands)</b>		
<b>Revenue:</b>			
Product sales, net	\$ 1,467	\$ —	\$ 1,467
Collaboration revenue	212,609	146,401	66,208
<b>Operating Expenses:</b>			
Cost of goods sold	429	—	429
Research and development	69,689	89,096	(19,407)
Selling, general and administrative	89,234	25,674	63,560
<b>Income from operations</b>	<b>54,724</b>	<b>31,631</b>	<b>23,093</b>
Interest expense	(8,811)	—	(8,811)
Other income, net	449	1,527	(1,078)
<b>Net income</b>	<b>\$ 46,362</b>	<b>\$ 33,158</b>	<b>\$ 13,204</b>

**Product sales, net**

Product sales, net for the six months ended June 30, 2020 was \$1.5 million relating to our net product sales for NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020.

**Collaboration Revenue**

Collaboration revenue recognized from our collaboration agreements for the six months ended June 30, 2020 was \$212.6 million compared to \$146.4 million for the six months ended June 30, 2019, an increase of \$66.2 million. Revenue for the six months ended June 30, 2020 was primarily attributable to \$150.0 million for the milestone related to the MAA transfer to DSE and the \$60.0 million for the upfront payment in the Otsuka collaboration agreement signed on April 17, 2020. Revenue for the six months ended June 30, 2019 was attributable to the initial recognition of the upfront payment from our DSE collaboration agreement signed on January 2, 2019.

**Cost of goods sold**

Cost of goods sold for the six months ended June 30, 2020 was \$0.4 million, primarily related cost of goods sold from our supply agreements with collaboration partners and our net product sales of NEXLETOL and NEXLIZET.

**Research and development expenses**

Research and development expenses for the six months ended June 30, 2020, were \$69.7 million, compared to \$89.1 million for the six months ended June 30, 2019, a decrease of \$19.4 million. The decrease in research and development expenses was primarily attributable to a decline in costs related to the completion of enrollment of our CLEAR CVOT, which was fully enrolled during the third quarter of 2019, and a decline in costs related to our regulatory submission activities completed in 2019.

**Selling, general and administrative expenses**

Selling, general and administrative expenses for the six months ended June 30, 2020, were \$89.2 million, compared to \$25.7 million for the six months ended June 30, 2019, an increase of approximately \$63.5 million. The increase in selling, general and administrative expenses was primarily attributable to costs to support the commercialization of NEXLETOL and NEXLIZET in the U.S., increases in our headcount resulting from the buildout of our approximately 300-member customer-facing team, stock-based compensation expense, and other costs to support our growth.

### ***Interest Expense***

Interest expense for the six months ended June 30, 2020, was \$8.8 million. Interest expense was related to our RIPA with Oberland.

### ***Other income, net***

Other income, net for the six months ended June 30, 2020, was \$0.4 million, compared to \$1.5 million for the six months ended June 30, 2019, a decrease of \$1.1 million. The decrease is related to lower interest income on our investments due to lower interest rates.

### **Liquidity and Capital Resources**

We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock, the incurrence of indebtedness, milestone payments from collaboration agreements and revenue interest purchase agreements. Pursuant to the license and collaboration agreement with DSE signed on January 2, 2019, we received an upfront cash payment of \$150.0 million from DSE and a cash payment of \$150.0 million upon the MAA transfer in June 2020 and are eligible for substantial additional sales and regulatory milestone payments and royalties. Pursuant to the RIPA with Oberland, we received an upfront cash payment of \$124.4 million, net of issuance costs, and received an additional \$25.0 million upon regulatory approval of NEXLETOL. We are eligible for an additional \$50.0 million at our option upon reaching certain net product sales thresholds. In return, Oberland will have a right to receive revenue interests based on net product sales of our products. Pursuant to the license and collaboration agreement with Otsuka signed on April 17, 2020, we received an upfront cash payment of \$60.0 million in April 2020 and are eligible for substantial additional development and sales milestone payments and royalties. We anticipate that we will incur losses for the foreseeable future.

As of June 30, 2020, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled \$298.5 million and \$2.2 million, respectively. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade and government securities to preserve principal.

The following table summarizes the primary sources and uses of cash for the periods presented below:

	<b>Six Months Ended June 30,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Cash provided by operating activities	\$ 70,044	\$ 37,682
Cash provided by investing activities	31,699	72,412
Cash provided by financing activities	29,688	128,205
<b>Net increase in cash and cash equivalents</b>	<b>\$ 131,431</b>	<b>\$ 238,299</b>

### ***Operating Activities***

We have incurred and expect to continue to incur, significant costs related to the commercialization of NEXLETOL and NEXLIZET and related to ongoing research and development, regulatory and other clinical study costs associated with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets.

Net cash provided by operating activities totaled \$70.0 million for the six months ended June 30, 2020, consisting of the \$150.0 million milestone for the MAA transfer from our collaboration agreement with DSE, \$60.0 million from the Otsuka collaboration agreement and net product sales of NEXLETOL and NEXLIZET offset by cash used to fund the commercialization activities of NEXLETOL and NEXLIZET and the research and development costs related to bempedoic acid and the bempedoic acid / ezetimibe combination tablets, adjusted for non-cash expenses such as stock-based compensation expense, interest expense related to our RIPA with Oberland, depreciation and amortization and changes in working capital. Net cash provided by operating activities totaled \$37.7 million for the six months ended June 30, 2019, consisting of the \$150.0 million upfront payment from the DSE collaboration offset by cash used to fund the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets, adjusted for non-cash expenses such as stock-based compensation expense, depreciation and amortization and changes in working capital.

### ***Investing Activities***

Net cash provided by investing activities of \$31.7 million and \$72.4 million for the six months ended June 30, 2020 and 2019, respectively, consisted primarily of proceeds from the sale and maturities of highly liquid, interest-bearing investment-grade and government securities.

### ***Financing Activities***

Net cash provided by financing activities of \$29.7 million for the six months ended June 30, 2020 related primarily to the cash received from the RIPA with Oberland upon regulatory approval of NEXLETOL. Net cash provided by financing activities of \$128.2 million for the six months ended June 30, 2019 related primarily to the upfront cash received from the RIPA with Oberland.

### ***Plan of Operations and Funding Requirements***

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing CLEAR Outcomes CVOT and commercial launch activities associated with NEXLETOL and NEXLIZET in the U.S. Pursuant to the license and collaboration agreement with DSE, we received an upfront cash payment of \$150.0 million from DSE in the first quarter of 2019, \$150.0 million in June 2020 upon transfer to DSE of MMA for NUSTENDI and are eligible for substantial additional sales and regulatory milestone payments and royalties. Pursuant to the RIPA with Oberland, we received an upfront cash payment of \$125.0 million and received \$25.0 million upon regulatory approval of NEXLETOL. We are eligible for an additional \$50.0 million at our option upon reaching certain net product sales thresholds. In return, Oberland will have a right to receive revenue interest payments from us based on net product sales of certain of our products. Pursuant to the license and collaboration agreement with Otsuka, we received an upfront cash payment of \$60.0 million from Otsuka in April 2020 and are eligible for substantial additional development and sales milestone payments and royalties. We estimate that current cash resources and proceeds to be received in the future for product sales, under the DSE and Otsuka collaboration agreements and the RIPA with Oberland are sufficient to fund operations through the commercialization of NEXLETOL and NEXLIZET. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. We may need to secure additional cash resources to continue to fund the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets. Because of the numerous risks and uncertainties associated with the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablets and the extent to which we entered and may enter into collaborations with pharmaceutical partners regarding the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablets, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablets. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize NEXLETOL and NEXLIZET or other product candidates;
- the costs, timing and outcomes of our CLEAR Outcomes CVOT and other ongoing clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablets;
- the time and cost necessary to obtain regulatory approvals for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in other territories outside the U.S. and Europe;
- our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;
- our ability to realize the intended benefits of our existing and future collaboration and partnerships;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate U.S. substantial product sales, we expect to finance our cash needs through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings and equity offerings or other sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available and permitted under the terms of our RIPA, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners or royalty-based financing arrangements, such as the collaboration arrangements with DSE and Otsuka and the RIPA with Oberland, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. For instance, as part of the RIPA with Oberland, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products, and we have granted Oberland a senior security interest in certain of our assets. If our cash flows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. If we are unable to raise additional funds through equity or permitted debt financings or through collaborations, strategic alliances or licensing arrangements or permitted royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market bempedoic acid and the bempedoic acid / ezetimibe combination tablets that we would otherwise prefer to develop and market ourselves.

### **Contractual Obligations and Commitments**

On June 26, 2019, we entered into a RIPA with Oberland. Pursuant to the RIPA, Oberland paid us \$125.0 million at closing, less certain issuance costs, and, subject to the terms and conditions of the RIPA, we received \$25.0 million in March 2020 upon regulatory approval of NEXLETOL. We are eligible for an additional \$50.0 million at our option upon reaching certain product sales thresholds. As consideration for the payments, Oberland has the right to receive certain revenue interests from us based on the net product sales of certain products, which will be tiered payments initially ranging from 2.5% to 7.5% of our net product sales in the covered territory (as detailed in the RIPA). The initial mid-single digit repayment rate on U.S. revenue steps down to less than one percent rate upon certain revenue achievements. Esperion reacquires 100% revenue rights upon repayment completion. We recorded the proceeds from the RIPA as a liability on the condensed balance sheets and are accounting for the RIPA under the effective-interest method over the estimated life of the RIPA. Per the terms of the agreement, every \$100 million of net sales generated, less than or equal to \$250 million in an annual aggregate, would result in a repayment obligation of approximately \$7.5 million at the stated repayment rate in the first year. In the future, as net sales thresholds set forth in the agreement are met and the repayment percentage rate changes, the amount of the obligation and timing of payment is likely to change. A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. Refer to Note 8 “Liability Related to the Revenue Interest Purchase Agreement” in the Notes to the Condensed Financial Statements for further information.

We have entered into a contract manufacturing agreement with a third party commercial manufacturing organization for the production of certain inventory supplies of NEXLETOL and NEXLIZET. The agreement has an initial term of three years and will renew automatically for successive periods of one year each unless terminated by either party. Under the agreement we are obligated to purchase minimum order commitments on a rolling twelve-month period for the batches of inventory supplies produced.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

### **Off-Balance Sheet Arrangements**

We do not currently have, nor did we have during the periods presented, any off-balance sheet arrangements as defined by Securities and Exchange Commission rules.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

There have been no material changes with respect to the information appearing in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

#### **Item 4. Controls and Procedures**

##### ***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

##### ***Changes in Internal Control over Financial Reporting***

During the three months ended June 30, 2020, in connection with the approval of NEXLETOL and NEXLIZET and commercial availability of NEXLETOL, we implemented new procedures and controls around our net product sales and inventory processes.



## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

The information required with respect to this item can be found under “Commitments and Contingencies” in Note 5 to our condensed financial statements included elsewhere in this Form 10-Q and is incorporated by reference into this Item 1.

In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

### Item 1A. Risk Factors

*Except for the historical information contained herein or incorporated by reference, this report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in Part I, Item 2 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this report and in any documents incorporated in this report by reference.*

*You should consider carefully the following risk factors, together with those set forth in Part I, Item 1A in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#) and in all of the other information included or incorporated in this report. The following risk factors represent new risk factors or those containing changes, including material changes, to the risk factors set forth in Part I, Item 1A of our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#). If any of the previously identified or following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.*

***The outbreak of the novel strain of coronavirus, SARS-CoV-2, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our commercial launch of NEXLETOL and NEXLIZET, our intended commercial launch of NILEMDO and NUSTENDI lead by DSE in the EU, our ongoing CLEAR Outcomes trial, and operations and sales in general.***

In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), surfaced in Wuhan, China. Since then, SARS-CoV-2 and COVID-19 have spread to multiple countries, including the United States. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. In response to the spread of SARS-CoV-2 and COVID-19, our commercial and medical organizations are following internal guidelines and respective state guidelines when interacting with physicians and customers.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, including our clinical development and commercialization plans for the bempedoic acid and bempedoic acid / ezetimibe fixed dose combination tablets. As a result of the current pandemic, or future pandemics, we may not be able to meet expectations with respect to the net product sales of NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI or attain or maintain profitability and positive cash-flow from operations. Our ongoing clinical trial for bempedoic acid tablet and the timing for the review and approval of expanded indications for their effect on cardiovascular events may be impacted as well. Business interruptions from the current or future pandemics may also adversely impact the third parties we solely rely on to sufficiently manufacture NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI and to produce our product candidates in quantities we require, which may impair the commercialization of NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI and our research and development activities. So far, most of our manufacturing partners and CROs have continued to produce at anticipated levels despite these challenges.

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Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our business generally, and the third parties which we rely upon, include business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak impacts our business, including our commercial results and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 6. Exhibits**

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

**EXHIBIT INDEX**

Exhibit No.	Description	Incorporated by Reference to:		
		Form or Schedule	Exhibit No.	Filing Date with SEC
10.1*	<a href="#">Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan, as amended</a>			
10.2*†	<a href="#">License and Collaboration Agreement by and between the Registrant and Otsuka Pharmaceutical Co., Ltd. dated April 17, 2020</a>			
10.3*†	<a href="#">1<sup>st</sup> Amendment to the License and Collaboration Agreement by and between the Registrant and Daiichi Sankyo Europe GMBH dated June 18, 2020</a>			
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>			
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>			
32.1+	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document			
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document			
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)			

\* Filed herewith.

+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

**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 thereunto duly authorized.

ESPERION THERAPEUTICS, INC.

August 10, 2020

By: /s/ Tim M. Mayleben

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Tim M. Mayleben

*President and Chief Executive Officer  
(Principal Executive Officer)*

August 10, 2020

By: /s/ Richard B. Bartram

\_\_\_\_\_  
Richard B. Bartram

*Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)*

**ESPERION THERAPEUTICS, INC.****2020 EMPLOYEE STOCK PURCHASE PLAN**

The purpose of the Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan (“the Plan”) is to provide eligible employees of Esperion Therapeutics, Inc. (the “Company”) and each Designated Subsidiary (as defined in Section 11) with opportunities to purchase shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”). Eight-hundred and twenty-five thousand (825,000) shares of Common Stock in the aggregate have been approved and reserved for this purpose. The Plan is intended to constitute an “employee stock purchase plan” within the meaning of Section 423(b) of the Internal Revenue Code of 1986, as amended (the “Code”), and shall be interpreted in accordance with that intent.

1. Administration. The Plan will be administered by the person or persons (the “Administrator”) appointed by the Company’s Board of Directors (the “Board”) for such purpose. The Administrator has authority at any time to: (i) adopt, alter and repeal such rules, guidelines and practices for the administration of the Plan and for its own acts and proceedings as it shall deem advisable; (ii) interpret the terms and provisions of the Plan; (iii) make all determinations it deems advisable for the administration of the Plan; (iv) decide all disputes arising in connection with the Plan; and (v) otherwise supervise the administration of the Plan. All interpretations and decisions of the Administrator shall be binding on all persons, including the Company and the Participants. No member of the Board or individual exercising administrative authority with respect to the Plan shall be liable for any action or determination made in good faith with respect to the Plan or any option granted hereunder.

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2. Offerings. The Company will make one or more offerings to eligible employees to purchase Common Stock under the Plan (“Offerings”). Unless otherwise determined by the Administrator, an Offering will begin on the first business day occurring on or after each September 1 and March 1 and will end on the last business day occurring on or before the following February 28 or February 29 on a leap year and August 31, respectively. The Administrator may, in its discretion, designate a different period for any Offering, provided that no Offering shall exceed 27 months in duration or overlap any other Offering.

3. Eligibility. All individuals classified as employees on the payroll records of the Company and each Designated Subsidiary are eligible to participate in any one or more of the Offerings under the Plan, provided that as of the first day of the applicable Offering (the “Offering Date”) they are customarily employed by the Company or a Designated Subsidiary for more than 20 hours a week and have completed at least six months of employment. Notwithstanding any other provision herein, individuals who are not contemporaneously classified as employees of the Company or a Designated Subsidiary for purposes of the Company’s or applicable Designated Subsidiary’s payroll system are not considered to be eligible employees of the Company or any Designated Subsidiary and shall not be eligible to participate in the Plan. In the event any such individuals are reclassified as employees of the Company or a Designated Subsidiary for any purpose, including, without limitation, common law or statutory employees, by any action of any third party, including, without limitation, any government agency, or as a result of any private lawsuit, action or administrative proceeding, such individuals shall, notwithstanding such reclassification, remain ineligible for participation. Notwithstanding the foregoing, the exclusive means for individuals who are not contemporaneously classified as employees of the Company or a Designated Subsidiary on the

Company's or Designated Subsidiary's payroll system to become eligible to participate in this Plan is through an amendment to this Plan, duly executed by the Company, which specifically renders such individuals eligible to participate herein.

4. Participation.

(a) Participants. An eligible employee who is not a Participant in any prior Offering may participate in a subsequent Offering by submitting an enrollment form to his or her appropriate payroll location at least 15 business days before the Offering Date (or by such other deadline as shall be established by the Administrator for the Offering).

(b) Enrollment. The enrollment form will (a) state a whole percentage to be deducted from an eligible employee's Compensation (as defined in Section 11) per pay period, (b) authorize the purchase of Common Stock in each Offering in accordance with the terms of the Plan and (c) specify the exact name or names in which shares of Common Stock purchased for such individual are to be issued pursuant to Section 10. An employee who does not enroll in accordance with these procedures will be deemed to have waived the right to participate. Unless a Participant files a new enrollment form or withdraws from the Plan, such Participant's deductions and purchases will continue at the same percentage of Compensation for future Offerings, provided he or she remains eligible.

(c) Notwithstanding the foregoing, participation in the Plan will neither be permitted nor be denied contrary to the requirements of the Code.

5. Employee Contributions. Each eligible employee may authorize payroll deductions at a minimum of 1 percent up to a maximum of 10 percent of such employee's Compensation for each pay period. The Company will maintain book accounts showing the

amount of payroll deductions made by each Participant for each Offering. No interest will accrue or be paid on payroll deductions.

6. Deduction Changes. Except as may be determined by the Administrator in advance of an Offering, a Participant may not increase or decrease his or her payroll deduction during any Offering, but may increase or decrease his or her payroll deduction with respect to the next Offering (subject to the limitations of Section 5) by filing a new enrollment form at least 15 business days before the next Offering Date (or by such other deadline as shall be established by the Administrator for the Offering). The Administrator may, in advance of any Offering, establish rules permitting a Participant to increase, decrease or terminate his or her payroll deduction during an Offering.

7. Withdrawal. A Participant may withdraw from participation in the Plan by delivering a written notice of withdrawal to his or her appropriate payroll location. The Participant's withdrawal will be effective as of the next business day. Following a Participant's withdrawal, the Company will promptly refund such individual's entire account balance under the Plan to him or her (after payment for any Common Stock purchased before the effective date of withdrawal). Partial withdrawals are not permitted. Such an employee may not begin participation again during the remainder of the Offering, but may enroll in a subsequent Offering in accordance with Section 4.

8. Grant of Options. On each Offering Date, the Company will grant to each eligible employee who is then a Participant in the Plan an option ("Option") to purchase on the last day of such Offering (the "Exercise Date"), at the Option Price hereinafter provided for, the lowest of (a) a number of shares of Common Stock determined by dividing such Participant's accumulated payroll deductions on such Exercise Date by the lower of (i) 85 percent of the Fair Market Value



of the Common Stock on the Offering Date, or (ii) 85 percent of the Fair Market Value of the Common Stock on the Exercise Date, (b) a number of shares of Common Stock determined by dividing \$25,000 by the Fair Market Value of the Common Stock on the Offering Date of such Offering; or (c) such other lesser maximum number of shares as shall have been established by the Administrator in advance of the Offering; provided, however, that such Option shall be subject to the limitations set forth below. Each Participant's Option shall be exercisable only to the extent of such Participant's accumulated payroll deductions on the Exercise Date. The purchase price for each share purchased under each Option (the "Option Price") will be 85 percent of the Fair Market Value of the Common Stock on the Offering Date or the Exercise Date, whichever is less.

Notwithstanding the foregoing, no Participant may be granted an option hereunder if such Participant, immediately after the option was granted, would be treated as owning stock possessing 5 percent or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary (as defined in Section 11). For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of a Participant, and all stock which the Participant has a contractual right to purchase shall be treated as stock owned by the Participant. In addition, no Participant may be granted an Option which permits his or her rights to purchase stock under the Plan, and any other employee stock purchase plan of the Company and its Parents and Subsidiaries, to accrue at a rate which exceeds \$25,000 of the fair market value of such stock (determined on the option grant date or dates) for each calendar year in which the Option is outstanding at any time. The purpose of the limitation in the preceding sentence is to comply with Section 423(b)(8) of the Code and shall be applied taking Options into account in the order in which they were granted.

9. Exercise of Option and Purchase of Shares. Each employee who continues to be a Participant in the Plan on the Exercise Date shall be deemed to have exercised his or her Option on such date and shall acquire from the Company such number of whole shares of Common Stock reserved for the purpose of the Plan as his or her accumulated payroll deductions on such date will purchase at the Option Price, subject to any other limitations contained in the Plan. Any amount remaining in a Participant's account at the end of an Offering solely by reason of the inability to purchase a fractional share will be carried forward to the next Offering; any other balance remaining in a Participant's account at the end of an Offering will be refunded to the Participant promptly.

10. Issuance of Certificates. Certificates representing shares of Common Stock purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or in the name of a broker authorized by the employee to be his, her or their, nominee for such purpose.

11. Definitions.

The term "Compensation" means the amount of base pay, prior to salary reduction pursuant to Sections 125, 132(f) or 401(k) of the Code, but excluding overtime, commissions, incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances or travel expenses, income or gains on the exercise of Company stock options, and similar items.

The term "Designated Subsidiary" means any present or future Subsidiary (as defined below) that has been designated by the Board to participate in the Plan. The Board may so designate any Subsidiary, or revoke any such designation, at any time and from time to time, either before or after the Plan is approved by the stockholders.

The term “Fair Market Value of the Common Stock” on any given date means the fair market value of the Common Stock determined in good faith by the Administrator; provided, however, that if the Common Stock is admitted to quotation on the National Association of Securities Dealers Automated Quotation System (“NASDAQ”), NASDAQ Global Market or another national securities exchange, the determination shall be made by reference to the closing price on such date. If there is no closing price for such date, the determination shall be made by reference to the last date preceding such date for which there is a closing price.

The term “Parent” means a “parent corporation” with respect to the Company, as defined in Section 424(e) of the Code.

The term “Participant” means an individual who is eligible as determined in Section 3 and who has complied with the provisions of Section 4.

The term “Subsidiary” means a “subsidiary corporation” with respect to the Company, as defined in Section 424(f) of the Code.

12. Rights on Termination of Employment. If a Participant’s employment terminates for any reason before the Exercise Date for any Offering, no payroll deduction will be taken from any pay due and owing to the Participant and the balance in the Participant’s account will be paid to such Participant or, in the case of such Participant’s death, to his or her designated beneficiary as if such Participant had withdrawn from the Plan under Section 7. An employee will be deemed to have terminated employment, for this purpose, if the corporation that employs him or her, having been a Designated Subsidiary, ceases to be a Subsidiary, or if the employee is transferred to any corporation other than the Company or a Designated Subsidiary. [Unless otherwise determined by the Administrator, a Participant whose employment transfers between Designated Subsidiaries or a Designated Subsidiary and the Company or whose employment

terminates with an immediate rehire (with no break in service) by the Company or a Designated Subsidiary will not be treated as having terminated employment for purposes of participating in the Plan or an Offering.] Further, an employee will not be deemed to have terminated employment for this purpose, if the employee is on an approved leave of absence for military service or sickness or for any other purpose approved by the Company, if the employee's right to reemployment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise provides in writing.

13. Special Rules. Notwithstanding anything herein to the contrary, the Administrator may adopt special rules applicable to the employees of a particular Designated Subsidiary, whenever the Administrator determines that such rules are necessary or appropriate for the implementation of the Plan in a jurisdiction where such Designated Subsidiary has employees; provided that such rules are consistent with the requirements of Section 423(b) of the Code. Any special rules established pursuant to this Section 13 shall, to the extent possible, result in the employees subject to such rules having substantially the same rights as other Participants in the Plan.

14. Optionees Not Stockholders. Neither the granting of an Option to a Participant nor the deductions from his or her pay shall constitute such Participant a holder of the shares of Common Stock covered by an Option under the Plan until such shares have been purchased by and issued to him or her.

15. Rights Not Transferable. Rights under the Plan are not transferable by a Participant other than by will or the laws of descent and distribution, and are exercisable during the Participant's lifetime only by the Participant.

16. Application of Funds. All funds received or held by the Company under the Plan may be combined with other corporate funds and may be used for any corporate purpose.

17. Adjustment in Case of Changes Affecting Common Stock. In the event of a subdivision of outstanding shares of Common Stock, the payment of a dividend in Common Stock or any other change affecting the Common Stock, the number of shares approved for the Plan and the share limitation set forth in Section 8 shall be equitably or proportionately adjusted to give proper effect to such event.

18. Amendment of the Plan. The Board may at any time and from time to time amend the Plan in any respect, except that without the approval within 12 months of such Board action by the stockholders, no amendment shall be made increasing the number of shares approved for the Plan or making any other change that would require stockholder approval in order for the Plan, as amended, to qualify as an “employee stock purchase plan” under Section 423(b) of the Code.

19. Insufficient Shares. If the total number of shares of Common Stock that would otherwise be purchased on any Exercise Date plus the number of shares purchased under previous Offerings under the Plan exceeds the maximum number of shares issuable under the Plan, the shares then available shall be apportioned among Participants in proportion to the amount of payroll deductions accumulated on behalf of each Participant that would otherwise be used to purchase Common Stock on such Exercise Date.

20. Termination of the Plan. The Plan may be terminated at any time by the Board. Upon termination of the Plan, all amounts in the accounts of Participants shall be promptly refunded.

21. Governmental Regulations. The Company's obligation to sell and deliver Common Stock under the Plan is subject to obtaining all governmental approvals required in connection with the authorization, issuance, or sale of such stock.

22. Governing Law. This Plan and all Options and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.

23. Issuance of Shares. Shares may be issued upon exercise of an Option from authorized but unissued Common Stock, from shares held in the treasury of the Company, or from any other proper source.

24. Tax Withholding. Participation in the Plan is subject to any minimum required tax withholding on income of the Participant in connection with the Plan. Each Participant agrees, by entering the Plan, that the Company and its Subsidiaries shall have the right to deduct any such taxes from any payment of any kind otherwise due to the Participant, including shares issuable under the Plan.

25. Notification Upon Sale of Shares. Each Participant agrees, by entering the Plan, to give the Company prompt notice of any disposition of shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such shares were purchased or within one year after the date such shares were purchased.

26. Effective Date and Approval of Shareholders. The Plan shall take effect on the later of the date it is adopted by the Board and the date it is approved by the holders of a majority of the votes cast at a meeting of stockholders at which a quorum is present or by written consent of the stockholders.

**FIRST AMENDMENT TO  
ESPERION THERAPEUTICS, INC.  
2020 EMPLOYEE STOCK PURCHASE PLAN**

**WHEREAS**, Esperion Therapeutics, Inc. (the “Company”) maintains the Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan (the “Plan”);

**WHEREAS**, pursuant to Section 18 of the Plan, the Company’s Board of Directors (the “Board”) may amend the Plan from time to time; and

**WHEREAS**, the Board has determined it is in the best interests of the Company to amend the Plan as described below.

**NOW THEREFORE, LET IT BE RESOLVED**, that effectively as of the date of this First Amendment, the Plan be amended as follows:

NOW, THEREFORE, the Plan is amended as follows:

1. The first sentence of Section 3 of the Plan is deleted and hereby replaced with the following:

All individuals classified as employees on the payroll records of the Company and each Designated Subsidiary are eligible to participate in any one or more of the Offerings under the Plan, provided that as of the first day of the applicable Offering (the “Offering Date”) they are customarily employed by the Company or a Designated Subsidiary for more than 20 hours a week and have completed at least three months of employment.

2. All capitalized terms used and not defined herein shall have the meanings ascribed to such terms in the Plan.
3. Except as expressly amended hereby, the Plan remains in full force and effect in accordance with its terms.

Adopted by the Board of Directors of Esperion Therapeutics , Inc.: July 31, 2020

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**LICENSE AND COLLABORATION AGREEMENT**

**by and between**

**OTSUKA PHARMACEUTICAL CO., LTD.**

**and**

**ESPERION THERAPEUTICS, INC.**

**April 17, 2020**

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- Schedule 1.45 Esperion Trademarks
- Schedule 2.1.2 Initial Development Plan for Initial Product
- Schedule 7.3 Press Releases
- Schedule 10.2.2 Existing Esperion Patent Rights

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## LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this “**Agreement**”), entered into as of April 17, 2020 (the “**Effective Date**”), is entered into by and between Otsuka Pharmaceutical Co., Ltd., a corporation organized and existing under the laws of Japan (“**Otsuka**”) and Esperion Therapeutics, Inc., a corporation organized and existing under the laws of the state of Delaware, United States (“**Esperion**”).

### RECITALS

**WHEREAS**, Esperion owns or otherwise controls certain technology and information relating to Bempedoic Acid and the Licensed Products;

**WHEREAS**, Otsuka is a pharmaceutical company that conducts research, development, manufacturing and commercialization of pharmaceutical products; and

**WHEREAS**, Otsuka desires to obtain an exclusive license to Develop, Manufacture and Commercialize Licensed Products in the Field in the Otsuka Territory and to obtain API(s) and Bulk Tablets for clinical and commercial use in the Field in the Otsuka Territory (as each term is defined below), and Esperion desires to grant such license and provide such supply to Otsuka on the terms and conditions set forth in this Agreement.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

#### 1. **DEFINITIONS**

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

**1.1 “Achievement of Primary MACE Endpoint”** means, with respect to the CLEAR Outcome Study, a statistically significant improvement ( $p < 0.05$ ) shown in relative risk reduction in the primary end point of four-point MACE composite that specifically includes cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, and coronary revascularization.

**1.2 “Acquired Business”** has the meaning set forth in Section 14.15.3 (Acquired Programs).

**1.3 “Acquirer”** has the meaning set forth in Section 14.15.2 (Future Acquisition of a Party or its Business).

**1.4 “Action”** has the meaning set forth in Section 14.4 (Jurisdiction).

**1.5** “**Affiliate**” means, with respect to a Person, any other Person which controls, is controlled by, or is under common control with the applicable Person. For purposes of this definition, “control” shall mean: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors, or otherwise having the power to control or direct the affairs of such Person; and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest or the power to direct the management and policies of such non-corporate entities.

**1.6** “**Agreement**” has the meaning set forth in the Preamble.

**1.7** “**Alliance Manager**” has the meaning set forth in Section 6.1.4(a) (Alliance Managers; Appointment).

**1.8** “**API(s)**” has the meaning set forth in Section 5.1 (Licensed Products).

**1.9** “**Assessment Period**” has the meaning set forth in Section 2.2 (Option to New Indications).

**1.10** “**Authorized Generic Product**” means a generic version of a Licensed Product for which an application for Regulatory Approval is submitted to the applicable Regulatory Authority by or on behalf of, or pursuant to authorization granted by, Otsuka or its Affiliate, and which is manufactured by the same manufacturer that manufactures the corresponding Licensed Product.

**1.11** “**BA Product**” has the meaning set forth in Section 1.75 (Definition of Net Sales).

**1.12** “**Bempedoic Acid**” means 8-Hydroxy-2,2,14,14-tetramethylpentadecanedioic acid.

**1.13** “**Bulk Tablets**” means the Licensed Product in bulk tablet form packaged in drums.

**1.14** “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each calendar year, provided that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term and (b) the first Calendar Quarter of a Royalty Term for a Licensed Product shall begin on the First Commercial Sale of such Licensed Product in the Otsuka Territory and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of a Royalty Term for a Licensed Product shall end on the last day of such Royalty Term.

**1.15 “Calendar Year”** means each successive period of twelve (12) months commencing on January 1 and ending on December 31, provided that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term and (b) the first Calendar Year of a Royalty Term for a Licensed Product shall begin on the First Commercial Sale of such Licensed Product in the Otsuka Territory and end on the first December 31 thereafter and the last Calendar Year of a Royalty Term for a Licensed Product shall end on the last day of such Royalty Term.

**1.16 “cGMP” or “current Good Manufacturing Practices”** means, as applicable, the then-current standards for good manufacturing practices for biological or therapeutic products, as appropriate, as set forth in the FD&C Act, or applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by other Governmental Authorities in countries in which Licensed Products are intended to be manufactured or sold.

**1.17 “CLEAR Outcome Study”** means the Clinical Study (1002-043 study) conducted by or on behalf of Esperion pursuant to the protocol entitled “A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempeoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant”.

**1.18 “Clinical Study” or “Clinical Studies”** means a human clinical study conducted on human subjects that involves a test product, drug or device and that either is subject to requirements for prior submission to a Regulatory Authority or is not subject to requirements for prior submission to a Regulatory Authority but the results of which are intended to be submitted later to, or held for inspection by, a Regulatory Authority as part of an application for a research permit or Regulatory Approval, and includes studies relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of the product, drug or device.

**1.19 “CMO”** means a Third Party contract manufacturing organization.

**1.20 “Co-Chairpersons”** has the meaning set forth in Section 6.1.3 (JCC Co-Chairpersons).

**1.21 “COGS”** means, with respect to a Licensed Product supplied to Otsuka pursuant to this Agreement, and without duplication: (a) Esperion’s or its Affiliate’s internal costs for the Manufacture and supply of such Licensed Product, including, without limitation: (i) direct material costs (the actual costs incurred in Manufacturing or purchasing materials for Manufacture, including freight-in costs, sales and excise taxes imposed thereon (provided that Esperion and its Affiliate will use Commercially Reasonable Efforts to avoid or minimize such taxes) and customs duty and charges levied by government authorities, and all costs of packaging components), (ii) direct labor costs (the actual cost of employees engaged in direct Manufacturing activities), (iii) costs of quality assurance and quality control activities (including the actual cost of employees

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engaged in such activities), (iv) storage, packaging and shipping costs, and (v) indirect charges and overhead that are reasonably allocable to such Manufacturing, including applicable FTEs, all of the foregoing determined in accordance with IFRS or U.S. Generally Accepted Accounting Principles consistently applied; and (b) the actual Out-of-Pocket Costs paid by Esperion to a CMO or other Third Party Manufacturer for the Manufacture and supply of Licensed Products without mark-up.

**1.22 “Combination Product”** means a product comprising Bempedoic Acid in combination with ezetimibe for use in the Field.

**1.23 “Commercialization” or “Commercialize”** means any and all activities directed to marketing, promoting, distributing, importing, exporting, using, offering to sell, selling or having sold a product, but excluding for the avoidance of doubt, Developing and Manufacturing and including, for avoidance of doubt, the establishment and maintenance of patient registries or similar patient advocacy activities and programs.

**1.24 “Commercially Reasonable Efforts”** means, with respect to a Party’s obligations that relate to the achievement of an objective related to a Licensed Product, at any given time as the case may be, efforts reasonably used by a similarly situated entity in the pharmaceutical industry having similar resources and expertise as such Party, for such similar entity’s own products (including internally developed, acquired and in-licensed products) of a similar modality with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration all Relevant Factors.

**1.25 “Competing Infringement”** has the meaning set forth in Section 12.3.1 (Notice of Infringement).

**1.26 “Competing Product”** has the meaning set forth in Section 10.4 (Exclusivity).

**1.27 “Competing Program”** has the meaning set forth in Section 14.15.3(a) (Acquired Programs).

**1.28 “Confidential Information”** means any and all confidential or proprietary information and data, including Esperion Technology, Otsuka Technology, and Joint Technology, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement. Esperion Technology is hereby deemed to be the Confidential Information of Esperion. Otsuka Technology is hereby deemed to be the Confidential Information of Otsuka. Joint Technology and the terms of this Agreement are hereby deemed to be the Confidential Information of both Parties.

**1.29 “Control”, “Controls” or “Controlled by”** means, with respect to any intellectual property right (including any Patent Right or Know-How), the possession of

(whether by ownership or license, other than pursuant to this Agreement) the ability of a Person or its Affiliates to assign, transfer, or grant access to, or to grant a license or sublicense of, such right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Person would be required hereunder to assign, transfer or grant another Person such access or license or sublicense.

**1.30** “Cover,” “Covering” or “Covers” means as to a compound or product and a Patent Right, that, in the absence of a license granted under, or ownership of, such Patent Right, the making, using, selling, offering for sale or importation of such compound or product would infringe any claim of such Patent Right.

**1.31** “CSR” has the meaning set forth in Section 2.2 (Option to New Indication).

**1.32** “Data Milestone Payment” has the meaning set forth in Section 9.4 (Data Milestone Payment).

**1.33** “Development,” “Developing” or “Develop” means under this Agreement, with respect to Licensed Products, the research and development activities conducted before or after obtaining Regulatory Approval that are reasonably related to or leading to the development, preparation and submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting or expanding a Regulatory Approval, including but not limited to all activities related to pharmacokinetic profiling, design and conduct of pre-clinical development, non-clinical development, pre-clinical studies, in vitro studies, Clinical Studies, other studies and scientific activities ordinarily conducted in the pharmaceutical industry in the Otsuka Territory as a prerequisite to or in connection with a Clinical Study, regulatory affairs, statistical analysis, report writing and regulatory filing creation and submission, including (a) Post-Approval Studies and (b) studies that will result in an amendment to the indication included in the product labelling for the Licensed Product, but excluding, for the avoidance of doubt, Commercialization and Manufacturing.

**1.34** “Development Plan” has the meaning set forth in Section 2.1.2 (Development Plans).

**1.35** “DMF” has the meaning set forth in Section 3.1 (Responsibility for Regulatory Matters).

**1.36** “DSUR” or “Development Safety Update Report” has the meaning set forth in Section 3.9 (Pharmacovigilance).

**1.37** “Effective Date” has the meaning set forth in the Preamble.

**1.38** “Esperion” has the meaning set forth in the Preamble.

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**1.39 “Esperion Indemnitees”** has the meaning set forth in Section 11.1 (General Indemnification by Otsuka).

**1.40 “Esperion Know-How”** means Know-How Controlled by Esperion on the Effective Date or during the Term that is reasonably necessary or useful to the Development, Manufacture or Commercialization of the Licensed Products in the Field in the Otsuka Territory, but excluding Joint Know-How.

**1.41 “Esperion Patent Rights”** means any Patent Right Controlled by Esperion on the Effective Date or during the Term that is reasonably necessary or useful to the Development, Manufacture or Commercialization of the Licensed Products in the Field in the Otsuka Territory, but excluding Joint Patent Rights. The Esperion Patent Rights existing as of the Effective Date are those Patent Rights identified on Schedule 10.2.2 (Esperion Patent Rights). Schedule 10.2.2 (Esperion Patent Rights) shall be amended from time to time at the initiative of Esperion or the reasonable request of Otsuka to reflect the then-current status of the Esperion Patent Rights including by adding or deleting Patent Rights as required for accuracy and completeness.

**1.42 “Esperion Technology”** means Esperion Know-How and Esperion Patent Rights.

**1.43 “Esperion Territory”** means worldwide, excluding the Otsuka Territory.

**1.44 “Esperion Third Party Agreements”** means such agreements between Esperion and a Third Party pursuant to which Esperion Controls Know-How or Patent Rights reasonably necessary or useful to Develop, Manufacture or Commercialize Licensed Products, including any Third Party IP Agreement entered into by Esperion pursuant to Section 12.4.2.

**1.45 “Esperion Trademarks”** means any and all Trademarks pertaining to the Licensed Products that are owned by Esperion and set forth in Schedule 1.45 (Esperion Trademarks), excluding any Esperion house marks and the name “Esperion.”

**1.46 “Existing Esperion Patent Rights”** has the meaning set forth in Section 10.2.2 (Additional Representations and Warranties of Esperion).

**1.47 “FD&C Act”** means the United States Federal Food, Drug and Cosmetic Act, as amended.

**1.48 “Field”** means the use of a Licensed Product for any Initial Indication and for any New Indications that are added to this Agreement by amendment in accordance with Section 2.2 (Option to New Indications).

**1.49 “First Commercial Sale”** means, with respect to a Licensed Product, the first sale for end use or consumption of such Licensed Product in the Otsuka Territory (excluding named patient sales, compassionate use or other patient access programs) after



all Regulatory Approvals legally required for such sale and NHI Price Listing have been granted by the Regulatory Authority(ies) of the Otsuka Territory.

**1.50 “GCP” or “Good Clinical Practices”** means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) the Ministerial Ordinance on Standards for Implementation of Clinical Studies on Drugs (GCP Ministerial Ordinance) by the MHLW, (b) the Pharmaceutical and Medical Device Act, (c) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“**ICH**”), Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for clinical trials on medicinal products in the European Union; (d) the Declaration of Helsinki (1964) as last amended at the 59<sup>th</sup> World Medical Association (WMA) General Assembly in October 2008 and any further amendments or clarifications thereto; and (e) the equivalent applicable Laws in any relevant country or jurisdiction, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reports results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.51 “Generic Product”** means, with respect to a Licensed Product, a pharmaceutical product that is approved for use in the Otsuka Territory by a Regulatory Authority through a regulatory pathway referencing or relying on clinical data, or any findings of safety or efficacy therein, that are first submitted by Otsuka or its Sublicensees for obtaining Regulatory Approval for such Licensed Product, in each case other than any Authorized Generic Product of such Licensed Product.

**1.52 “Global Branding Strategy”** has the meaning set forth in Section 4.3.1 (Global Branding).

**1.53 “Governmental Authority”** means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

**1.54 “ICH”** has the meaning set forth in Section 1.50 (Definition of GCP).

**1.55 “IFRS”** means International Financial Reporting Standards, consistently applied.

**1.56 “Indemnitee”** has the meaning set forth in Section 11.3 (Indemnification Procedure).

**1.57 “Infringement Action”** has the meaning set forth in Section 12.3.2 (Right to Enforce).

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**1.58 “Initial Indication”** means the use of a Licensed Product for: (a) the treatment or prevention of hypercholesterolemia (familial and/or non-familial) and/or any other LDL-cholesterol lowering treatment that is the subject of any Clinical Studies in the Otsuka Territory that are set forth in any agreed Development Plan; or (b) (i) the treatment or prevention of hypercholesterolemia (familial and/or non-familial) and/or any other LDL-cholesterol lowering treatment that is the subject of any Clinical Studies in the Otsuka Territory that are set forth in any agreed Development Plan, and (ii) risk reduction of cardiovascular events such as myocardial infarction, stroke, and coronary revascularization.

**1.59 “Initial Product”** means a product comprising Bempedoic Acid as its sole active pharmaceutical ingredient for use in the Field.

**1.60 “Invent”** means the act of invention by inventors, as determined in accordance with the applicable patent laws.

**1.61 “JNDA”** means an application for Regulatory Approval of a Licensed Product in the Otsuka Territory.

**1.62 “Joint Collaboration Committee” or “JCC”** means the joint collaboration committee as more fully described in Section 6.1 (Joint Collaboration Committee).

**1.63 “Joint Know-How”** means any Know-How that is discovered, made or developed jointly in connection with the activities undertaken under this Agreement by one or more employees of Esperion or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Otsuka or its Affiliates that are Sublicensees (or a Third Party acting on any of their behalf).

**1.64 “Joint Patent Rights”** means any Patent Right that is Invented jointly in connection with the activities undertaken under this Agreement by one or more employees of Esperion or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Otsuka or its Affiliates that are Sublicensees (or a Third Party acting on any of their behalf).

**1.65 “Joint Technology”** means Joint Know-How and Joint Patent Rights.

**1.66 “JPY”** has the meaning set forth in Section 9.3 (NHI Price Listing Milestone Payment).

**1.67 “Know-How”** means all chemical or biological materials and other tangible materials, inventions, improvements, practices, discoveries, developments, data, information, technology, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical data and analytical and quality control data, in all cases, whether or not proprietary or patentable, in written, electronic or any other form now known or hereafter developed, including any

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physical embodiments of any of the foregoing; but excluding in any event any Patent Right and Trademarks.

**1.68 “Laws”** means all applicable laws, statutes, rules, regulations, orders, judgments, injunctions, ordinances or other pronouncements having the binding effect of law of any Governmental Authority, including a legal obligation to a Regulatory Authority or other Governmental Authority to which either Party is or becomes subject (such as a corporate integrity agreement or settlement agreement with a Governmental Authority).

**1.69 “Licensed Product”** means any product comprising or containing Bempedoic Acid, either alone or in combination with other active pharmaceutical ingredients including the Initial Product, any Combination Product and any Authorized Generic Product, for use in the Field, including all dosage strengths, presentations, forms and formulations.

**1.70 “Losses”** has the meaning set forth in Section 11.1 (General Indemnification by Otsuka).

**1.71 “Manufacturing” or “Manufacture”** means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, purifying, filling, finishing, packaging, labeling, shipping, importing and storage of Licensed Products, and any part or component thereof, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release, but excluding for the avoidance of doubt Developing and Commercializing.

**1.72 “Material Communications”** means formal written, telephonic or in-person communications from or with any Regulatory Authority concerning any of the following: key product quality attributes (e.g., purity) of Licensed Products, safety findings affecting a Licensed Product (e.g., Serious Adverse Events, emerging safety signals), clinical or non-clinical findings affecting patient safety, efficacy, receipt or denial of Regulatory Approval, the design of Clinical Studies or the need for additional non-clinical studies (e.g., additional toxicology or carcinogenicity studies).

**1.73 “MHLW”** means the Japanese Ministry of Health, Labour and Welfare, or a successor agency thereto.

**1.74 Negotiation Period** has the meaning set forth in Section 2.2 (Option to New Indications).

**1.75 “Net Sales”** means, with respect to a Licensed Product, the aggregate gross invoiced sales prices from sales of all units of such Licensed Product sold by Otsuka or its Sublicensees to independent Third Parties in accordance with IFRS after deducting, if not previously deducted, from the amount invoiced or received:

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- (a) [\*\*\*];
- (b) [\*\*\*];
- (c) [\*\*\*];
- (d) [\*\*\*];
- (e) [\*\*\*];
- (f) [\*\*\*].

In the case of any sale or other disposal for value, such as barter or counter-trade, of a Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated [\*\*\*].

Notwithstanding the foregoing, the following will not be included in Net Sales: [\*\*\*].

Solely for purposes of calculating Net Sales, if Otsuka or its Sublicensee sells a Licensed Product in the Otsuka Territory as part of a therapy or product that is a combination containing the Initial Product or the Combination Product (each, a **"BA Product"**) and one or more other active ingredients, delivery devices or other components that are not a BA Product (each, an **"Other Product"**) (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold under a single label approved by a Regulatory Authority) (a **"New Combination Product"**), Net Sales of such New Combination Product for the purposes of determining payments based on Net Sales hereunder will be calculated by multiplying actual Net Sales of such New Combination Product as determined in the first paragraph of this Net Sales definition (**"New Combination Product Net Sales"**) by the fraction  $A/(A+B)$  where A is the NHI Price of the BA Product in the Otsuka Territory when sold separately (*i.e.*, without the Other Product) and B is the NHI Price of the Other Product (or, as applicable, the weighted average of each NHI Price of the generic versions of the Other Product) in the Otsuka Territory when sold separately, in each case, during the relevant period. If the NHI Price of the Other Product in the Otsuka Territory when sold separately cannot be determined but the NHI Price of the BA Product in the Otsuka Territory when sold separately (*i.e.*, without the Other Product) can be determined, New Combination Product Net Sales for purposes of determining payments based on Net Sales hereunder will be calculated by multiplying the New Combination Product Net Sales by the fraction  $A/C$  where A is the NHI Price of the BA Product in the Otsuka Territory when sold separately (*i.e.*, without the Other Product) and C is the NHI Price of the New Combination Product in the Otsuka Territory.

**1.76** **"New Combination Product"** has the meaning set forth in Section 1.75 (Definition of Net Sales).

**1.77** **"New Combination Product Net Sales"** has the meaning set forth in Section 1.75 (Definition of Net Sales).

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**1.78** “**New Indication**” means an indication other than an Initial Indication.

**1.79** “**NHI Price**” means, with respect to a Licensed Product, the National Health Insurance price (yakka) applicable to such Licensed Product in the Otsuka Territory, which is determined and may be amended from time to time by the MHLW. Following any National Health Insurance price (yakka) revision, a new NHI Price shall be automatically adopted from the day of the official implementation of such National Health Insurance price (yakka) revision by the MHLW and, at the time of such adoption, the royalty rates hereunder may be reduced in accordance with Section 9.6.3(b) (NHI Price Reduction).

**1.80** “**NHI Price Listing**” means, with respect to a Licensed Product, the listing of such Licensed Product and its NHI Price on a list of drugs for which medical providers can be reimbursed under the NHI, following approval of the NHI Price by the Central Social Insurance Medical Council (Chuikyo) of the MHLW.

**1.81** “**NHI Price Listing Milestone Event**” has the meaning set forth in Section 9.3 (NHI Price Listing Milestone Payment).

**1.82** “**Non-Clinical Studies**” means non-human studies of Licensed Products, including chemistry, manufacturing and control-related studies.

**1.83** “**Option**” has the meaning set forth in Section 2.2 (Option to New Indications).

**1.84** “**Other Product**” has the meaning set forth in Section 1.75 (Definition of Net Sales).

**1.85** “**Otsuka**” has the meaning set forth in the Preamble.

**1.86** “**Otsuka BA Patent Rights**” has the meaning set forth in Section 12.2.2(a) (Prosecution of Otsuka Patent Rights).

**1.87** “**Otsuka BA Technology**” means Otsuka Know-How and Otsuka BA Patent Rights.

**1.88** “**Otsuka Indemnitees**” has the meaning set forth in Section 11.2 (General Indemnification by Esperion).

**1.89** “**Otsuka Know-How**” means Know-How Controlled by Otsuka or its Affiliates that are Sublicensees during the Term that is developed in the course of activities under this Agreement, and is reasonably necessary or useful to the Development, Manufacture or Commercialization of the Licensed Products, but excluding Joint Know-How.

**1.90** “**Otsuka Patent Right**” means any Patent Right Controlled by Otsuka or its Affiliates that are Sublicensees during the Term that Covers Otsuka Know-How and is

reasonably necessary or useful to the Development, Manufacture or Commercialization of the Licensed Products, but excluding Joint Patent Rights.

**1.91 “Otsuka Technology”** means Otsuka Know-How and Otsuka Patent Rights.

**1.92 “Otsuka Territory”** means Japan.

**1.93 “Otsuka Territory Commercialization Plan”** has the meaning set forth in Section 4.2.1 (Initial Commercialization Plan Summary).

**1.94 “Otsuka Territory Promotional Materials”** has the meaning set forth in Section 4.3.2 (Otsuka Advertising & Promotion).

**1.95 “Otsuka Territory-Specific Brand Strategy”** has the meaning set forth in Section 4.3.2 (Otsuka Advertising & Promotion).

**1.96 “Out-of-Pocket Costs”** means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties and specifically identifiable, incurred and invoiced to conduct such activities, as applicable, including payments to contract personnel; provided, however, that [\*\*\*] will not be considered Out-of-Pocket Costs.

**1.97 “Party”** means Otsuka or Esperion.

**1.98 “Patent Challenge”** has the meaning set forth in Section 13.2.3 (Challenges of Patent Rights).

**1.99 “Patent Rights”** means (a) all issued patents (including any extensions, restorations by any existing or future extension or registration mechanism (including patent term adjustments, patent term extensions, supplemental protection certificates or the equivalent thereof), substitutions, confirmations, re-registrations, re-examinations, reissues, patents and patent claims maintained after post grant examination (including *inter partes* review, post grant review or opposition proceeding) and patents of addition); (b) patent applications (including all provisional applications, substitutions, requests for continuation, continuations, continuations-in-part, divisionals and renewals); (c) inventor’s certificates; and (d) all equivalents of the foregoing in any country of the world.

**1.100 “Payment Forms”** means all of the following documents which, at the time Esperion provides such documents to Otsuka, must be currently effective (un-expired), completed and signed: one (1) copy of the United States Internal Revenue Service Form 6166 (United States Residency Certification); two (2) copies of Form 3 (Application Form for Income Tax Convention); and one (1) copy of Form 17 (Attachment Form for Limitation on Benefits Article).

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**1.101 “Person”** means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.

**1.102 “PMDA”** means the Japanese Pharmaceuticals and Medical Devices Agency and any successor thereto.

**1.103 “Pharmacovigilance Agreement”** has the meaning set forth in Section 3.9 (Pharmacovigilance).

**1.104 “Phase II Clinical Trial”** means a human clinical trial, the principal purpose of which is to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety, effectiveness and dose ranging for a particular indication or indications in a target patient population, consistent with the requirements of U.S. 21 C.F.R. § 312.21(b) or (for trial conducted outside the U.S.) its equivalents in the applicable non-U.S. jurisdictions.

**1.105 “Phase III Clinical Trial”** means a human clinical trial, the principal purpose of which is to establish that the product is safe and efficacious for its indicated use, define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, to support the filing of an application for Regulatory Approval for such product, consistent with the requirements of U.S. 21 C.F.R. §312.21(c) or (for trial conducted outside the U.S.) its equivalents in the applicable non-U.S. jurisdictions.

**1.106 “Post-Approval Study”** means all studies required as a condition to the grant of Regulatory Approval for the Licensed Product, such as confirmatory trials or PASS (post approval safety study).

**1.107 “Product Trademark Infringement Action”** has the meaning set forth in Section 12.7.2 (Enforcement of Product Trademarks).

**1.108 “Product Trademarks”** means the Esperion Trademarks and any alternative or additional Trademarks approved by the JCC for Licensed Products in the Otsuka Territory pursuant to Section 6.1.7 (JCC Decision-Making).

**1.109 “PSUR”** has the meaning set forth in Section 3.9 (Pharmacovigilance).

**1.110 “Quality Agreement”** has the meaning set forth in Section 5.3 (Licensed Product Supply Agreements).

**1.111 “Registration Dossier”** means the registration dossier of technical data and information compiled by or on behalf of Otsuka with respect to a Licensed Product submitted to a Regulatory Authority for obtaining Regulatory Approval of a Licensed Product in the Field in the Otsuka Territory, including any JNDA.

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**1.112 “Regulatory Approval”** means any and all approvals, licenses, registrations or authorizations of any Regulatory Authority that are necessary for the marketing and sale of a product in a country or group of countries, including a marketing authorization application filed with a Regulatory Authority in the Otsuka Territory, including all additions, amendments, supplements, extensions and modifications thereto, but excluding NHI Price Listing.

**1.113 “Regulatory Authority”** means any Governmental Authority involved in granting approvals for the Development, Manufacturing, Commercialization, reimbursement or pricing of Licensed Products, including the PMDA.

**1.114 “Regulatory Documentation”** means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Authorities (including Registration Dossiers, minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents, in each case relating to the Licensed Product, and all data contained in any of the foregoing, including all clinical trial applications, Regulatory Approvals and applications therefor, regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

**1.115 “Regulatory Exclusivity”** means, with respect to a Licensed Product in the Otsuka Territory, any exclusive marketing right, data exclusivity right or other status conferred by any Governmental Authority with respect to such Licensed Product in the Otsuka Territory, other than a Patent Right, that limits or prohibits a Person from (i) relying on pivotal safety or efficacy data generated by or for Otsuka or its Sublicensees with respect to a Licensed Product in an application for Regulatory Approval of a Generic Product or (ii) Commercializing a Licensed Product or a Generic Product.

**1.116 “Relevant Factors”** means all relevant factors that may affect the Development or Commercialization of a Licensed Product, including (as applicable): [\*\*\*].

**1.117 “Responsible Party”** has the meaning set forth in Section 12.3.3 (Control; Cooperation).

**1.118 “RMP”** has the meaning set forth in Section 3.9 (Pharmacovigilance).

**1.119 “Royalty Term”** has the meaning set forth in Section 9.6.2 (Royalty Term).

**1.120 “Safety Concern”** means, with respect to any Licensed Product, (a) any safety concern required to be reported under 21 C.F.R. § 312.32(c)(1)(iii) (“Findings from animal or in vitro testing”) or (b) a material toxicity or material drug safety issue or a Serious Adverse Event reasonably related to a Licensed Product.

**1.121 “Safety Reasons”** means a Party’s reasonable belief that there is an unacceptable risk for harm in humans based upon (a) preclinical safety data, including data from animal toxicology studies, or (b) the observation of serious adverse effects in humans



after the Licensed Product has been administered to humans, such as during a Clinical Study or after the First Commercial Sale, in each of clauses (a) and (b), which would materially impact the safety or efficacy and the commercial feasibility of Licensed Product.

**1.122 “Serious Adverse Event”** means an adverse drug experience or circumstance that results in any of the following outcomes (a) death, (b) life-threatening event, (c) inpatient hospitalization or prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) a congenital anomaly/birth defect, (f) significant intervention required to prevent permanent impairment or damage or (g) a medical event that may not result in death, be life-threatening or require hospitalization but, based on appropriate medical judgment, that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes described in clauses (a) through (e).

**1.123 “Sublicensee”** means a Third Party to whom a Party grants a direct or indirect sublicense under any Esperion Technology, Otsuka Technology or Joint Technology, as the case may be, to Develop, Manufacture or Commercialize a Licensed Product in the Field pursuant to Section 8.1.2 (Otsuka Sublicense Rights) or Section 8.2.2 (Esperion Sublicense Rights) or the last sentence of Section 12.1.2 (Ownership). In addition, a Party’s Affiliate to whom such Party grants a direct or indirect sublicense under any Esperion Technology, Otsuka Technology or Joint Technology, as the case may be, to Develop, Manufacture or Commercialize a Licensed Product in the Field pursuant to Section 8.1.2 (Otsuka Sublicense Rights) or Section 8.2.2 (Esperion Sublicense Rights) shall be deemed a Sublicensee for purposes of this Agreement. For clarity, Third Party contract research organizations, distributors, wholesalers, CMOs and the like will not be Sublicensees, and agreements between a Party and such entities will not be sublicenses, for purposes of this Agreement.

**1.124 “Sued Party”** has the meaning set forth in Section 12.4.1 (Third Party Infringement Suit).

**1.125 “Supply Agreement”** has the meaning set forth in Section 5.3 (Licensed Product Supply Agreements).

**1.126 “Term”** has the meaning set forth in Section 13.1 (Term).

**1.127 “Territory”** means (a) the Esperion Territory and/or (b) the Otsuka Territory, as applicable.

**1.128 “Third Party”** means a Person other than a Party and its Affiliates.

**1.129 “Third Party IP Agreement”** has the meaning set forth in Section 12.4.2.

**1.130 “Tier 1”** has the meaning set forth in Section 9.3 (NHI Price Listing Milestone Payment).

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1.131 “**Tier 2**” has the meaning set forth in Section 9.3 (NHI Price Listing Milestone Payment).

1.132 “**Tier 3**” has the meaning set forth in Section 9.3 (NHI Price Listing Milestone Payment).

1.133 “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, in any language, including any katakana trademark, including the goodwill and activities associated with each of the foregoing.

1.134 “**Transition Activities**” has the meaning set forth in Section 13.4.5(a) (Transition Activities).

1.135 “**United States**” means the United States of America and its territories, possessions and commonwealths.

1.136 “**Valid Claim**” means any claim, within any Esperion Patent Rights in the Field, that: (a) has been granted by a patent granting authority, that is in force and unexpired, and that has not been surrendered, abandoned, revoked, disclaimed or held invalid or unenforceable by a decision taken by an administrative or civil court in the Otsuka Territory; or (b) is a pending claim in a patent application within the Esperion Patent Rights in the Field [\*\*\*]; provided that any such pending claim in such patent application that has been pending for more than [\*\*\*] years following the first filing date of such patent application in the Otsuka Territory shall cease to be a Valid Claim in the Otsuka Territory unless and until it becomes a granted claim fulfilling the requirements under (a) above while the Royalty Term is otherwise ongoing. For clarity, for purposes of the foregoing proviso, if such patent application is a continuation application or a divisional application, the “first filing date” with respect to such patent application shall mean the filing date in the Otsuka Territory of the original (parent) patent application on which such continuation application or divisional application is based.

## 2. DEVELOPMENT

### 2.1 Licensed Products.

2.1.1 Overview. Subject to the terms and conditions of this Agreement, including oversight by the JCC, except with respect to Non-Clinical Studies, Otsuka shall be solely responsible for the Development of the Licensed Products in the Field in the Otsuka Territory, including for the conduct of all Clinical Studies to obtain and maintain Regulatory Approvals of the Licensed Products in the Otsuka Territory. In accordance with Section 2.1.5, Esperion shall be solely responsible for the conduct of Non-Clinical Studies identified by the Parties as required for Otsuka to obtain Regulatory Approval of a Licensed Product in the Otsuka Territory.

Subject to the terms and conditions of this Agreement, including Sections 2.1.6 and 3.8, Otsuka shall use Commercially Reasonable Efforts to Develop the Licensed Products in the Field in the Otsuka Territory, including: (a) as provided in Section 2.1.2, Developing each Licensed Product pursuant

to the applicable Development Plan; and (b) pursuing Regulatory Approval of each Licensed Product in the Otsuka Territory.

**2.1.2 Development Plans.** For each Licensed Product, other than Authorized Generic Products, the Development activities to be undertaken by Otsuka for such Licensed Product to achieve Regulatory Approval in the Field in the Otsuka Territory shall be set forth in a development plan (each such plan, as amended from time to time in accordance with this Agreement, a “**Development Plan**”). Development activities set forth in each Development Plan shall at all times be designed to be in compliance with all applicable Laws and in accordance with professional and ethical standards customary in the pharmaceutical industry. The Development activities to be undertaken by Otsuka for the Initial Product to achieve Regulatory Approval for the Initial Indication in the Otsuka Territory are set forth in the Development Plan attached hereto as Schedule 2.1.2 (Initial Development Plan for Initial Product). For clarity, no Development Plan will be required or prepared for any Authorized Generic Product.

**2.1.3 Performance.** Otsuka shall conduct all Development activities in a sound scientific manner and in compliance with applicable Law and the applicable Development Plan, as such Development Plan may be amended from time to time in accordance with this Agreement. Notwithstanding anything to the contrary in this Agreement, Otsuka shall not be obligated to undertake or continue any activity under a Development Plan if: (a) Otsuka reasonably determines that performance of such activity would violate applicable Law; or (b) with respect to any Clinical Study, (i) a Regulatory Authority or independent safety data review board for such Clinical Study has required or recommended termination or suspension of such Clinical Study or (ii) Otsuka believes in good faith that termination or suspension of such Clinical Study is warranted because of safety or tolerability risks or the lack of suitable risk benefit ratio to the study subjects. In the event that Otsuka determines not to undertake or continue any activity under a Development Plan in accordance with the immediately preceding sentence, Otsuka shall promptly notify Esperion of such determination, and shall use all reasonable efforts to notify and consult with Esperion prior to making such determination.

**2.1.4 Development Costs.** Otsuka shall be solely responsible for all costs and expenses incurred in connection with the Development of the Licensed Products in the Field in the Otsuka Territory.

**2.1.5 Non-Clinical Studies.** Esperion shall conduct all Non-Clinical Studies identified by the Parties as required by the applicable Regulatory Authority for Otsuka to obtain Regulatory Approval of Licensed Products in the Otsuka Territory. Otsuka shall reimburse the Out-of-Pocket Costs incurred by Esperion for such Non-Clinical Studies and any direct labor (FTE) costs that are reasonably allocable to such Non-Clinical Studies within [\*\*\*] of receipt of an invoice and supporting documentation, which supporting documentation shall include [\*\*\*] to such Non-Clinical Studies.

**2.1.6 Combination Products.** With respect to the Combination Product, Otsuka shall use Commercially Reasonable Efforts to Develop and Commercialize the Combination Product in the Field in the Otsuka Territory, including (a) as provided in Section

2.1.2, Developing such Combination Product pursuant to the applicable Development Plan; and (b) pursuing Regulatory Approval of such Combination Product in the Otsuka Territory; provided, however, that notwithstanding anything to the contrary in this Agreement, Otsuka shall have final decision-making authority with respect to such Development and Commercialization, including the timing of the initiation of the Development of such Combination Product.

**2.2 Option to New Indications.** If Esperion obtains positive results from a Phase II Clinical Trial which supports the initiation of a Phase III Clinical Trial for a New Indication for a Licensed Product in the United States, Esperion shall provide Otsuka with the applicable clinical study report (“CSR”) for such Phase II Clinical Trial and any other data and information reasonably requested by Otsuka that relates to such Phase II Clinical Trial and, upon Otsuka’s written request, Esperion shall make an oral presentation to Otsuka with respect thereto. Otsuka will have an exclusive option (the “**Option**”) to include such New Indication in the Field and the licenses under Section 8.1 in return for adjustments and/or additions to the regulatory milestone payments in Section 9.2 (Regulatory Milestone Payments), which could include the possible addition of Development milestones and additional or adjusted regulatory milestones but which would not include adjustments or additions to any other payments in Section 9 (Financial Terms; Royalty Reports; Payments and Audits) (and, for clarity would not include any adjustment to the sales milestones or royalty terms as set forth in Section 9.5 and Section 9.6 as of the Effective Date). Esperion’s oral presentation to notify Esperion whether Otsuka wishes to proceed with a further assessment of the Option, and in the event Otsuka provides written notice to Esperion of its intent to proceed with such further assessment within such [\*\*\*] period, Otsuka shall have an additional [\*\*\*] from the date of such written notice to further assess whether to exercise the Option (such [\*\*\*] and [\*\*\*] periods, collectively, the “**Assessment Period**”). During the Assessment Period, Esperion shall promptly respond to all reasonable requests by Otsuka for additional information relating to such New Indication. In the event Otsuka provides written notice of its intent to exercise the Option within the Assessment Period, the Parties shall negotiate in good faith for a period of [\*\*\*] (or such longer period as the Parties may agree) following such written notice (the “**Negotiation Period**”) to agree upon the terms of an amendment to this Agreement to adjust and/or add to the regulatory milestone payments (including the possible addition of Development milestone payments) in Section 9.2 (Regulatory Milestone Payments). If the Parties cannot agree upon the terms of such amendment within the Negotiation Period, the Parties shall, [\*\*\*].

### **2.3 Records, Reports and Information Sharing.**

**2.3.1 Records.** Otsuka shall maintain complete and accurate records of all Development and other scientific activities conducted by or on behalf of it in connection with each Licensed Product (other than Authorized Generic Products), including all data and other information resulting from such activities (which records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection with such Development and scientific activities)), in sufficient detail and in sound scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the

Development activities and Clinical Studies with respect to each Licensed Product (other than Authorized Generic Products) by Otsuka.

**2.3.2 Development Activities Reports.** Otsuka shall provide to Esperion, on a [\*\*\*] basis through the JCC, a confidential written progress presentation that summarizes for each Licensed Product (other than Authorized Generic Products) the Development activities conducted by or on behalf of Otsuka with respect to each such Licensed Product since the previous progress presentation. In addition, Otsuka shall promptly share with Esperion summaries of all material developments and information that it comes to possess relating to the Development of any Licensed Products, including Safety Concerns and data generated from Clinical Studies of such Licensed Product. In addition, Otsuka shall translate CSRs and top-line data derived from Clinical Studies of Licensed Products as soon as practically possible into English and shall share such translated CSRs and top-line data with Esperion promptly after completion of such translation into English; provided that Esperion shall reimburse Otsuka for all Out-of-Pocket Costs incurred by Otsuka for such translations of CSRs and top-line data.

**2.3.3 Access to Records.** At any time during the Term, Esperion shall have the right, at its sole cost and expense, to review all records relating to such Development undertaken by Otsuka with respect to each Licensed Product, at reasonable times, and upon prior written request.

**2.4 Third Parties.** Otsuka shall be entitled to utilize the services of Third Parties to perform Development activities under this Section 2.4 (Third Parties), provided that (a) Otsuka shall require that such Third Party operates in a manner consistent with this Agreement, including [\*\*\*] and (b) Otsuka shall remain at all times fully liable for its respective responsibilities and the acts and omissions of such Third Parties engaged by it under this Agreement. Otsuka shall require that any Third Party agreement entered into pursuant to this Section 2.4 (Third Parties) include [\*\*\*]. Otsuka shall [\*\*\*]. Otsuka shall be solely responsible for direction of and communications with such Third Parties.

### **3. REGULATORY MATTERS**

**3.1 Responsibility for Regulatory Matters.** Subject to the terms and conditions of this Agreement, including oversight by the JCC, Otsuka shall be solely responsible, at its sole cost and expense, for all regulatory matters relating to each Licensed Product in the Otsuka Territory, including (a) overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, the applicable Regulatory Authority with respect to Licensed Products; (b) interfacing, corresponding and meeting with the applicable Regulatory Authority with respect to Licensed Products; (c) seeking and maintaining all Regulatory Approvals with respect to Licensed Products, including any amendments, supplements or modifications to Regulatory Approvals; and (d) maintaining and submitting all records required to be maintained or required to be submitted to the applicable Regulatory Authority with respect to Licensed Products, in each case in the Otsuka Territory. Notwithstanding anything to the contrary in this Agreement, Esperion shall be responsible, at its sole cost and expense, for (i) preparing the drug master file(s) for the API(s) containing data and information related to the Manufacture of the

API(s) for the Licensed Products (the “DMF”), including preparing the DMF in the applicable format required by the PMDA (ii) providing the DMF directly to the applicable Regulatory Authority in the Otsuka Territory, and (iii) communicating with Regulatory Authorities in the Otsuka Territory regarding the DMF. Otsuka shall be entitled to reference the DMF in Regulatory Documentation, including in applications for Regulatory Approval and in the Registration Dossier, for the Licensed Product in the Otsuka Territory. Esperion shall also provide to Otsuka, at Esperion’s sole cost and expense, (A) the open part of the DMF, such as the sections containing general information, control of drug substance, container closure system, and stability, (B) an eCTD containing data and information related to the Manufacture of Bulk Tablets, and (C) upon Otsuka’s request, but subject to Esperion’s consent, information in the closed part of the DMF which Otsuka reasonably believes is necessary for preparing Regulatory Documentation for the Otsuka Territory. Otsuka shall be responsible, at its sole cost and expense, for preparing the Japanese translation of such eCTD and converting such eCTD to the applicable format required by the PMDA. Otsuka shall provide Esperion with copies of the English translations of Module 1.2 and Module 2.3 of the Registration Dossiers for the Licensed Products in the Otsuka Territory (excluding the subsection of Module 2.3 covered by the DMF). Esperion shall provide all assistance reasonably requested by Otsuka in connection with such preparation and filing of Regulatory Documentation and communications with Regulatory Authorities, and, at the request of Otsuka, Esperion shall send representative(s) of Esperion to attend in-person meetings with Regulatory Authorities in the Otsuka Territory relating to the Manufacture of API(s) or Bulk Tablets, all at Esperion’s cost and expense.

**3.2 Communications with Regulatory Authorities.** Otsuka shall respond to all communications with the applicable Regulatory Authority relating to the Licensed Products in the Otsuka Territory. Within [\*\*\*] days after receipt of any Material Communication from such Regulatory Authority with respect to such Licensed Product, Otsuka shall provide Esperion with a brief written description, in English, of the principal issues raised in such Material Communication with such Regulatory Authority. Upon Esperion’s reasonable request after receiving a notice from Otsuka in accordance with the immediately preceding sentence, Otsuka shall, at its sole cost and expense, translate such Material Communication as soon as practically possible and shall provide to Esperion such translated Material Communication promptly after completion of such translation into English. Notwithstanding the foregoing, Otsuka shall not be required to provide a brief written description or a translation of any Material Communication that is conveyed at any meeting or teleconference that is attended by any Esperion representative pursuant to Section 3.3 (Meetings with Regulatory Authorities). Otsuka will allow Esperion a reasonable opportunity to review and comment on Otsuka’s proposed response to any Material Communications with such Regulatory Authority with respect to such Licensed Product, and Otsuka will reasonably consider all comments timely provided by Esperion in connection therewith; provided, however, Otsuka shall not be required to comply with the foregoing if to do so would cause Otsuka to fail to meet any deadline requested or required by any Regulatory Authority in the Otsuka Territory.

**3.3 Meetings with Regulatory Authorities.** Otsuka shall provide Esperion with reasonable advance notice of all formal meetings and formal teleconferences with the applicable Regulatory Authority pertaining to any Licensed Product in the Otsuka Territory, or with as much

advance notice as practicable under the circumstances. Otsuka shall use reasonable efforts, to the extent reasonably practicable and not restricted or prohibited by applicable Laws or the Regulatory Authority, to permit Esperion to have, at Esperion's expense, mutually acceptable representatives of Esperion attend, as observers, such formal meetings and formal teleconferences with such Regulatory Authority pertaining to such Licensed Product in the Otsuka Territory; provided, however, that Otsuka shall not be obligated to change or re-schedule any such meeting in order to accommodate the schedule of Esperion's representatives and if attendance by Esperion representatives would require Otsuka to reduce the number of required Otsuka participants at such meeting due to limitations on the number of attendees imposed by such Regulatory Authority, then at least one (1) Esperion representative shall be permitted to observe such meeting unless Otsuka provides reasonable reasons why attendance by Esperion representatives would be inappropriate or inadvisable or otherwise should not be permitted, in which case no Esperion representative will be permitted to observe such meeting. If Esperion requires an interpreter for its representatives attending any such Regulatory Authority meeting, Esperion shall retain, at its sole cost and expense, an interpreter who can provide simultaneous interpretation.

**3.4 Submissions.** With respect to each such Licensed Product, Otsuka shall allow Esperion a reasonable opportunity to review and comment on all material sections (specifically, Modules 1.8, 2.5.1 and 2.5.6) of the Registration Dossier to be submitted to Regulatory Authorities or other Governmental Authorities in the Otsuka Territory related to such Licensed Product and for that purpose Otsuka shall provide English versions of such Modules to Esperion in advance of submission of any such filings. Otsuka shall consider all comments timely provided by Esperion in connection therewith and accept such comments if reasonable, provided, however, Otsuka shall not be required to comply with the foregoing or delay submission of the Registration Dossier if to do so would cause Otsuka to fail to meet the filing target date set forth in the Development Plan or any deadline requested by any Regulatory Authority in the Otsuka Territory.

**3.5 NHI Price Listing.** Subject to the terms and conditions of this Agreement, Otsuka shall have the sole right, at its sole cost and expense, and shall use Commercially Reasonable Efforts to timely prepare and submit all necessary applications and documentation to seek to acquire, hold and maintain all NHI Price Listing necessary or useful to Commercialize each Licensed Product throughout the Otsuka Territory.

**3.6 Regulatory Documentation.** Upon Otsuka's reasonable request, Esperion shall provide Otsuka with all Regulatory Documentation, data and information owned or controlled by Esperion that relates to the Licensed Products to the extent necessary or useful to obtain or maintain Regulatory Approval of the Licensed Products in the Field in the Otsuka Territory.

**3.7 Right of Reference.** Each Party hereby grants to the other Party (as well as to the other Party's Sublicensees, when and if designated by the other Party from time to time) a non-exclusive, non-transferable right to rely upon, access, and reference all information and data (including all chemistry, manufacturing and controls information as well as data made, collected or otherwise generated in the conduct of any Clinical Studies or early access/named patient programs for the Licensed Products) included in or used in support of any regulatory filing, Regulatory Approval, drug master file or other Regulatory Documentation owned or Controlled

by such Party that relates to any Licensed Product as necessary or useful to obtain or maintain Regulatory Approval of a Licensed Product in the Otsuka Territory or the Esperion Territory, as the case may be. Such Party shall, if requested by the other Party, provide a signed statement that the other Party may rely upon, and the Regulatory Authority may access, in support of the other Party's application for such Regulatory Approval in its Territory, any underlying raw data or information submitted by such Party to the Regulatory Authority with respect to any regulatory filing, Regulatory Approval, drug master file or other Regulatory Documentation (including orphan drug applications and designations) owned or controlled by such Party or its Sublicensees that relates to any Licensed Product. In addition, upon request of either Party (on behalf of itself or a Sublicensee), the other Party shall obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of the Licensed Products in the Otsuka Territory or the Esperion Territory, as applicable (e.g., Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments).

**3.8 Authorized Generic Products.** Otsuka or its Affiliate that are Sublicensees may submit, or authorize submission of, an application for Regulatory Approval of an Authorized Generic Product at any time during the Term of this Agreement; provided, however, that Otsuka shall ensure that the launch of such Authorized Generic Product shall not occur more than [\*\*\*] days prior to the launch of an unauthorized Generic Product version of the applicable Licensed Product by a Third Party. Notwithstanding anything to the contrary in this Agreement, Otsuka shall have final decision-making authority with respect to the Development and Commercialization of Authorized Generic Products, including the timing of the initiation of the Development of Authorized Generic Products.

**3.9 Pharmacovigilance.** Within [\*\*\*] days after the Effective Date, the Parties shall negotiate in good faith and enter into a pharmacovigilance agreement ("**Pharmacovigilance Agreement**"), which shall define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures governing the coordination of collection, investigation, reporting and exchange of information concerning any adverse experiences, and any product complaints associated with adverse experiences, related to any Licensed Product sufficient to enable each Party (and their respective Sublicensees, if any) to comply with its legal and regulatory obligations. In addition, as appropriate, such Pharmacovigilance Agreement shall include the safety data exchange procedures governing the exchange of information affecting the class (e.g., Serious Adverse Events, emerging safety issues) and address responsibilities for Development Safety Update Report ("**DSUR**"), Periodic Safety Update Reports ("**PSUR**") and Risk Management Plans ("**RMP**"). Otsuka shall be responsible for all pharmacovigilance activities for the Licensed Products in the Field in the Otsuka Territory. Esperion shall own and shall be responsible for maintaining the global safety database for Licensed Products. The language of all communications and exchanges under the Pharmacovigilance Agreement shall be English.



#### **4. COMMERCIALIZATION**

##### **4.1 Responsibility, Cost and Diligence.**

**4.1.1 Otsuka Territory.** Subject to the terms and conditions of this Agreement, Otsuka shall be solely responsible, at its sole cost and expense, for all Commercialization activities relating to Licensed Products in the Otsuka Territory.

**4.1.2 Otsuka Commercial Diligence.** Subject to the terms and conditions of this Agreement, including Sections 2.1.6 and 3.8, Otsuka will use Commercially Reasonable Efforts to Commercialize each Licensed Product throughout the Otsuka Territory. Otsuka shall conduct all Commercialization activities for each Licensed Product in accordance with the applicable Otsuka Territory Commercialization Plan (other than with respect to Authorized Generic Products) and in compliance with applicable Laws and this Agreement.

##### **4.2 Initial Otsuka Territory Commercialization Plan.**

**4.2.1 Initial Commercialization Plan Summary.** By no later than the date of filing of the applicable application for Regulatory Approval for a Licensed Product (other than any Authorized Generic Product) in the Field in the Otsuka Territory, Otsuka shall deliver to the JCC an initial written plan setting forth a summary of the anticipated activities to be undertaken by Otsuka in connection with the Commercialization of such Licensed Product in the Otsuka Territory (the “**Otsuka Territory Commercialization Plan**”). Each Otsuka Territory Commercialization Plan shall provide an outline of the Commercialization activities for a Licensed Product (other than an Authorized Generic Product) in the Otsuka Territory, including [\*\*\*]. Commercialization activities set forth in each Otsuka Territory Commercialization Plan shall at all times be designed to be in compliance with this Agreement, all applicable Laws and in accordance with professional and ethical standards customary in the pharmaceutical industry. For clarity, Otsuka shall have no obligation to prepare or provide any Otsuka Territory Commercialization Plan for any Authorized Generic Product; provided, however that, commencing no later [\*\*\*] months prior to the First Commercial Sale of each Authorized Generic Product, and thereafter on or before [\*\*\*] of each Calendar Year, Otsuka shall provide to the JCC annual sales projections of each Authorized Generic Product.

**4.2.2 Amendments to Otsuka Territory Commercialization Plan.** The Otsuka Territory Commercialization Plan for a Licensed Product (other than an Authorized Generic Product) shall subsequently be updated and modified by Otsuka, from time to time at its discretion but no less frequently than [\*\*\*], based upon, among other things, Otsuka’s Commercialization activities with respect to such Licensed Product in the Otsuka Territory. A copy of the Otsuka Territory Commercialization Plan as so updated shall be promptly provided to the JCC.

##### **4.3 Advertising and Promotional Materials; Product Trademarks.**

**4.3.1 Global Branding.** Esperion shall, from time to time during the Term, develop (and thereafter modify and update) a global branding strategy (including global

positioning, promotional messages, colors and other visual branding elements) for each Licensed Product for use throughout the world (the “**Global Branding Strategy**”). Esperion shall submit the Global Branding Strategy for a Licensed Product to the JCC at least [\*\*\*]. Esperion shall consider in good faith any comments provided by Otsuka with respect to the Global Branding Strategy.

**4.3.2 Otsuka Advertising & Promotion.** Otsuka shall be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of relevant written sales, promotion and advertising materials relating to each Licensed Product for use in the Otsuka Territory (“**Otsuka Territory Promotional Materials**”). All such Otsuka Territory Promotional Materials will be compliant with applicable Law and consistent in all material respects with the Global Branding Strategy for such Licensed Product in the Otsuka Territory. Notwithstanding the foregoing, if the Parties, in accordance with Section 6.1.7 (JCC Decision-Making) mutually agree upon a Licensed Product brand strategy that is specific to the Otsuka Territory, including any Licensed Product positioning or key messaging for the Otsuka Territory that is inconsistent with the Global Branding Strategy (“**Otsuka Territory-Specific Brand Strategy**”), Otsuka shall have the right to implement such Otsuka Territory-Specific Brand Strategy. Otsuka will submit representative samples, printed in the English language, of its Otsuka Territory Promotional Materials developed by it for use in the Otsuka Territory to the JCC [\*\*\*]. Otsuka shall consider in good faith any timely comments Esperion may have with respect to such samples of Otsuka Territory Promotional Materials.

**4.3.3 Esperion Advertising & Promotional Materials.** From time to time, and in any event upon the reasonable request of Otsuka, Esperion shall provide to Otsuka copies of Licensed Product promotional materials which have been used in countries where Esperion commercializes the Licensed Product, including the United States, in order for Otsuka to align its promotional materials with the Global Branding Strategy.

**4.3.4 Product Trademarks.** Otsuka may propose and the Parties will discuss at the JCC a katakana Trademark which is a Japanese notation of an Esperion Trademark for Licensed Products in the Otsuka Territory. In addition, if Otsuka believes the Esperion Trademarks are not appropriate for the Otsuka Territory, whether due to linguistic reasons, any notice, rejection or refusal by MHLW or other Regulatory Authority, market research showing that Esperion Trademarks are not appropriate or otherwise, Otsuka may propose for discussion at the JCC an alternative Trademark (other than the Esperion Trademarks) for Licensed Products in the Otsuka Territory. Otsuka may also propose and the Parties will discuss at the JCC additional Trademarks (e.g., logos and slogans) to be used in the Commercialization of Licensed Products in the Otsuka Territory. Any such katakana Trademark, alternative Trademark or additional Trademark that is approved by the JCC in accordance with Section 6.1.7 (JCC Decision-Making) shall be a Product Trademark.

**4.4 Reporting Obligations.** Following the First Commercial Sale of each Licensed Product, [\*\*\*], Otsuka shall provide Esperion through the JCC a written presentation summarizing in reasonable detail Otsuka’s progress under the Otsuka Territory Commercialization Plan during the prior [\*\*\*] period. In addition, Otsuka shall provide Esperion with written notice of the First

Commercial Sale of each Licensed Product in the Otsuka Territory within [\*\*\*] days after such event; provided, however, that in all circumstances, Otsuka shall inform Esperion of such event prior to public disclosure of such event by Otsuka. Otsuka shall provide such other information to the JCC as Esperion may reasonably request with respect to Commercialization of such Licensed Product and shall keep the JCC reasonably informed of Otsuka's Commercialization activities with respect to such Licensed Product.

**4.5 Sales and Distribution.** Each Party or its Sublicensees, if applicable, shall be responsible for booking sales in its respective Territory. The Parties will use their good faith efforts to coordinate the timing of any public disclosure of Net Sales of the Licensed Products in the Otsuka Territory prior to such disclosure and, in any event, Esperion shall communicate and coordinate with Otsuka's investor relations department before making any such public disclosure. Each Party and/or its Sublicensees may warehouse Licensed Products both inside and outside of such Party's Territory, provided that any sales with respect to such Licensed Products are booked in such Party's Territory. Each Party and/or its Sublicensees shall be solely responsible for handling all returns of any Licensed Product sold in its Territory, as well as all aspects of Licensed Product order processing, invoicing and collection, distribution, inventory and receivables of Licensed Products sold in its Territory.

**4.6 Ex-Territory Sales; Export Monitoring.**

**4.6.1 Ex-Territory Sales.** Subject to applicable Law, neither Party shall engage in any advertising or promotional activities relating to any Licensed Product directed primarily to customers or other buyers or users of such Licensed Product located outside its Territory or accept orders for Licensed Products from or sell Licensed Products into such other Party's Territory for its own account. If a Party receives any order for any Licensed Product from, or for delivery into, the other Party's Territory, it shall refer such orders to the other Party. [\*\*\*].

**4.6.2 Export Monitoring.** Each Party and its Sublicensees will use Commercially Reasonable Efforts to monitor and prevent exports of Licensed Products from its own Territory for Commercialization in the other Party's Territory using methods permitted under applicable Law that are commonly used in the industry for such purpose, and shall promptly inform the other Party of any such exports of Licensed Products from its Territory of which it becomes aware, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Law [\*\*\*].

**4.7 Recalls, Market Withdrawals or Corrective Actions.**

**4.7.1 Notification and Determination.** In the event that any Regulatory Authority threatens or initiates any action to remove a Licensed Product from the market, the Party receiving notice thereof shall notify the other Party of such communication immediately (but in no event later than [\*\*\*] hours after receipt thereof).

**4.7.2 Responsibility of the Parties.** During the Term, Otsuka shall at all times be responsible for and shall determine whether to initiate any recall, withdrawal or market notification of a Licensed Product in the Field in the Otsuka Territory and Esperion shall at all

times be responsible for and shall determine whether to initiate any recall, withdrawal or market notification of a Licensed Product in the Field in the Esperion Territory, including the scope of such recall or withdrawal (e.g., a full or partial recall, or temporary or permanent recall or market notification); provided, however, that before such responsible Party initiates a recall, withdrawal or market notification in its respective Territory, the Parties shall promptly meet in-person or by means of teleconference, videoconference or other similar communications equipment and discuss in good faith the reasons therefor; provided further, that such discussions shall not delay any action that such responsible Party believes has to be taken in relation to any recall, withdrawal or market notification.

## 5. MANUFACTURE AND SUPPLY

**5.1 Licensed Products.** Subject to the terms and conditions of this Agreement and the Supply Agreement (as defined below), Esperion shall Manufacture and supply Bulk Tablets to Otsuka in compliance with all applicable Laws, including, as applicable, cGMP, for clinical and commercial use in the Otsuka Territory, unless and until Otsuka is ready to Manufacture (or have Manufactured) the Bulk Tablets from the active pharmaceutical ingredient(s) (the “**API(s)**”) supplied by Esperion. Otsuka shall be responsible, at its sole cost and expense, for the primary and secondary packaging of the Bulk Tablets for clinical and commercial use in the Otsuka Territory.

**5.2 Pricing.** For clinical use, Esperion shall supply the API(s) or Bulk Tablets on an [\*\*\*] basis at [\*\*\*]. For commercial use, Esperion shall supply the API(s) or Bulk Tablets on an [\*\*\*] basis at [\*\*\*]. [\*\*\*]. At the time Esperion submits the first invoice to Otsuka under each Supply Agreement, Esperion will provide to Otsuka a summary of [\*\*\*]. The Parties will negotiate in good faith and include in each Supply Agreement a provision pursuant to which Esperion will be required to provide a similar summary of [\*\*\*] to Otsuka at any time [\*\*\*].

**5.3 Licensed Product Supply Agreements.** Within [\*\*\*] days following the Effective Date, the Parties will commence negotiations in good faith towards a supply agreement (and any other necessary ancillary agreements including a quality technical agreement (“**Quality Agreement**”)) for clinical supply of Bulk Tablets from Esperion to Otsuka and, reasonably in advance of the First Commercial Sale of the first Licensed Product, the Parties will negotiate in good faith towards a supply agreement (and any other necessary ancillary agreements including a Quality Agreement) for commercial supply of Bulk Tablets from Esperion to Otsuka (each, a “**Supply Agreement**”). Each Supply Agreement will be on commercially reasonable terms customary to CMO supply agreements, as applicable, and shall include (a) the terms and conditions in this Section 5 (Manufacture and Supply), (b) forecasting and ordering terms that are consistent with Esperion’s obligations to its CMO’s Manufacturing, (c) key performance indicators (including criteria regarding Manufacturing capacity, quantity, timeliness of delivery, quality and cost that are consistent with prevailing industry standards for CMO agreements), (d) specifications (including shelf life requirements), provisions relating to safety stock and failure to supply (including appropriate remedies in the event of a failure to supply), change control provisions, warranties, and acceptance and rejection procedures, in each case as applicable, and (e) provisions relating to (i) audits and inspections by Governmental Authorities as set forth in Section 5.7.2 (By

Governmental Authority), (ii) validation and testing as set forth in Section 5.5 (Validation and Testing), and (iii) the disposition, including Esperion's buy-back, of any inventory of API(s) held by Otsuka following termination of this Agreement as set forth in Section 13.4 (Special Consequences of Certain Terminations). The Parties anticipate that the specifications for Bulk Tablets for the Otsuka Territory as set forth in the Supply Agreement will be the same in all material respects as the then-current FDA-approved specifications for Bulk Tablets. In the event the specifications for Bulk Tablets for the Otsuka Territory as set forth in a Supply Agreement differ in any material respect from the then-current FDA-approved specifications for Bulk Tablets as a result of changes required by the PMDA or changes mutually agreed to by the Parties, the Parties will discuss sourcing for the supply of Bulk Tablets conforming to such differing specifications, Esperion shall use Commercially Reasonable Efforts to supply the Bulk Tablets conforming to such differing specifications through Esperion's supply chain, and Esperion shall supply the Bulk Tablets conforming to such differing specifications on an [\*\*\*] basis at [\*\*\*]; provided, that [\*\*\*].

**5.4 Technology Transfer.** In the event Otsuka sends Esperion written notice requesting technology transfer to enable Otsuka, or the applicable CMOs selected by mutual agreement of the Parties, to Manufacture Bulk Tablets from API(s) supplied by Esperion for the Otsuka Territory, then the Parties shall mutually agree on a technology transfer plan for such technology transfer and shall implement the technology transfer activities in accordance with such mutually agreed technology transfer plan. For clarity, such technology transfer shall not include the manufacturing process for any API(s). Esperion shall use Commercially Reasonable Efforts to support the technology transfer to Otsuka, or the applicable CMO, and shall [\*\*\*]. Otsuka shall [\*\*\*] to implement the technology transfer.

**5.5 Validation and Testing.** At Otsuka's request and, if applicable, as required by any Regulatory Authority in the Otsuka Territory, Esperion shall conduct validation, annual stability testing and any other specific testing of Bulk Tablets Manufactured and supplied by or on behalf of Esperion as required for the Otsuka Territory. Otsuka shall reimburse the Out-of-Pocket Costs incurred by Esperion for such validation and testing activities and any labor (FTE) costs that are reasonably allocable to such activities within [\*\*\*] of receipt of an invoice and supporting documentation, which supporting documentation shall include copies of Third Party contracts and invoices reflecting the Out-of-Pocket Costs incurred by Esperion and a statement of Esperion's direct labor costs reflecting FTE rates and the number of FTEs allocable to such validation and testing activities.

**5.6 Third Parties.** Each Party shall be entitled to utilize the services of CMOs or other Third Parties to perform Manufacturing activities under this Agreement, provided that [\*\*\*].

**5.7 Audits and Inspections.**

**5.7.1 By Otsuka.** If Esperion elects to inspect or audit any facilities of its CMOs or other Third Party Manufacturers with respect to Manufacture of Bulk Tablets or API(s) for the Otsuka Territory, Esperion shall notify Otsuka of such audit or inspection and Otsuka shall have the right, but not the obligation, to accompany Esperion and observe and review such

inspection or audit (to the extent permitted); and in any event, Esperion shall provide Otsuka with copies of all reports of Esperion's audits or inspections of its CMOs and other Third Party Manufacturers relating to Manufacture of Bulk Tablets or API(s) for the Otsuka Territory. Such reports shall be deemed Esperion's Confidential Information. All inspections and audits of such CMOs and other Third Party Manufacturers shall be led by Esperion including with respect to the drafting of any audit reports, the review and approval of such reports and any responses from the applicable CMO or other Third-Party Manufacturer with respect to such reports. Esperion shall have final say with respect to any disputes between the Parties related to the content of any audit report or the responses from the applicable CMO or Third-Party Manufacturer with respect to such audit report. If permitted by the applicable CMO or Third-Party Manufacturer, Otsuka shall be permitted to have one (1) auditor (together with an interpreter) participate in the audit of such facilities, provided that Esperion shall use good faith efforts to ensure that one (1) auditor (plus one (1) interpreter) from Otsuka participates in such audit. Esperion shall use Commercially Reasonable Efforts to include in each agreement between Esperion and its CMOs and other Third Party Manufacturers that Manufacture Bulk Tablets or API(s) for the Otsuka Territory [\*\*\*]. Esperion retains the sole right to conduct "for cause" audits of the facilities of its CMOs or other Third Party Manufacturers; provided, however, that if Otsuka identifies the need to perform a "for cause" audit of such facilities to address quality or compliance issues related to Bulk Tablets or API(s) Manufactured for the Otsuka Territory (including to address any notice from a Governmental Authority of noncompliance with applicable Laws), as well as in connection with the preparation for submission of Regulatory Documentation in Otsuka Territory and in response to Regulatory Authority requirements in Otsuka Territory, Otsuka shall notify Esperion and Esperion shall schedule and conduct such audit as permissible by the applicable contractual agreement with the such CMO or Third Party Manufacturer. In the event Bulk Tablets or API(s) are Manufactured for the Otsuka Territory by Esperion or its Affiliates, instead of or in addition to such Manufacture by a CMO or other Third Party Manufacturer, Esperion shall permit Otsuka's representatives to conduct remote (off-site) audits and to visit, inspect and audit Esperion's and its Affiliates' facilities used in such Manufacture of Bulk Tablets or API(s) for the Otsuka Territory to observe such Manufacturing, discuss such Manufacturing with appropriate personnel, audit batch documentation and other records relating to such Manufacturing and otherwise audit compliance with this Agreement, the applicable Supply Agreement and Quality Agreement and applicable Laws. Otsuka may inspect and conduct onsite audits of such facilities of Esperion and its Affiliates during regular business hours, and may conduct remote and onsite audits of such facilities upon reasonable advance notice to Esperion, not more than once in any [\*\*\*] month period; provided, however, that Otsuka shall be entitled to conduct "for cause" audits of such facilities of Esperion and its Affiliates more frequently as and when necessary to address quality or compliance problems relating to Bulk Tablets or API(s) Manufactured by Esperion or its Affiliates for the Otsuka Territory (including to address any notice from a Governmental Authority of noncompliance with applicable Laws if such noncompliance relates to or may affect such Manufacture for the Otsuka Territory, or issuance by the FDA of a Form 483 or Warning Letter or a comparable notice issued by any other Governmental Authority), as well as in preparation for submission of Regulatory Documentation in the Otsuka Territory and in response to Regulatory Authority requirements in the Otsuka Territory.

**5.7.2 By Governmental Authority.** If any Governmental Authority carries

out or gives notice of its intention to carry out any inspection or audit of Esperion or any of its Affiliates or CMOs or other Third Party Manufacturers in relation to Manufacture of Bulk Tablets or API(s) for the Otsuka Territory, Esperion shall promptly notify Otsuka thereof and (a) if such inspection or audit is of Esperion or its Affiliates, Esperion shall use reasonable efforts to ensure that Otsuka will have the right to be present at such inspection or audit to the extent related to Esperion's or its Affiliates' Manufacture of Bulk Tablets or API(s) for the Otsuka Territory, and (b) if such inspection or audit is of Esperion's CMOs or other Third Party Manufacturers, Esperion shall, to the extent permitted by its contractual agreement with the applicable CMO or Third Party Manufacturer, permit Otsuka to observe any such inspection or audit to the extent related to the Manufacture of Bulk Tablets or API(s) for the Otsuka Territory. Following receipt of the inspection results or audit observations of the Governmental Authority from such inspection or audit (a redacted copy of which Esperion will promptly provide to Otsuka to the extent it relates to the Bulk Tablets or API(s) Manufactured for the Otsuka Territory), Esperion will prepare any appropriate responses. A copy of the responses will be provided to Otsuka for review and comment on such responses in advance of the date such responses are due, to the extent such responses pertain to the Manufacture of Bulk Tablets or API(s) for the Otsuka Territory, and Esperion shall consider Otsuka's comments in good faith prior to responding. With respect to any dispute between the Parties related to such responses, Esperion shall have the final say. For inspections at Esperion's CMOs and other Third-Party Manufacturers, Esperion shall provide to Otsuka a summary of any inspections and related findings that specifically pertain to the Manufacture of Bulk Tablets or API(s) for the Otsuka Territory to Otsuka. Such information shall be redacted with respect to any CMO or Third Party Manufacturer confidential or proprietary information.

## **6. COLLABORATION MANAGEMENT**

### **6.1 Joint Collaboration Committee.**

**6.1.1 Overview.** Within [\*\*\*] days after the Effective Date, the Parties shall establish a Joint Collaboration Committee to oversee the Development and regulatory activities relating to the Licensed Products in the Field in the Otsuka Territory, including reviewing and guiding implementation of the Development in the Otsuka Territory. The JCC shall also be responsible for the enumerated responsibilities set forth in Section 6.1.6 (JCC Responsibilities).

**6.1.2 Composition.** The JCC shall be comprised of [\*\*\*] members, with each Party contributing [\*\*\*] representatives who are employees of such Party. Each Party shall appoint its respective representatives to the JCC as of the Effective Date and may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other Party of such change. Each Party shall have at least [\*\*\*] JCC representatives who are executive level employees (vice president or above), and all JCC representatives shall have appropriate expertise, seniority, decision-making authority and ongoing familiarity with the Parties' activities hereunder. Additional representatives or consultants may from time to time, with prior notice to the other Party, be invited to attend JCC meetings, subject to such representatives and consultants (or the representative's or consultant's employer) undertaking confidentiality obligations, whether in a written agreement or by operation of law, no less stringent than the requirements of Section 7.1 (Nondisclosure Obligation).

**6.1.3 JCC Co-Chairpersons.** The JCC shall be co-chaired by a representative of each of Otsuka and Esperion (the “**Co-Chairpersons**”), the name of such representative of each Party to be communicated to the other Party prior to the first scheduled meeting of the JCC. The Co-Chairpersons’ JCC responsibilities shall include conducting meetings, including, when feasible, ensuring that objectives for each meeting are set and achieved and ensuring the objectives and results of each meeting are communicated to the senior management of each Party, in each case in close consultation with the Alliance Managers. A Co-Chairperson can be an Alliance Manager at the same time.

**6.1.4 Alliance Managers.**

(a) **Appointment.** Within [\*\*\*] days following the Effective Date, each Party will appoint (and notify the other Party of the identity of) an employee of such Party having a general understanding in matters related to pharmaceutical development, commercialization, and promotion, to act as its alliance manager under this Agreement (each, an “**Alliance Manager**”). The Alliance Managers shall be a member of the JCC and will serve as a primary point of contact for the other Party and will undertake such other tasks as are detailed in this Agreement or as may be assigned by the JCC. Each Alliance Manager shall attend each scheduled meeting of the JCC. Each Party may change its Alliance Manager at any time in its sole discretion with written notice to the other Party.

(b) **General Responsibilities.** Each Alliance Manager will be responsible to ensure a collaborative work environment between the Parties to ensure that the alliance is run smoothly, professionally and productively. Each Alliance Manager shall act in his or her discretion to facilitate the execution of the collaboration throughout their organization and will oversee and support implementation plans; promote effectiveness of the governance model and implementation of contractual provisions and lead any changes to enhance the alliance between both Parties; and facilitate the JCC (and other bodies) for effective decision making in a timely manner.

(c) **Specific Responsibilities.** The Alliance Managers shall be responsible for (i) scheduling meetings of the JCC, (ii) setting agendas for meetings with solicited input from other members and (iii) for acting as secretary at each meeting and preparing the draft minutes of such meeting, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JCC. Within [\*\*\*] days after each meeting, the drafting Alliance Manager shall provide the draft minutes to the other Alliance Manager for review and comment. The drafting Alliance Manager shall reasonably consider all comments from the other Alliance Manager that are provided within [\*\*\*] days. The drafting Alliance Manager shall prepare and submit revised final draft minutes for approval within [\*\*\*] days after receipt of such comments or upon the expiration of such [\*\*\*] day comment period. Beginning with Otsuka’s Alliance Manager, such responsibilities shall alternate between the Alliance Managers on a meeting-by-meeting basis after each meeting of the applicable committee.



**6.1.5 Meetings.** The JCC shall meet no less frequently than each Calendar Quarter until receipt of the first Regulatory Approval for the first Licensed Product in the Otsuka Territory and semi-annually (each [\*\*\*] months) thereafter, provided that either Party may propose an unscheduled JCC meeting any time during the Term and the Parties may mutually agree upon alternative meeting schedules, including less frequently. Meetings can be conducted in person or by means of teleconference, videoconference or other similar communications equipment. All meetings and proceedings for the JCC shall take place in English. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives.

**6.1.6 JCC Responsibilities.** The JCC shall have the following responsibilities with respect to the Development, Manufacturing and Commercialization of Licensed Products pursuant to this Agreement:

(a) discussing, reviewing and approving the Development Plans and amendments or modifications to the Development Plans;

(b) discussing, reviewing and approving the Development of new formulations of Licensed Products or the Development of any New Combination Product;

(c) discussing and reviewing the implementation of the Development Plans, and reviewing the status and results of such Development Plans;

(d) discussing, reviewing and approving Clinical Studies, including post-marketing studies proposed to be sponsored or supported (through supply of Licensed Products) by Otsuka, of Licensed Products in the Otsuka Territory, including the approval of the relevant study design or summary of the relevant protocol and related documentation;

(e) discussing and reviewing the status of Licensed Products, including material Development and Manufacturing matters in the Esperion Territory and the Otsuka Territory;

(f) discussing and reviewing the Global Branding Strategy and discussing, reviewing and approving any Otsuka Territory-Specific Brand Strategy;

(g) discussing, reviewing and approving the Otsuka Territory Commercialization Plans and amendment or modifications to the Otsuka Territory Commercialization Plans;

(h) discussing and reviewing the implementation of such Otsuka Territory Commercialization Plans, and reviewing the status and results of such Otsuka Territory Commercialization Plans;

(i) discussing, reviewing and approving any alternative or additional Product Trademarks for the Otsuka Territory pursuant to Section 4.3.4 (Product Trademarks);

(j) reviewing representative samples of Otsuka Territory Promotional Materials developed for use in the Otsuka Territory as provided in Section 4.3.2;

(k) reviewing a publication strategy pursuant to which the Parties may publish certain key results achieved in connection with this Agreement as provided in Section 7.2.1;

(l) overseeing the JCC's subcommittees and ensuring effective participation in each such committee's operations by any of its members;

(m) addressing any other matters regarding the Development, and Manufacturing of Licensed Products referred to the JCC by the terms of this Agreement; and

(n) performing such other activities as the Parties agree in writing shall be the responsibility of the JCC.

#### **6.1.7 JCC Decision-Making.**

(a) **Voting.** With respect to decisions of the JCC, the representatives of each Party shall have collectively one (1) vote on behalf of such Party. For each meeting of the JCC, the attendance of at least [\*\*\*] representatives of each Party shall constitute a quorum. Action on any matter may be taken at a meeting, by teleconference, by videoconference or by written agreement.

(b) **Escalation.** The JCC shall attempt to resolve any and all decisions and disputes before it by consensus. If the JCC is unable to reach consensus with respect to a decision or dispute regarding any matter within the JCC's responsibilities for a period in excess of [\*\*\*] days, then the dispute shall be submitted to the Chief Executive Officer of Esperion and the Chief Executive Officer of Otsuka or his or her designee for resolution. If such dispute cannot be resolved for a period in excess of [\*\*\*] days following escalation (or such other period as the Parties may agree), then Section 6.1.7(c) (Tie-Breaking) shall apply.

(c) **Tie-Breaking.** If a dispute cannot be resolved under Section 6.1.7(b) (Escalation), then:

(i) The Chief Executive Officer of Otsuka or his or her designee shall have the deciding vote if the dispute relates to [\*\*\*].

(ii) The Chief Executive Officer of Esperion shall have the deciding vote if the dispute relates to:

a) [\*\*\*];

b) [\*\*\*]; and

c) [\*\*\*].

(iii) All matters within the JCC's responsibilities that cannot be resolved under Section 6.1.7(b) (Escalation) that are not subject to a Party's deciding vote pursuant to clause (i) or clause (ii) of this Section 6.1.7(c) (including [\*\*\*]), shall be subject to the mutual agreement of both Parties and shall not be subject to arbitration or any other form of external dispute resolution.

For the avoidance of doubt, all matters relating to the Development, Manufacturing and Commercialization of a Licensed Product in the Esperion Territory shall be decided by Esperion and shall not be subject to decision-making by the JCC.

(d) **Limitations.** Neither the JCC nor any subcommittee of the JCC shall have decision-making authority regarding any of the following matters, and neither Party shall be permitted to exercise its tie-breaking authority under Section 6.1.7(c) (Tie-Breaking), such that the resulting decision would have any of the following results:

(i) the imposition of any requirements on the other Party to undertake obligations beyond those for which it is responsible, or forgo any rights, under this Agreement;

(ii) the imposition of any requirements that the other Party take or decline to take any action that would result in a violation of any Law or any agreement with any Third Party or the infringement of intellectual property rights of Third Parties;

(iii) any matters that would excuse such Party from any of its obligations specifically enumerated under this Agreement; or

(iv) modifying the terms of this Agreement or taking any action to expand or narrow the responsibilities of the JCC (but excluding amendments and modifications to any schedules or exhibits to this Agreement that are expressly permitted under this Agreement).

**6.1.8 Subcommittee.** The Parties or the JCC shall have the right to create such subcommittees of the JCC as they or it may deem appropriate or necessary (such as a finance subcommittee, or other appropriate subcommittees). Each such subcommittee shall report to the JCC, which shall have authority to approve or reject recommendations or actions proposed thereby, subject to the terms of this Agreement.

(a) **Collaboration Principles.** In performing its obligations and exercising its rights hereunder (including acting through its executives, representatives on any of the committees and its Alliance Managers), each Party shall [\*\*\*] to undertake and perform its obligations in a timely and efficient manner [\*\*\*].

(b) **Confidentiality.** All information disclosed by either Party or its representatives to the other Party or its representatives under this Section 6 (Collaboration Management) shall be deemed to be Confidential Information of the disclosing Party and maintained in accordance with Section 7 (Confidentiality and Publication).

(c) **Modifications.** The Parties shall meet from time to time to discuss whether any changes to the governance structure for the Parties' activities hereunder are necessary or advisable.

## 7. **CONFIDENTIALITY AND PUBLICATION**

### 7.1 **Nondisclosure Obligation.**

7.1.1 All Confidential Information disclosed by one Party to the other Party under this Agreement shall be maintained in confidence by the receiving Party and shall not be disclosed to a Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Confidential Information:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

(b) is known to the public before its receipt from the disclosing Party, or thereafter becomes known to the public through no breach of this Agreement by the receiving Party;

(c) is subsequently disclosed to the receiving Party by a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party; or

(d) is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

7.1.2 Notwithstanding the obligations of confidentiality and non-use set forth above and in Section 7.1.3 (Nondisclosure Obligation) below, a receiving Party may provide Confidential Information disclosed to it, and disclose the existence and terms of this Agreement as may be reasonably required in order to perform its obligations and to exploit its rights under this Agreement, and specifically to (i) Sublicensees, and their employees, directors, agents, consultants, advisors or other Third Parties as necessary or useful in connection with the exploitation of the Licensed Products in such Party's Territory in each case who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms of this Section 7.1 (Nondisclosure Obligation); (ii) Governmental Authorities or other Regulatory Authorities in any country, in order to obtain patents, and comply with statutory tax and legal requirements in any country or perform its obligations or exploit its rights under this Agreement, provided that such Confidential Information shall be disclosed only to the extent reasonably necessary to do so; (iii) the extent required by Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; and (iv) (a) any bona fide actual or prospective underwriters, investors, lenders or acquirers of a Party or substantially all its assets and to consultants and advisors of such Third Party, and (b) any bona fide actual or prospective

collaborators or strategic partners, including prospective Third Party Sublicensees, and to consultants and advisors of such Third Party, in each case of (a) and (b) during bona fide business discussions provided that the receiving party of such information is under an obligation of confidentiality of reasonable scope and duration with respect to such information. If a Party is required by Law to disclose Confidential Information that is subject to the non-disclosure provisions of this Section 7.1 (Nondisclosure Obligation), such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure. Notwithstanding Section 7.1.1 (Nondisclosure Obligation), Confidential Information that is required to be disclosed by Law shall remain otherwise subject to the confidentiality and non-use provisions of this Section 7.1 (Nondisclosure Obligation). If either Party concludes that a copy of any of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party shall provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, shall provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and shall take such Party's comments into consideration before filing such agreement.

**7.1.3** Each Party recognizes that the value to the other Party of the transactions under this Agreement depend, in part, on each Party protecting the secrecy of its Know-How. Therefore, without limiting any Party's right to license its Know-How, subject to the terms of this Agreement, in any way it chooses, each Party shall use Commercially Reasonable Efforts to protect the confidentiality of its Know-How as determined in such Party's reasonable business judgment.

## **7.2 Publication and Publicity.**

**7.2.1 Publication.** Esperion shall develop and share with the JCC a publication strategy pursuant to which the Parties may publish certain key results achieved in connection with this Agreement, including in connection with Development of the Licensed Products in the Otsuka Territory, that will be coordinated with the publication by Esperion of similar results achieved with respect to such activities in the Esperion Territory, with the goal of protecting the Parties' ability to obtain Patent Rights with respect to such activities as applicable, and to position the Licensed Products for Regulatory Approval and successful Commercialization in the Parties' respective Territories. All publications of such key results shall also be subject to this Section 7.2.1 (Publication). Except for disclosures permitted pursuant to Section 7.1 (Nondisclosure Obligation) and Section 7.2.2 (Publicity), if a Party desires to make a publication or public presentation regarding any such key results, or that contains the Confidential Information of the other Party, the publishing Party shall deliver to the other Party a copy of the proposed written publication or presentation at least [\*\*\*] days prior to submission for publication or presentation. The non-publishing Party shall have the right (i) to require modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons, and the publishing Party shall remove all Confidential Information of the non-publishing Party if requested by the non-publishing Party, or (ii) to request a reasonable delay in publication or presentation in order to protect patentable information. If the non-publishing Party requests a delay, the publishing

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Party shall delay submission or presentation for a period of [\*\*\*] days to enable the non-publishing Party to file patent applications protecting such Party's rights in such information.

**7.2.2 Publicity.** Except as set forth in Section 7.1 (Nondisclosure Obligation) and Section 7.2.1 (Publication) above and Section 7.3 (Press Release) below, the terms of this Agreement may not be disclosed by either Party. Neither Party shall use the name or Trademark of the other Party or its employees in any publicity, news release or disclosure relating to any of this Agreement, its subject matter, or the activities of the Parties hereunder without the prior express written permission of the other Party, except as may be required by Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in any country other than the United States or of any stock exchange or listing entity, or except as expressly permitted by the terms hereof.

**7.3 Press Release.** Following the execution of this Agreement, the Parties may each issue a press release in substantially the form set forth in Schedule 7.3 (Press Releases) or such other forms mutually agreed by the Parties. After such initial press releases, neither Party shall issue a press release or public announcement relating to the Parties' respective rights and obligations under this Agreement without the prior written approval of the other Party, not to be unreasonably withheld, conditioned or delayed, except that the Parties may (i) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (ii) issue a press release or public announcement as required, in the reasonable judgment of such Party, by Law, including by the rules or regulations of the United States Securities and Exchange Commission, or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity on which such Party desires to list or does list its securities.

**7.4 Survival.** The provisions in this Section 7 (Confidentiality and Publication) shall survive the expiration or the termination of this Agreement for a period of [\*\*\*] years thereafter, except that with respect to trade secrets, such provisions and obligations shall survive for as long as the trade secrets remain secret.

## **8. LICENSES**

### **8.1 License Grants to Otsuka.**

**8.1.1 Exclusive License Grant.** Subject to the terms and conditions of this Agreement, Esperion hereby grants to Otsuka a non-transferable (except as provided in Section 14.2 (Assignment)), sublicensable (subject to Section 8.1.2 (Otsuka Sublicense Rights)), exclusive (even as to Esperion and its Affiliates) license under the Esperion Technology, Esperion's interest in the Joint Technology, and the Product Trademarks to Develop, have Developed, Manufacture, have Manufactured and Commercialize Licensed Products in the Field in the Otsuka Territory. The license granted hereunder shall be royalty-bearing for the Royalty Term applicable to each Licensed Product (and its corresponding Authorized Generic Product) in the Otsuka Territory, and, after the Royalty Term applicable to such Licensed Product (and its corresponding Authorized Generic Product), shall convert to a fully-paid, royalty-free perpetual license. Notwithstanding the

foregoing, the Parties' respective rights and obligations with respect to the Manufacture and having Manufactured the Licensed Products in and for supply to the Otsuka Territory shall be subject to the terms set forth in this Agreement and in the Supply Agreement.

**8.1.2 Otsuka Sublicense Rights.** Otsuka shall have the right to sublicense any of its rights under Section 8.1.1 (Exclusive License Grant), including rights to co-promote Licensed Products in the Field in the Otsuka Territory, to any of its Affiliates without the prior consent of Esperion or to any Third Party Sublicensee with the prior consent of Esperion, such consent not to be unreasonably withheld, conditioned or delayed. Each sublicense granted by Otsuka pursuant to this Section 8.1.2 (Otsuka Sublicense Rights) shall be subject and subordinate to the terms of this Agreement and shall contain provisions consistent with those in this Agreement. Otsuka shall promptly provide Esperion with a copy of the fully executed sublicense agreement covering any sublicense granted hereunder (which copy may be redacted to remove provisions which are not necessary to monitor compliance with this Section 8.1.2 (Otsuka Sublicense Rights)), and each such sublicense agreement shall contain the following provisions: (i) a requirement that the Sublicensee comply with the confidentiality and non-use provisions of Section 7 (Confidentiality and Publication) with respect to Esperion's Confidential Information and (ii) a requirement that the Sublicensee submit applicable sales or other reports to Otsuka to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement. Notwithstanding any sublicense, Otsuka shall remain primarily liable to Esperion for the performance of all of Otsuka's obligations under, and Otsuka's compliance with all provisions of, this Agreement.

## **8.2 License Grants to Esperion.**

**8.2.1 License Grant for Esperion Territory.** Subject to the terms and conditions of this Agreement, Otsuka hereby grants Esperion a non-transferable (except as provided in Section 14.2 (Assignment)), sublicensable (subject to Section 8.2.2 (Esperion Sublicense Rights)), exclusive, royalty-free license under the Otsuka Technology solely for exploitation of products comprising or containing Bempedoic Acid, either alone or in combination with other active pharmaceutical ingredients, including all dosage strengths, presentations, forms and formulations, in the Esperion Territory.

**8.2.2 Esperion Sublicense Rights.** Esperion shall have the right to sublicense any of its rights under Section 8.2.1 (License Grant for Esperion Territory) to any of its Affiliates or to any Third Party without the prior consent of Otsuka, subject to the requirements of this Section 8.2.2 (Esperion Sublicense Rights). Each sublicense granted by Esperion pursuant to this Section 8.2.2 (Esperion Sublicense Rights) shall be subject and subordinate to this Agreement and shall contain provisions consistent with those in this Agreement. Esperion shall promptly provide Otsuka with a copy of the fully executed sublicense agreement covering any sublicense granted hereunder (which copy may be redacted to remove provisions which are not necessary to monitor compliance with this Section 8.2.2 (Esperion Sublicense Rights)), and each such sublicense agreement shall contain a requirement that the Sublicensee comply with the confidentiality and non-use provisions of Section 7 (Confidentiality and Publication) of this Agreement with respect to Otsuka's Confidential Information. Notwithstanding any sublicense, Esperion shall remain

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primarily liable to Otsuka for the performance of all of Esperion’s obligations under, and Esperion’s compliance with all provisions of, this Agreement.

**8.3 Retained Rights.** For the avoidance of doubt, notwithstanding the provisions of Section 8.1 (License Grants to Otsuka) or any other provision of this Agreement, Esperion shall retain rights under the Esperion Patent Rights, Esperion Know-How, Regulatory Documentation, Esperion Trademarks and Esperion house marks to (a) perform its responsibilities under this Agreement or any ancillary agreement; and (b) Develop and Manufacture the Licensed Product in the Territory for purposes of global Development of the Licensed Product and for purposes of Commercializing the Licensed Product in the Esperion Territory.

**8.4 No Implied Licenses.** Except as specifically set forth in this Agreement, neither Party shall acquire any license or other right or interest, by implication or otherwise, in any intellectual property rights of the other Party or any of its Affiliates.

**8.5 No Other Rights.** Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest or other right in any Know-How, Patent Rights or other intellectual property rights of the other Party, including items owned, controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.

**9. FINANCIAL TERMS; ROYALTY REPORTS; PAYMENTS AND AUDITS**

**9.1 Upfront Payment.** Following the Effective Date, as consideration for the license and rights granted hereunder, Otsuka shall pay Esperion Sixty Million United States dollars (\$60,000,000) as a one-time, nonrefundable, nonreimbursable, noncreditable upfront payment within [\*\*\*] days after the receipt of invoice and Payment Forms from Esperion.

**9.2 Regulatory Milestone Payments.** Otsuka shall provide Esperion with written notice of the achievement by Otsuka or any of its Sublicensees of any regulatory milestone event set forth below in this Section 9.2 (Regulatory Milestone Payments) within [\*\*\*] days after such event has occurred. Esperion shall send Otsuka an invoice and Payment Forms for the applicable milestone payment following receipt of such written notice, and Otsuka shall pay the associated milestone payment within [\*\*\*] days of the receipt of such invoice and Payment Forms. Each milestone payment shall be payable only once.

<b>Regulatory Milestone Event</b>	<b>Regulatory Milestone Payment (USD)</b>
[***]	[***]
[***]	[***]

**9.3 NHI Price Listing Milestone Payment.** Following the first NHI Price Listing in the Otsuka Territory for the Initial Product for the Initial Indication (the “**NHI Price Listing Milestone Event**”), Otsuka shall pay Esperion one of the milestone payments set forth in the table below (the “**NHI Price Listing Milestone Payment**”) depending upon the first NHI Price Listing in the Otsuka Territory for the Initial Product for the Initial Indication. Otsuka shall provide



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Esperion with written notice of the first NHI Price Listing in the Otsuka Territory for the Initial Product for the Initial Indication within [\*\*\*] days after such price listing has occurred. Esperion shall send Otsuka an invoice and Payment Forms for the applicable NHI Price Listing Milestone Payment on the earlier to occur of (a) receipt of such written notice or (b) publication of such NHI Price Listing, and Otsuka shall pay the applicable milestone payment within [\*\*\*] days of the receipt of such invoice and Payment Forms. The applicable NHI Price Listing Milestone Payment shall be payable only once.

NHI Price Listing	NHI Price Listing Milestone Payment (USD)
[***]	[***]
[***]	[***]
[***]	[***]

**9.4 Data Milestone Payment.** If applicable, Esperion shall promptly provide Otsuka with written notice of the achievement by Esperion or any of its Sublicensees of one of the data milestone events set forth below in this Section 9.4 (Data Milestone Payment). If either such data milestone event is achieved, then following Regulatory Approval and NHI Price Listing in the Otsuka Territory for the Initial Product for the Initial Indication, Esperion shall send Otsuka an invoice and Payment Forms for the applicable data milestone payment set forth below corresponding to such data milestone event, and Otsuka shall pay such milestone payment (the “**Data Milestone Payment**”) within [\*\*\*] days of the receipt of such invoice and Payment Forms. The applicable Data Milestone Payment shall be payable only once. For the avoidance of doubt, the Data Milestone Payment will not be paid to Esperion unless and until receipt of Regulatory Approval and NHI Price Listing for the Initial Product in the Otsuka Territory for the Initial Indication.

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Data Milestone Event	Data Milestone Payment (USD)
[***]	[***]
[***]	[***]

**9.5 Sales Milestone Payment.** Otsuka shall provide Esperion with written notice of the first achievement by Otsuka or any of its Sublicensees of any sales milestone event set forth below in this Section 9.5 (Sales Milestone Payment) within [\*\*\*] days after the end of the Calendar Quarter in which such sales milestone event was first achieved. Esperion shall send Otsuka an invoice and Payment Forms for the applicable milestone payment following the receipt of such notice, and Otsuka shall pay the associated milestone payment within [\*\*\*] days of the receipt of such invoice and Payment Forms. The Parties acknowledge that more than one commercial milestone payment may become due and payable in any given Calendar Year. Each sales milestone payment set forth below shall be payable only once, regardless of the number of times a sales milestone event is achieved.

Sales Milestone Event	Commercial Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**9.6 Royalties Payable to Esperion.**

**9.6.1 Royalty Rates.** Subject to the terms and conditions of this Agreement, Otsuka shall pay to Esperion, on a Licensed Product-by-Licensed Product basis, royalties on annual Net Sales by Otsuka or its Sublicensees of each Licensed Product in the Otsuka Territory during the Royalty Term for such Licensed Product, on a tiered basis as set forth below. For clarity, the Net Sales of an Authorized Generic Product will be added to the Net Sales of the corresponding non-generic Licensed Product and the total Net Sales of the Authorized Generic

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Product and corresponding non-generic Licensed Product will be applied for the calculation of the royalties during the Royalty Term applicable to the corresponding Licensed Product.

The following royalty rates are applicable on a Licensed Product-by-Licensed Product basis if Tier 1 NHI Price Listing Milestone Event is reached:

Portion of Aggregate Annual Net Sales of a Licensed Product in the Otsuka Territory (JPY)	Royalty (as a percentage of Aggregate Annual Net Sales)
Equal to or less than [***]	[15]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***]	[***]%

The following royalty rates are applicable on a Licensed Product-by-Licensed Product basis if Tier 2 NHI Price Listing Milestone Event is reached:

Portion of Aggregate Annual Net Sales of a Licensed Product in the Otsuka Territory (JPY)	Royalty (as a percentage of Aggregate Annual Net Sales)
Equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***]	[***]%

The following royalty rates are applicable on a Licensed Product-by-Licensed Product basis if Tier 3 NHI Price Listing Milestone Event is reached:

Portion of Aggregate Annual Net Sales of a Licensed Product in the Otsuka Territory (JPY)	Royalty (as a percentage of Aggregate Annual Net Sales)
Equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***] and equal to or less than [***]	[***]%
Greater than [***]	30%

**9.6.2 Royalty Term.** The period during which the royalties set forth in [Section 9.6.1](#) (Royalty Rates) shall be payable, on a Licensed Product-by-Licensed Product (excluding an Authorized Generic Product) basis, shall commence with the First Commercial Sale of such Licensed Product and continue until the latest of (a) the date of expiration of the last Valid Claim that Covers such Licensed Product in the Otsuka Territory, (b) the expiration of Regulatory

Exclusivity for such Licensed Product in the Otsuka Territory and (c) the [\*\*\*] anniversary of the First Commercial Sale of such Licensed Product in the Otsuka Territory (each such period, a “**Royalty Term**”). For clarity, references to Licensed Product for purposes of the Royalty Term shall not mean or include any Authorized Generic Product; provided that royalties shall be payable on each Authorized Generic Product sold during the Royalty Term for the corresponding Licensed Product. Further for clarity, upon expiration of the Royalty Term for a Licensed Product, no further royalties shall be payable with respect to such Licensed Product or its corresponding Authorized Generic Product.

### **9.6.3 Royalty Reductions.**

(a) **Generic Entry.** If a Third Party obtains Regulatory Approval for a Generic Product in the Otsuka Territory in any Calendar Quarter during the Royalty Term for a Licensed Product, then the royalty rate set forth in Section 9.6.1 (Royalty Rates) shall be reduced by [\*\*\*] in such Calendar Quarter.

(b) **NHI Price Reduction.** If during the Royalty Term for a Licensed Product (prior to any reduction in the royalty rate for Regulatory Approval of a Generic Product) the NHI Price for such Licensed Product in the Otsuka Territory is reduced by [\*\*\*] or more (the “**NHI Price Reduction Percentage**”) at one time due to high sales performance of such Licensed Product or for any other reason, then, at the time the new (reduced) NHI Price is adopted as provided in Section 1.79 (Definition of NHI Price), the applicable royalty rates set forth in Section 9.6.1 (Royalty Rates) shall be reduced by [\*\*\*] of the applicable original royalty rates set forth in Section 9.6.1 (Royalty Rates). For example, [\*\*\*].

(c) **Otsuka Third Party Payments.** In the event that Otsuka reasonably determines, on a Licensed Product-by-Licensed Product basis, that it is necessary or useful to acquire rights under a Third Party’s Patent Rights, Know-How or other intellectual property, through a license, acquisition or other agreement with such Third Party, for the Development, Manufacture or Commercialization of such Licensed Product in the Otsuka Territory under this Agreement, Otsuka may deduct [\*\*\*] of all payments by Otsuka to such Third Party for such rights (including all upfront payments, milestone payments, license fees, royalties and other amounts payable to such Third Party for such rights) in a given Calendar Quarter in the Otsuka Territory against the royalties due and payable by Otsuka to Esperion on the Net Sales for such Licensed Product in such Calendar Quarter in the Otsuka Territory; provided, however, that the royalties that otherwise would be payable to Esperion on the Net Sales for such Licensed Product shall not be reduced by more than [\*\*\*] in any given Calendar Quarter as a result of any deduction under this Section 9.6.3(c); and provided further, that Otsuka shall be entitled to carry forward to subsequent Calendar Quarters any amounts with respect to which Otsuka would have been entitled to take a deduction pursuant to this Section 9.6.3(c) but is unable to take such deduction pursuant to the first proviso in this Section 9.6.3(c).

(d) **Cumulative Reductions Floor.** In no event will the royalty rate under Section 9.6.1 (Royalty Rates) in any given Calendar Quarter during the Royalty Term for any Licensed Product be reduced by more than [\*\*\*] of the royalty rate that otherwise would have

applied in such Calendar Quarter for such Licensed Product but for the reductions set forth in this Section 9.6.3 (Royalty Reductions).

**9.7 Reports; Payment of Royalty.** Otsuka shall provide Esperion with a written report within [\*\*\*] days after the end of each Calendar Quarter showing, on a Licensed Product-by-Licensed Product basis Net Sales of each Licensed Product in the Otsuka Territory and the royalties payable under this Agreement with respect to each such Licensed Product. Esperion shall send Otsuka an invoice and Payment Forms for the applicable royalties within [\*\*\*] days of receipt of such report, and Otsuka shall pay the associated royalties within [\*\*\*] days of the receipt of such invoice and Payment Forms.

**9.8 Audits.**

**9.8.1** Upon the written request of a Party (the “**Auditing Party**”) at least [\*\*\*] days in advance and not more than [\*\*\*], Esperion (with respect to COGS and amounts invoiced by Esperion under this Agreement and the Supply Agreements, including pursuant to Sections 2.1.5, 5.2 and 5.5 of this Agreement) and Otsuka or any Sublicensee that is selling Licensed Products in the Otsuka Territory (with respect to royalties and other payments under this Section 9 (Financial Terms; Royalty Reports; Payments and Audits)) (each, an “**Audited Party**”) shall permit an independent certified public accounting firm of internationally-recognized standing selected by the Auditing Party and reasonably acceptable to the Audited Party, at the Auditing Party’s expense except as set forth below, to have access during normal business hours to such of the records of the Audited Party as may be reasonably necessary to verify the accuracy of, with respect to Esperion as the Audited Party, COGS and amounts invoiced by Esperion under this Agreement and under each Supply Agreement, and, with respect to Otsuka or its Sublicensee, the royalty and other amounts payable or reports under this Section 9 (Financial Terms; Royalty Reports; Payments and Audits) for any year ending not more than [\*\*\*] years prior to the date of such request for the sole purpose of verifying the basis and accuracy of amounts invoiced or payments made, respectively, and compliance with the financial terms of this Agreement. Notwithstanding the foregoing, the Auditing Party may not make more than [\*\*\*] such request in a Calendar Year.

**9.8.2** If such accounting firm identifies a discrepancy made during such period, then, in the case of an underpayment by Otsuka, Otsuka shall pay Esperion the amount of such underpayment and, in the case of an overpayment to Esperion (whether pursuant to this Agreement or a Supply Agreement), Esperion will refund to Otsuka the amount of such overpayment, in each case within [\*\*\*] days after the date the Auditing Party delivers to the Audited Party such accounting firm’s written report so concluding, or as otherwise agreed by the Parties in writing. The fees charged by such accounting firm shall be paid by the Auditing Party, unless, in the case of Otsuka as the Audited Party, such discrepancy represents an underpayment by Otsuka of at least [\*\*\*] of the payments due in the audited period, and in the case of Esperion as the Audited Party, such discrepancy represents an overpayment by Otsuka of at least [\*\*\*] of the payments due in the audited period, in which case such fees shall be paid by the Audited Party.

**9.8.3** Unless an audit for such year has been commenced prior to and is ongoing upon the [\*\*\*] anniversary of the end of such year, the calculation of royalties, expense reimbursement and other payments payable or amounts invoiced under this Agreement and any Supply Agreement with respect to such year shall be binding and conclusive upon both Parties, and, as the case may be, Otsuka and its Sublicensees shall be released from any further liability or accountability with respect to such royalties or expense reimbursement, and Esperion shall be released from any further liability or accountability with respect to such amounts invoiced, for such year.

**9.8.4** The Auditing Party shall treat all financial information subject to review under this Section 9.8 (Audits) or under any sublicense agreement in accordance with the confidentiality and non-use provisions of Section 7 (Confidentiality and Publication), and shall cause its accounting firm to enter into a confidentiality agreement with the Audited Party obligating the accounting firm to retain all such information in confidence pursuant to such confidentiality agreement, which terms shall be no less stringent than the provisions of Section 7 (Confidentiality and Publication).

**9.9** **Payment.** All payments to be made under this Agreement shall be made in United States Dollars (legal tender of the United States of America).

**9.10** **Late Payments.** If Esperion does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Esperion from the due date until the date of payment at a per-annum rate of [\*\*\*], or the maximum rate allowable by applicable Law, whichever is less.

**9.11** **Taxes.** Otsuka shall use reasonable efforts to minimize tax withholding on payments made to Esperion. Notwithstanding such efforts, if Otsuka concludes that tax withholdings under the Laws of any country are required with respect to payments to Esperion, Otsuka shall first notify Esperion sufficiently in advance to provide Esperion at least [\*\*\*] days to determine whether there are actions Esperion can undertake to avoid such withholding. During this [\*\*\*]-day notice period, Otsuka shall refrain from making such payment until Esperion instructs Otsuka that (a) Esperion intends to take actions (satisfactory to both Parties) that shall obviate the need for such withholding, in which case Otsuka shall make such payment only after it is instructed to do so by Esperion, or (b) Otsuka should make such payment and withhold the required amount and pay it to the appropriate Governmental Authority and Otsuka shall promptly provide Esperion with copies of receipts or other evidence reasonably required and sufficient to allow Esperion to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits, the Parties shall cooperate reasonably in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable Law, in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment, and the Parties shall cooperate to minimize such taxes in accordance with applicable Laws, including using reasonable efforts to access the benefits of any applicable treaties.

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**9.12 Payment of Back Royalties.** If Otsuka would owe a royalty payment to Esperion under this Section 9 (Financial Terms; Royalty Reports; Payments and Audits) but for a decision by a court or other governmental agency of competent jurisdiction holding a claim within Esperion Patent Rights in the Otsuka Territory unenforceable, unpatentable or invalid and if such decision is later vacated or reversed by a final non-appealable decision by a court or other governmental agency of competent jurisdiction such that such claim qualifies as a Valid Claim that Covers a Licensed Product in the Otsuka Territory, Esperion may invoice Otsuka for such unpaid royalty payments after such decision is vacated or reversed and Otsuka shall make any such unpaid royalty payments to Esperion within [\*\*\*] days after receipt of such invoice.

**9.13 Payment.** All payments to be made under this Agreement shall be paid by bank wire transfer in immediately available funds to Esperion's following designated bank account:

Beneficiary Name: [\*\*\*]  
Address: [\*\*\*]  
Bank Account Number: [\*\*\*]  
SWIFT code: [\*\*\*]  
Bank Name: [\*\*\*]  
Bank Address [\*\*\*]

Esperion may from time to time designate formally in writing another bank account in the United States to which Otsuka shall thereafter make all payments hereunder.

## **10. REPRESENTATIONS, WARRANTIES AND COVENANTS**

**10.1 Mutual Representations and Warranties as of the Effective Date.** Each Party represents and warrants to the other Party that, as of the Effective Date:

**10.1.1** Such Party is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation.

**10.1.2** Such Party has all requisite corporate power and corporate authority to enter into this Agreement and to carry out its obligations under this Agreement.

**10.1.3** All requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken.

**10.1.4** The execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound, or (c)

violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents).

**10.1.5** No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by such Party in connection with the authorization, execution and delivery by Otsuka of this Agreement.

**10.2 Additional Representations and Warranties of Esperion.** Esperion represents and warrants to Otsuka that, as of the Effective Date:

**10.2.1** (a) Esperion has sufficient legal or beneficial title and ownership of, or sufficient license rights under, the Esperion Technology and Esperion Trademarks to grant the licenses under such Esperion Technology and Esperion Trademarks to Otsuka as purported to be granted pursuant to this Agreement, and (b) to Esperion's knowledge, neither any license granted by Esperion or its Affiliates to any Third Party, nor any license granted by any Third Party to Esperion or its Affiliates conflicts with the rights and licenses granted under the Esperion Technology or the Esperion Trademarks to Otsuka hereunder.

**10.2.2** (a) Schedule 10.2.2 (Esperion Patent Rights) sets forth a complete and accurate list of the Esperion Patent Rights owned, either solely or jointly, or in-licensed by Esperion and its Affiliates (the "**Existing Esperion Patent Rights**") and indicates, for each Existing Esperion Patent Right, whether such Patent Right is owned solely or jointly by Esperion or licensed by Esperion from a Third Party and if so, identifies the co-owner or the licensor or sublicensee from which the Patent Right is licensed, (b) to Esperion's knowledge, the Existing Esperion Patent Rights are all Patent Rights owned or in-licensed by Esperion and its Affiliates related to the Initial Product and/or the Combination Product and/or the Development, Manufacture or Commercialization thereof in the Field in the Otsuka Territory, (c) to Esperion's knowledge, Esperion Controls all Existing Esperion Patent Rights and Esperion Trademarks and no payments are, as of the Effective Date, or will be after the Effective Date owed or payable to any Third Party in connection with any rights, licenses or access in, to or under the Existing Esperion Patent Rights or Esperion Trademarks, (d) to Esperion's knowledge, the Existing Esperion Patent Rights are, or, upon issuance, will be, valid and enforceable patents and no Third Party has challenged or threatened to challenge the scope, validity or enforceability of any Existing Esperion Patent Rights (including, by way of example, through opposition or the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority), and (e) Esperion or its Affiliates have timely paid all filing and renewal fees payable with respect to the Existing Esperion Patent Rights and all registration and maintenance fees payable with respect to the Esperion Trademarks in the Otsuka Territory.

**10.2.3** To Esperion's knowledge, Esperion has complied with all applicable Laws, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Existing Esperion Patent Rights and the Esperion Trademarks.



[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**10.2.4** Esperion has obtained from all inventors of Esperion Technology owned by Esperion valid and enforceable agreements assigning to Esperion each such inventor's entire right, title and interest in and to all such Esperion Technology.

**10.2.5** To Esperion's knowledge, the Development, Manufacture and Commercialization in the Otsuka Territory of any Licensed Product as formulated and manufactured as of the Effective Date does not and will not constitute misappropriation of any Know-How of any Third Party or infringe any issued patent or any Trademark of any Third Party.

**10.3 Warranty Disclaimer.** EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY, OTSUKA TECHNOLOGY (WITH RESPECT TO OTSUKA), ESPERION TECHNOLOGY (WITH RESPECT TO ESPERION), PRODUCT, PROGRAM, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THE AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT PURSUANT TO THIS AGREEMENT SHALL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY LICENSED PRODUCT SHALL BE ACHIEVED.

**10.4 Exclusivity.** During the period [\*\*\*], on a Licensed Product-by-Licensed Product and indication-by-indication basis in the Otsuka Territory, neither Otsuka nor Esperion shall, either alone or with or through any Affiliates or Third Parties, [\*\*\*].

**10.5 Certain Other Covenants.**

**10.5.1 Compliance.** Otsuka and its Sublicensees shall Develop, Manufacture and Commercialize the Licensed Products in material compliance with this Agreement and all applicable Laws, including current governmental regulations concerning GLP, GCP and cGMP.

**10.5.2 Conflicting Agreements.** Neither Party shall enter into any agreement with any Third Party that would conflict with, limit or restrict either Parties' ability to comply with this Agreement.

**10.5.3 No Debarment.** Otsuka shall use Commercially Reasonable Efforts to not use, in any capacity in connection with this Agreement or the performance of its obligations under this Agreement, any Person that has been debarred pursuant to Section 306 of the FD&C Act, or that is the subject of a conviction described in such section. Otsuka agrees to inform Esperion in writing immediately if it or any Person that is performing activities under this Agreement, is debarred or is subject to debarment or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Otsuka's knowledge, is threatened, relating to the debarment or

conviction of Otsuka or any Person or entity used in any capacity by Otsuka or any of its Affiliates in connection with performance of its other obligations under this Agreement.

## **11. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE**

**11.1 General Indemnification by Otsuka.** Otsuka shall indemnify, hold harmless and defend Esperion, its Sublicensees, and their respective directors, officers, employees and agents (“**Esperion Indemnitees**”) from and against any and all Third Party claims, suits, losses, liabilities, damages, costs, fees and expenses (including reasonable attorneys’ fees and litigation expenses) (collectively, “**Losses**”) arising out of or resulting from (a) the Development, Manufacture or Commercialization of the Licensed Products by Otsuka or its Sublicensees in the Otsuka Territory, (b) any breach of, or inaccuracy in, any representation or warranty made by Otsuka in this Agreement, or any breach or violation of any covenant or agreement of Otsuka in or in the performance of this Agreement or (c) the negligence or willful misconduct by or of Otsuka and its Sublicensees and subcontractors, including CMOs, and their respective directors, officers, employees and agents in the performance of Otsuka’s obligations under this Agreement. Otsuka shall have no obligation to indemnify the Esperion Indemnitees to the extent that the Losses arise out of or result from any breach of, or inaccuracy in, any representation or warranty made by Esperion in this Agreement, or any breach or violation of any covenant or agreement of Esperion in or in the performance of this Agreement, or the negligence or willful misconduct by or of any of the Esperion Indemnitees, or matters for which Esperion is obligated to indemnify Otsuka under Section 11.2 (General Indemnification by Esperion).

**11.2 General Indemnification by Esperion.** Esperion shall indemnify, hold harmless, and defend Otsuka, its Sublicensees and their respective directors, officers, employees and agents (“**Otsuka Indemnitees**”) from and against any and all Losses arising out of or resulting from (a) the Development, Manufacture or Commercialization of the Licensed Products by Esperion or its Sublicensees in the Esperion Territory, (b) any breach of, or inaccuracy in, any representation or warranty made by Esperion in this Agreement, or any breach or violation of any covenant or agreement of Esperion in or in the performance of this Agreement or (c) the negligence or willful misconduct by or of Esperion and its Sublicensees and subcontractors, including CMOs, and their respective directors, officers, employees and agents in the performance of Esperion’s obligations under this Agreement. Esperion shall have no obligation to indemnify the Otsuka Indemnitees to the extent that the Losses arise out of or result from any breach of, or inaccuracy in, any representation or warranty made by Otsuka in this Agreement, or any breach or violation of any covenant or agreement of Otsuka in or in the performance of this Agreement, or the negligence or willful misconduct by or of any of the Otsuka Indemnitees, or matters for which Otsuka is obligated to indemnify Esperion under Section 11.1 (General Indemnification by Otsuka).

**11.3 Indemnification Procedure.** In the event of any such claim against any Otsuka Indemnitee or Esperion Indemnitee (individually, an “**Indemnitee**”), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee shall cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party shall not be liable for any settlements, litigation

costs or expenses incurred by any Indemnitee without the indemnifying Party's written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Sections 11.1 (General Indemnification by Otsuka), or 11.2 (General Indemnification by Esperion) may apply, the indemnifying Party shall promptly notify the Indemnitees, which shall then have the right to be represented in any such action or proceeding by separate counsel at their expense, provided that the indemnifying Party shall be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party for the matters to which the indemnifying Party notified the Indemnitees that such exception(s) may apply.

**11.4 Limitation of Liability.** NEITHER PARTY HERETO SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THE AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A PARTY'S WILLFUL MISCONDUCT OR A BREACH OF SECTION 7 (CONFIDENTIALITY AND PUBLICATION), SECTION 10.4 (EXCLUSIVITY) OR THE EXCLUSIVITY TERMS OF THE LICENSES GRANTED IN SECTION 8 (LICENSES). NOTHING IN THIS SECTION 11.4 (LIMITATION OF LIABILITY) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

**11.5 Insurance.** Each Party shall, at its own expense, maintain general commercial liability insurance, including products liability insurance, contractual liability, bodily injury, property damage and personal injury coverage adequate to cover its obligations and liabilities under this Agreement and the Supply Agreement, and which are consistent with normal business practices of comparable companies with respect to similar obligations and liabilities. Such coverage shall be purchased for a minimum limit of [\*\*\*] for any one (1) claim or all damages combined. The Parties shall maintain such insurance for so long as this Agreement or the Supply Agreement is in effect, and shall from time to time provide copies of certificates evidencing such insurance to each other upon request. If the insurance policy is written on a claims-made basis, then the coverage must be kept in place for at least [\*\*\*] years after the termination of this Agreement.

## **12. INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS**

### **12.1 Inventorship; Ownership.**

**12.1.1 Inventorship.** Inventorship for inventions made during the course of the performance of this Agreement shall be determined in accordance with applicable patent Laws for determining inventorship.

**12.1.2 Ownership.** Esperion shall own the entire right, title and interest in and to all inventions it solely Invents (i.e., solely by one or more employees of Esperion or its Affiliates (or a Third Party acting on any of their behalf)) during the Term. Otsuka shall own the entire right, title and interest in and to all inventions it solely Invents (i.e., by one or more employees of Otsuka

or its Affiliates that are Sublicensees (or a Third Party acting on any of their behalf)) during the Term. The Parties shall jointly own the entire right, title and interest in and to all inventions they Invent jointly (i.e., by one or more employees of Esperion or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Otsuka or its Affiliates that are Sublicensees (or a Third Party acting on any of their behalf)) during the Term.

**12.1.3 Employee Assignment.** Each Party shall ensure that all of its employees and all employees of its Affiliates that are Sublicensees who are acting under its or such Affiliates' authority in the performance of this Agreement assign to such Party under a binding written agreement all Know-How and Patent Rights discovered, made, conceived by such employee as a result of such employee's employment. In the case of all Third Parties acting in the performance a Party's obligations under this Agreement, such as consultants, subcontractors, licensees, Third Party Sublicensees, outside contractors, clinical investigators, agents, or non-employees working for non-profit academic institutions, the Party that engages such Third Party shall ensure that such Third Party is also so obligated under such an agreement, unless otherwise approved by the Parties.

**12.1.4 Right to Practice Joint Technology.** Subject to the rights, licenses (including the licenses granted to Otsuka under Section 8.1) and obligations (including royalty obligations) of the Parties hereunder, both Parties are entitled to practice Joint Technology for all purposes on a worldwide basis and license Joint Technology without consent of and without a duty of accounting to the other Party. For the avoidance of doubt, Esperion shall have no right to grant any rights or licenses under Joint Technology that would conflict with the exclusive licenses to Otsuka in the Field in the Otsuka Territory. Each Party will grant and hereby does grant all permissions, consents and waivers with respect to, and all licenses under, the Joint Technology, throughout the world, necessary to provide the other Party with such rights of use and exploitation of the Joint Technology, and will execute documents as necessary to accomplish the foregoing.

## **12.2 Prosecution and Maintenance of Patent Rights.**

### **12.2.1 Prosecution of Esperion Patent Rights and Joint Patent Rights.**

(a) Esperion has the sole responsibility to, at Esperion's discretion, file, prosecute, and maintain (including the defense of any interference or opposition proceedings or *inter partes* review and any equivalent proceedings in the Territory), all Esperion Patent Rights and Joint Patent Rights.

(b) Esperion shall furnish to Otsuka, via electronic mail or such other method as mutually agreed by the Parties, copies of documents received from outside counsel in the course of filing, prosecution or maintenance of or copies of documents filed with the relevant national patent offices with respect to the filing, prosecution, and maintenance of all Esperion Patent Rights and Joint Patent Rights in the Otsuka Territory within a reasonable time after the receipt or filing of such documents. Esperion shall provide Otsuka and its patent counsel with a reasonable opportunity to consult with and provide comments to Esperion and its patent counsel regarding the filing and contents of any such application, amendment, submission or response. All timely advice and suggestions of Otsuka and its patent counsel shall be taken into consideration in good faith by Esperion and its patent counsel in connection with such filing.

(c) Esperion shall not, without the prior written consent of Otsuka, abandon, forfeit or otherwise cease the prosecution or maintenance of any of the Existing Esperion Patent Rights in the Otsuka Territory; provided that, Otsuka's consent shall not be unreasonably withheld, conditioned or delayed if Esperion has, and informs Otsuka of, a reasonable strategic reason for ceasing the prosecution and maintenance of an Existing Esperion Patent Right in the Otsuka Territory. In the event that Otsuka provides consent pursuant to the preceding sentence with respect to any Existing Esperion Patent Right or Esperion elects not to maintain patent protection on any other Esperion Patent Rights or on any Joint Patent Rights in the Otsuka Territory, Esperion shall notify Otsuka at least [\*\*\*] days before any such Patent Rights would become abandoned or otherwise forfeited. Otsuka may, upon written notice to Esperion, elect to assume prosecution and maintenance of such Esperion Patent Rights or Joint Patent Rights in the Otsuka Territory and, in that event, Esperion shall assign all of its right, title and interest in and to such Esperion Patent Rights or Joint Patent Rights to Otsuka at Otsuka's sole cost and expense, and such Esperion Patent Rights or Joint Patent Rights shall become Otsuka Patent Rights; provided that, if such assignment is not possible, then Otsuka shall have the right (but not the obligation), at its sole cost and expense, to prosecute and maintain in the Otsuka Territory patent protection on such Esperion Patent Rights or Joint Patent Right in the name of Esperion.

(d) Esperion shall bear all costs incurred in connection with the filing, prosecution and maintenance (including the defense of any interference or opposition proceedings or *inter partes* review and any equivalent proceedings) of the Esperion Patent Rights and Joint Patent Rights in the Otsuka Territory and in the Esperion Territory, except to the extent Otsuka will bear such costs in accordance with Section 12.2.1(c).

#### **12.2.2 Prosecution of Otsuka Patent Rights.**

(a) Otsuka has the sole responsibility to, at Otsuka's discretion, file, prosecute, and maintain (including the defense of any interference or opposition proceedings or *inter partes* review and any equivalent proceedings), all Otsuka Patent Rights. Otsuka will use good faith efforts to segregate into separate Patent Rights claims of Otsuka Patent Rights that solely relate to Bempedoic Acid, or any product comprising or containing Bempedoic Acid, from claims that relate to other subject matter, to the extent such segregation is feasible under applicable patent rules and regulations. Any such separate Otsuka Patent Rights that contain claims solely relating to Bempedoic Acid, or a product comprising or containing Bempedoic Acid, and no other subject matter shall be referred to herein as "**Otsuka BA Patent Rights.**"

(b) With respect to Otsuka Patent Rights that are Otsuka BA Patent Rights or that contain both claims related to Bempedoic Acid, or any product comprising or containing Bempedoic Acid, and claims related to other subject matter, Otsuka shall furnish to Esperion, via electronic mail or such other method as mutually agreed by the Parties, copies of documents received from outside counsel in the course of filing, prosecution or maintenance of or copies of documents filed with the relevant national patent offices with respect to the filing, prosecution, and maintenance of such Otsuka Patent Rights within a reasonable time after the receipt or filing of such documents. Otsuka shall provide Esperion and its patent counsel with a reasonable opportunity to consult with and provide comments to Otsuka and its patent counsel

regarding the filing and contents of any such application, amendment, submission or response. All timely advice and suggestions of Esperion and its patent counsel shall be taken into consideration in good faith by Otsuka and its patent counsel in connection with such filing.

(c) In the event that Otsuka is able to segregate claims and file separate Otsuka BA Patent Rights and in the event Otsuka elects not to maintain patent protection on any such Otsuka BA Patent Rights in any country(ies), Otsuka shall notify Esperion at least [\*\*\*] days before any such Otsuka BA Patent Rights would become abandoned or otherwise forfeited. Esperion may, upon written notice to Otsuka, elect to assume prosecution and maintenance of such Otsuka BA Patent Rights in such country(ies) and, in that event, Otsuka shall assign all of its right, title and interest in and to such Otsuka BA Patent Rights to Esperion at Esperion's sole cost and expense, and such Otsuka BA Patent Rights shall become Esperion Patent Rights; provided that, if such assignment is not possible, then Esperion shall have the right (but not the obligation), at its sole cost and expense, to prosecute and maintain in such country(ies) patent protection on such Otsuka BA Patent Rights in the name of Otsuka. Notwithstanding the foregoing, Otsuka shall be entitled to abandon, forfeit or otherwise elect not to maintain patent protection on any Otsuka BA Patent Right in any country(ies) for reasonable strategic reasons provided that Otsuka also abandons or forfeits any other Patent Rights in such country(ies) that contain the same specification as such Otsuka BA Patent Right.

(d) In the event Otsuka is unable to segregate claims and file separate Otsuka BA Patent Rights, and in the event Otsuka elects not to maintain patent protection in any country(ies) on any Otsuka Patent Rights that contain both claims related to Bempedoic Acid, or any product comprising or containing Bempedoic Acid, and claims related to other subject matter, Otsuka shall notify Esperion at least [\*\*\*] days before any such Otsuka Patent Rights would become abandoned or otherwise forfeited. Esperion may, upon written notice to Otsuka, assume prosecution and maintenance of such Otsuka Patent Rights in such country(ies) and, in that event, Otsuka shall assign all of its right, title and interest in and to such Otsuka Patent Rights to Esperion at Esperion's sole cost and expense, and such Otsuka Patent Rights shall become Esperion Patent Rights; provided that, if such assignment is not possible, then Esperion shall have the right (but not the obligation), at its sole cost and expense, to prosecute and maintain in such country(ies) patent protection on such Otsuka Patent Rights in the name of Otsuka. With respect to any Otsuka Patent Right that is assigned to Esperion and becomes an Esperion Patent Right pursuant to this Section 12.2.2(d), Esperion shall, and hereby does, grant to Otsuka and its Affiliates, effective as of the date of such assignment without any further action required on the part of either Party, a non-exclusive, royalty-free, fully paid-up, irrevocable and perpetual license, with the right to grant sublicenses through multiple tiers, under such Esperion Patent Right (formerly Otsuka Patent Right) solely to research, develop, make, have made, use, sell, have sold, offer to sell, import and otherwise exploit any products other than products comprising or containing Bempedoic Acid. Notwithstanding the foregoing, Otsuka shall be entitled to abandon, forfeit or otherwise elect not to maintain patent protection on any Otsuka Patent Right that contains both claims related to Bempedoic Acid, or any product comprising or containing Bempedoic Acid, and claims related to other subject matter for reasonable strategic reasons.

(e) Otsuka shall bear all costs incurred in connection with the filing, prosecution and maintenance (including the defense of any interference or opposition proceedings or *inter partes* review and any equivalent proceedings) of the Otsuka Patent Rights in the Otsuka Territory and in the Esperion Territory, except to the extent Esperion will bear such costs in accordance with Section 12.2.2(c) or Section 12.2.2(d).

### 12.3 Third Party Infringement.

**12.3.1 Notice of Infringement.** During the Term, each Party will promptly notify the other Party in writing of any known or suspected infringement or unauthorized use or misappropriation by a Third Party of Otsuka Technology, Esperion Technology, or Joint Technology concerning any product intended for use in preventing, diagnosing or treating any disease or condition in humans (including development, Manufacture, or Commercialization) (such infringement or unauthorized use or misappropriation, “**Competing Infringement**”) of which such Party becomes aware. The notifying Party will provide the other Party with all evidence available to it supporting its belief that there is Competing Infringement.

#### 12.3.2 Right to Enforce.

(a) Subject to the provisions of any Esperion Third Party Agreement, Otsuka shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Competing Infringement in the Otsuka Territory under any Otsuka Technology, Esperion Technology or Joint Technology. Such measures may include (a) initiating or prosecuting an infringement, misappropriation or other appropriate suit or action (each an “**Infringement Action**”) in the Otsuka Territory, or (b) subject to Section 8.1.2 (Otsuka Sublicense Rights), granting adequate rights and licenses to any Third Party necessary to render continued Competing Infringement in the Otsuka Territory non-infringing. Notwithstanding the foregoing, if Otsuka does not inform Esperion that it intends to either initiate such an Infringement Action or grant adequate rights and licenses to such Third Party within [\*\*\*] days after Otsuka’s receipt of a notice of infringement pursuant to Section 12.3.1 (Notice of Infringement) and does not provide Esperion commercially reasonable reasons why Otsuka does not intend to initiate such Infringement Action or grant such rights or licenses within such [\*\*\*]-day period, then Esperion will have the second right, but not the obligation, to initiate such Infringement Action, but solely with respect to any Esperion Technology or Joint Technology.

(b) Esperion shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate with respect to any Competing Infringement in the Esperion Territory under any Otsuka BA Technology, Esperion Technology or Joint Technology. Such measures may include (a) initiating or prosecuting an Infringement Action, or (b) granting adequate rights and licenses to any Third Party necessary to render continued Competing Infringement in the Esperion Territory non-infringing. Notwithstanding the foregoing, if Esperion does not inform Otsuka that it intends to either initiate such an Infringement Action or grant adequate rights and licenses to such Third Party within [\*\*\*] days after Esperion’s receipt of a notice of infringement pursuant to Section 12.3.1 (Notice of Infringement) and does not provide Otsuka commercially reasonable reasons why Esperion does not intend to initiate such

Infringement Action or grant such rights or licenses within such [\*\*\*]-day period, then Otsuka will have the second right, but not the obligation, to initiate such Infringement Action, but solely with respect to any Otsuka BA Technology. For clarity, with respect to Otsuka Patent Rights, Esperion shall only have the right under this Section 12.3.2(b) to enforce Otsuka BA Patent Rights against any Competing Infringement in the Esperion Territory and Esperion shall not have the right to enforce any other Otsuka Patent Rights against Competing Infringement in the Esperion Territory.

**12.3.3 Control; Cooperation.** The Party initiating any Infringement Action (such Party, the “**Responsible Party**”) shall have the right to control the initiation and prosecution of any Infringement Action, including the right to select counsel therefor, at its own expense. If requested by the Responsible Party, the other Party shall join as a party to such Infringement Action and will execute and cause its Affiliates to execute all documents, including registration of exclusive license, necessary for the Responsible Party to initiate, prosecute, maintain or defend such action or proceeding. In addition, at the Responsible Party’s request, the other Party shall provide reasonable assistance to the Responsible Party in connection with an Infringement Action at no charge to the Responsible Party except for reimbursement by the Responsible Party of reasonable Out-of-Pocket Costs incurred in rendering such assistance.

**12.3.4 Sharing of Recoveries.** Any amounts recovered by either Party pursuant to this Section 12.3 (Third Party Infringement) will be used first to reimburse the Parties for their reasonable costs and expenses, including attorneys’ fees incurred in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses) with any remainder [\*\*\*].

**12.4 Third Party Claims.**

**12.4.1 Third Party Infringement Suit.** If a Third Party sues a Party (the “**Sued Party**”) alleging that the Sued Party’s, or the Sued Party’s Sublicensee’s, Development, Manufacture or Commercialization of the Licensed Product in the Otsuka Territory infringes or will infringe said Third Party’s intellectual property (“**Third Party Infringement Suit**”), then upon the Sued Party’s request and in connection with the Sued Party’s defense of any such Third Party Infringement Suit, the other Party will provide reasonable assistance to the Sued Party for such defense. The Sued Party will keep the other Party, if such other Party has not joined in such suit, reasonably informed on a quarterly basis, in person or by telephone, prior to and during the pendency of any such suit. The Sued Party will not enter into any settlement of any Third Party Infringement Suit that is instituted or threatened to be instituted against the other Party without the other Party’s prior written consent, which will not be unreasonably withheld, conditioned or delayed; *except that*, such consent will not be required if such settlement includes a release of all liability in favor of the other Party. Further, the Sued Party shall not settle or compromise any Third Party Infringement Suit, or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party’s rights or interests, without the written consent of such other Party. Any monetary damages that are required to be paid by the Sued Party to a Third Party with respect to the Otsuka Territory pursuant to a judgment rendered in a Third Party Infringement Suit will be borne by the Parties equally.



**12.4.2 Esperion Third Party Agreements.** Esperion shall remain responsible for the payment of all royalties, license fees, milestone payments and other payment obligations under all agreements, including all Esperion Third Party Agreements, entered into by Esperion prior to the Effective Date. On a Licensed Product-by-Licensed Product basis, in the event that Esperion reasonably determines that it is necessary or useful to acquire rights under a Third Party's Patent Rights, Know-How or other intellectual property, through a license, acquisition or other agreement with such Third Party, for the Development, Manufacture or Commercialization of such Licensed Product in both the Otsuka Territory and the Esperion Territory, or if Otsuka and Esperion agree that Esperion, rather than Otsuka, will acquire rights under a Third Party's Patent Rights, Know-How or other intellectual property, through a license, acquisition or other agreement with such Third Party, for the Development, Manufacture or Commercialization of such Licensed Product in the Otsuka Territory only (any such agreement, a "**Third Party IP Agreement**"), Esperion shall ensure that such Third Party IP Agreement shall include the right to grant a sublicense to Otsuka in the Otsuka Territory in order for Otsuka to exercise its rights and licenses hereunder and Esperion shall negotiate such Third Party IP Agreement on commercially reasonable terms that shall not favor or burden one Party's Territory over the other. In the event Esperion enters into such a Third Party IP Agreement, Otsuka shall bear [\*\*\*] of royalty payments due thereunder that are attributable to Net Sales of Licensed Products in the Otsuka Territory and [\*\*\*] of any milestone payments thereunder that are specific to the Otsuka Territory, and Esperion shall bear all other payments under such Third Party IP Agreement. Esperion shall send Otsuka an invoice for its share of such Otsuka Territory-specific royalty payments and milestone payments, and Otsuka shall pay such payments within [\*\*\*] days of the receipt of such invoice.

**12.5 Common Interest.** All information exchanged between the Parties' representatives pursuant to this Section 12 (Intellectual Property Ownership, Protection and Related Matters) regarding the preparation, filing, prosecution, maintenance, or enforcement of Patent Rights will be deemed Confidential Information. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution, maintenance, and enforcement of the Esperion Patent Rights and Joint Patent Rights the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning such Patent Rights, including privilege under the common interest doctrine and similar or related doctrines.

**12.6 Patent Term Extensions.**

**12.6.1 Esperion Patent Rights.** Subject to the provisions of any Esperion Third Party Agreement, Esperion shall use Commercially Reasonable Efforts to obtain all available extensions of Esperion Patent Rights and Joint Patent Rights in the Otsuka Territory, as requested by Otsuka, provided that Otsuka shall reimburse Esperion all Out-of-Pocket costs incurred by Esperion in connection with seeking and obtaining such extensions.

**12.6.2 Otsuka Patent Rights.** Otsuka shall use Commercially Reasonable Efforts to obtain all available extensions of Otsuka Patent Rights that are Otsuka BA Patent Rights or that contain both claims related to Bempedoic Acid, or any product comprising or containing

Bempedico Acid, and claims related to other subject matter in the Esperion Territory, as requested by Esperion, provided that Esperion shall reimburse Otsuka all Out-of-Pocket costs incurred by Otsuka in connection with seeking and obtaining such extensions.

## **12.7 Prosecution and Enforcement of Product Trademarks; General.**

**12.7.1 Prosecution of Product Trademarks; General.** Esperion shall own all rights, title and interest in and to all Product Trademarks. Esperion shall have the sole responsibility to file, prosecute, register and maintain (including the defense of opposition proceedings and any equivalent proceedings) all Product Trademarks, including Esperion Trademarks and back-up Trademarks for the Licensed Products (including any logo associated therewith), which shall not be confusingly similar to any Otsuka mark, on a timely manner in the Otsuka Territory throughout the Term. Consistent with Otsuka's exclusive right to Product Trademarks under Section 8.1.1 (Exclusive License Grant), Otsuka shall use Product Trademarks in a manner consistent with this Agreement, including the Global Branding Strategy, and for no other purpose. Otsuka shall use any Product Trademarks in a manner consistent with trademark usage guidelines provided by Esperion from time-to-time. Subject to the foregoing: (a) Otsuka shall not use any other marks that are confusingly similar to any Product Trademark, (b) all rights in each of the Product Trademarks shall remain at all times the sole property of Esperion, and all use of such Product Trademarks shall inure to the benefit of Esperion, and (c) Otsuka agrees not to contest or attack Esperion's ownership of the Product Trademarks. Otsuka shall reimburse Esperion for its reasonable Out-of-Pocket Cost incurred in connection with the filing, prosecution, registration and maintenance (including the defense of opposition proceeding and equivalent proceeding) of the Product Trademarks in the Otsuka Territory. Esperion shall invoice Otsuka from time to time for such Out-of-Pocket Costs, and Otsuka shall pay Esperion within [\*\*\*] days of receipt of such invoice.

**12.7.2 Enforcement of Product Trademarks.** During the Term, each Party will promptly notify the other Party in writing of any known or suspected infringement or unauthorized use or misappropriation by a Third Party of any Product Trademarks in the Otsuka Territory. Otsuka shall have the right, but not the obligation, to take any reasonable measures it deems appropriate, at its sole cost and expense, including initiating or prosecuting an infringement, misappropriation or other appropriate suit or action to enforce the Product Trademarks in the Otsuka Territory ("**Product Trademark Infringement Action**"). Otsuka shall have the right to control the initiation and prosecution of any Product Trademark Infringement Action, including the right to select counsel therefor, at its own expense. If requested by Otsuka, Esperion shall join as a party to such Product Trademark Infringement Action and will execute and cause its Affiliates to execute all documents necessary for Otsuka to initiate, prosecute, maintain or defend such action or proceeding. In addition, at Otsuka's request, Esperion shall provide reasonable assistance to Otsuka in connection with a Product Trademark Infringement Action at no charge to Otsuka except for reimbursement by Otsuka of reasonable Out-of-Pocket Costs incurred by Esperion in rendering such assistance.

### 13. TERM AND TERMINATION; REMEDIES

**13.1 Term.** The Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Section 13.2 (Termination Rights), this Agreement shall continue in effect, on a Licensed Product-by-Licensed Product basis until the expiration of the Royalty Term for such Licensed Product (“**Term**”). Upon the expiration of the Term with respect to a Licensed Product (without this Agreement being terminated earlier pursuant to Section 13.2 (Termination Rights)), Otsuka’s rights to such Licensed Product (and all corresponding Authorized Generic Products) and all license grants to Otsuka hereunder with respect to such Licensed Product (and all corresponding Authorized Generic Products) shall continue, shall remain exclusive to Otsuka (even as to Esperion) and shall become fully paid-up, royalty-free, perpetual and irrevocable. Prior to expiration of the Term with respect to a Licensed Product (without this Agreement being terminated earlier pursuant to Section 13.2 (Termination Rights)), upon Otsuka’s written request, the Parties shall discuss a schedule for assignment to Otsuka of Esperion’s contracts with CMOs that relate to the Manufacture or supply of the API(s) and/or Bulk Tablets (if the technology transfer has not occurred under Section 5.4 (Technology Transfer)) for the Otsuka Territory, and Esperion shall implement such assignments in accordance with such schedule in order for the assignment of such contracts to be effective at the expiration of the Term with respect to such Licensed Product. Esperion shall use Commercially Reasonable Efforts to support such assignments and shall bear its internal costs to implement the assignments. Otsuka will bear its internal costs and all external expenses, including Esperion’s Out-of-Pocket Costs, if any, to implement such assignments.

**13.2 Termination Rights.** This Agreement may not be terminated by either Party except as provided in this Section 13.2 (Termination Rights).

**13.2.1 Termination of Agreement for Convenience.** Otsuka shall have the right to terminate this Agreement in its entirety at any time after the earlier of: [\*\*\*]. Notwithstanding the foregoing, Otsuka shall have the right to terminate this Agreement in its entirety at any time with respect to a Licensed Product: (i) due to Safety Reasons; or (ii) withdrawal of Regulatory Approval for such Licensed Product outside the Otsuka Territory.

**13.2.2 Termination of Agreement in its Entirety for Cause.** This Agreement may be terminated in its entirety at any time during the Term upon written notice by either Party if the other Party is in material breach of its obligations hereunder and has not cured such breach within [\*\*\*] days in the case of a payment breach, or within [\*\*\*] days in the case of all other breaches, after notice requesting cure of the breach; provided, however, that if any breach other than a payment breach is not reasonably curable within [\*\*\*] days and if a Party is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties, not to exceed an additional [\*\*\*] days, in order to permit such Party a reasonable period of time to cure such breach. Notwithstanding the foregoing, if the allegedly breaching Party disputes in good faith the existence, materiality, or failure to cure of any breach, and provides written notice to the other Party of such dispute within the relevant cure period, the other Party will not have the right to terminate this Agreement in accordance with this Section 13.2.2 unless and until the relevant dispute has been resolved pursuant to Section 14.4. During the pendency of

such dispute, the applicable cure period will be tolled, all the terms of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations hereunder.

**13.2.3 Challenges of Patent Rights.** If, during the Term, Otsuka (a) commences or participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any Esperion Patent Rights or (b) actively assists any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of such Esperion Patent Rights (each of (a) and (b), a “**Patent Challenge**”), then, to the extent permitted by the applicable Laws, Esperion shall have the right, exercisable within [\*\*\*] days following receipt of notice regarding such Patent Challenge, in its sole discretion, to give notice to Otsuka that Esperion may terminate the license(s) granted under such Esperion Patent Right(s) to Otsuka pursuant to this Agreement [\*\*\*] days following such notice (or such longer period as Esperion may designate in such notice), and, unless Otsuka withdraws or causes to be withdrawn all such challenge(s) (or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges that Otsuka does not have the power to unilaterally withdraw or cause to be withdrawn, Otsuka ceases actively assisting any other party to such Patent Challenge and, to the extent Otsuka is a party to such Patent Challenge, it withdraws from such Patent Challenge) within such [\*\*\*]-day period, Esperion shall have the right to terminate the license(s) granted under such Esperion Patent Right(s) to Otsuka pursuant to this Agreement by providing written notice thereof to Otsuka. Notwithstanding the foregoing, Esperion shall not have a right to terminate any license(s) pursuant to this Section 13.2.3 (Challenges of Patent Rights) with respect to any Patent Challenge that is made in response to and defense of any claim or action that Esperion first asserts against Otsuka or any of its Affiliates or Sublicensees.

**13.2.4 Bankruptcy.** In the event that the performance of the respective obligations of this Agreement become untenable as a result of a Party filing a petition of bankruptcy, enters into insolvency or liquidation proceedings either voluntarily or involuntarily, or if a receiver is appointed with respect to the assets of such Party, or any similar action is filed under applicable Laws, and such measure is not dismissed within [\*\*\*] days, to the extent permitted by the applicable Laws of such Party’s Territory, the other Party may terminate this Agreement by written notice to such Party. Notwithstanding the foregoing, the Parties acknowledge that a Party to this Agreement may, from time-to-time, make changes in its corporate structure, including inter alia changes in the shareholdings of Affiliates, which would not constitute a case of bankruptcy under this Section 13.2.4 (Bankruptcy).

### **13.3 Effect of Termination.**

**13.3.1 Consequences of Termination or Expiration of this Agreement.** If this Agreement expires or is terminated by a Party prior to its expiration, in each case, in its entirety at any time and for any reason, then the following terms will apply as specified below:

(a) **Licenses.** Upon termination of this Agreement under Section 13.2 prior to expiration (for clarity, not if this Agreement expires pursuant to Section 13.1), the licenses

granted by Esperion to Otsuka under this Agreement will terminate and Otsuka and its Sublicensees will cease selling Licensed Products.

(b) **Return of Information and Materials.** Upon termination or expiration, the Parties will return (or destroy, as directed by the other Party) all data, files, records, and other materials containing or comprising the other Party's Confidential Information. Notwithstanding the foregoing, the Parties will be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes, and the Parties will not be required to destroy Confidential Information that is stored automatically, such as through server backup processes.

(c) **Accrued Rights.** Termination of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination of this Agreement.

(d) **Survival.** The following provisions of this Agreement will survive the expiration or earlier termination of this Agreement: Sections 9.7 through 9.13, inclusive (solely to the extent applicable with respect to a payment obligation that accrued prior to expiration or termination), 10.3 (Warranty Disclaimer), 12.1 (Inventorship; Ownership) (excluding Section 12.1.3), 12.2.1 (Prosecution of Esperion Patent Rights and Joint Patent Rights) (solely with respect to Joint Patent Rights), 12.2.2(d) (license grant under second-to-last sentence only), 12.5 (Common Interest) (solely with respect to Joint Patent Rights); 13.1 (Term), 13.3 (Effect of Termination), 13.4 (Special Consequences of Certain Terminations), 14.2 (Assignment), 14.3 (Governing Law), 14.4 (Jurisdiction), 14.10 (No Implied Waivers; Rights Cumulative), 14.11 (Notices), 14.14 (Independent Parties), and 14.16 (Binding Effect; No Third Party Beneficiaries); and Articles 1 (Definitions) (to the extent the definitions are used in other surviving provisions), 7 (Confidentiality and Publication) (for the time period set forth in Section 7.4 (Survival)), and 11 (Indemnification; Limitation of Liability; Insurance).

**13.4 Special Consequences of Certain Terminations.** If Esperion terminates this Agreement under Section 13.2 for any reason, or Otsuka terminates this Agreement under Section 13.2, other than under Section 13.2.2 (Termination of Agreement in its Entirety for Cause) or Section 13.2.4 (Bankruptcy), (for clarity, not if this Agreement expires pursuant to Section 13.1 or if Otsuka terminates this Agreement under Section 13.2.2 (Termination of Agreement in its Entirety for Cause) or Section 13.2.4 (Bankruptcy)), then, in addition to the terms set forth in Section 13.3.1 (Consequences of Termination or Expiration of this Agreement), the following additional terms will also apply:

**13.4.1 License Grant.** The license granted by Otsuka to Esperion under Section 8.2 (License Grants to Esperion) shall automatically become irrevocable, perpetual and worldwide.

**13.4.2 Disclosure of Certain Commercialization Related Information.** Otsuka will disclose to Esperion for use with respect to the further Commercialization of the Licensed Product, material information pertaining to pricing and market access strategy and health

economic study information, in each case for the Licensed Product in the Otsuka Territory in the possession of Otsuka as of the date of such reversion that relate to such Licensed Products that is necessary for the continued Commercialization of such Licensed Products in the Otsuka Territory.

**13.4.3 Regulatory Materials.** Within [\*\*\*] days following the date of the termination, Otsuka will assign, and hereby does assign, to Esperion all of Otsuka's right, title and interest in and to all Regulatory Documentation for the Licensed Products, including any Regulatory Approvals and NHI Price Listing that relate to the applicable Licensed Product.

**13.4.4 Stock of API(s) and Finished Drug Product.** Otsuka will have the right to continue to sell and otherwise Commercialize all of the inventory of finished drug product for such Licensed Product held by Otsuka as of the effective date of termination and Otsuka shall continue to pay to Esperion any applicable royalties due on any such sales. The disposition, including buy-back by Esperion, of any inventory of API(s) held by Otsuka as of the effective date of termination will be governed by the Supply Agreement.

**13.4.5 Transition Activities.**

(a) The Parties wish to provide a mechanism to ensure that, assuming the Licensed Product is available to patients as of the reversion date, patients who were being treated with the Licensed Product prior to such termination or who desire access to the Licensed Product can continue to have access to such Licensed Product while the regulatory and commercial responsibilities for the Licensed Product are transitioned from Otsuka to Esperion. As such, Esperion may request Otsuka to perform transition activities that are necessary or useful to (1) transition Otsuka's Commercialization activities (if any) to Esperion to minimize disruption to sales, (2) provide patients with continued access to the applicable Licensed Products (if applicable), (3) enable Esperion (or Esperion's designee) to assume and execute the responsibilities under all Regulatory Approvals and ongoing Clinical Studies for the applicable Licensed Product, and (4) ensure long-term continuity of supply for the Licensed Product (collectively, the "**Transition Activities**"), but no longer than [\*\*\*] years following the effective date of termination.

(b) Esperion may elect to have Otsuka perform the applicable Transition Activities by providing written notice to Otsuka no later than [\*\*\*] days following the effective date of the termination. If Esperion requests Transition Activities, the Parties will mutually agree upon a transition plan for Otsuka to perform the applicable Transition Activities including delivery and transition dates. In addition, the Parties will establish a transition committee consisting of at least each Party's Alliance Managers, and up to [\*\*\*] additional representatives from each Party who are from other relevant functional groups to facilitate a smooth transition. While Otsuka is providing applicable Transition Activities, Otsuka and Esperion will agree on talking points and a communication plan to customers, specialty pharmacies, physicians, regulatory authorities, patient advocacy groups, and clinical study investigators, in each case only if applicable at the time of reversion, and Otsuka will make all such communications to such applicable entities in accordance with the mutually agreed talking points.

(c) Esperion will pay Otsuka's internal costs to perform the Transition Activities, calculated using the same methodology as Otsuka used to calculate such expenses for such Licensed Product in its most recently audited financial statements prior to the termination date. In addition, Esperion will reimburse Otsuka's Out-of-Pocket Costs to perform the Transition Activities. Except as set forth in Section 13.4.4, Esperion will own all revenue derived from the Licensed Product after the termination date and Otsuka will remit all such revenues to Esperion no later than the [\*\*\*] day following the end of the month in which such revenue was received.

#### **14. MISCELLANEOUS**

**14.1 Non-Disclosure and Standstill Letter Agreement.** Each of the Parties hereby acknowledges and agrees to continue to be bound by the terms of that certain Non-Disclosure and Standstill Letter Agreement, dated as of February 27, 2019, by and between Otsuka and Esperion.

**14.2 Assignment.** Except as provided in this Section 14.2 (Assignment), this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the written consent of the other Party, such consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a party that acquires, by or otherwise in connection with, merger, sale of assets or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates, provided that the assignee assumes all of the assigning Party's obligations under this Agreement, subject to Section 14.15.2 (Future Acquisition of a Party or its Business). The assigning Party shall remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned. Any purported assignment in violation of this Section 14.2 (Assignment) shall be void.

**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.

**14.5 Entire Agreement; Amendments.** This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral, excluding that certain Non-Disclosure and Standstill Letter Agreement, dated as of February 27, 2019, by and between Otsuka and Esperion. This Agreement (other than the Schedules attached hereto) may be amended, or any term hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties hereto. The Schedules attached hereto may be amended, or any term hereof modified, only by a written instrument duly-executed by authorized representatives of both Parties hereto, except to the extent expressly provided in this Agreement.

**14.6 Severability.** If any provision hereof should be held invalid, illegal or unenforceable in any respect by a competent court in any jurisdiction, the invalid, illegal or unenforceable provision(s) shall be severed from this Agreement and shall not affect the validity of this Agreement as a whole.

**14.7 Headings.** The captions to the Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections hereof.

**14.8 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**14.9 Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa); (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation” and shall not be interpreted to limit the provision to which it relates; (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”; (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person shall be construed to include the Person’s successors and permitted assigns; (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in each of their entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections or Schedules shall be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto; (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement,



[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (j) references to any specific law, rule or regulation, or article, Section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

**14.10 No Implied Waivers; Rights Cumulative.** Except as expressly provided in this Agreement, no failure on the part of Esperion or Otsuka to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at Law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

**14.11 Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Esperion, to: Esperion Therapeutics, Inc.  
3891 Ranchero Drive, Suite 150  
Ann Arbor, MI 48108  
U.S.A.  
Attention: Chief Executive Officer

With a copy to: Goodwin Procter LLP  
100 Northern Avenue  
Boston, Massachusetts 02110  
U.S.A.  
Attention: Christopher Denn

If to Otsuka, to: Otsuka Pharmaceutical Co., Ltd.  
Shinagawa Grand Central Tower,  
2-16-4 Konan, Minato-ku,  
Tokyo, 108-8242 Japan,  
Attention: Director, Global Business Development  
Email: OPC.License.Director@otsuka.jp  
Tel: +81-3-6717-1400

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

With a copy to: Otsuka Pharmaceutical Co., Ltd.  
Shinagawa Grand Central Tower  
2-16-4 Konan, Minato-ku  
Tokyo, 108-8242 Japan  
Attn: Director, Legal Affairs Department  
Email: OPC.Legal.Director@otsuka.jp  
Tel: +81-3-6717-1400

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. In addition, each Party shall deliver a courtesy copy to the other Party's Alliance Manager concurrently with such notice. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on receipt if sent by overnight courier; or (c) on receipt if sent by mail.

**14.12 Compliance with Export Regulations.** Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export Laws and other applicable foreign export Laws.

**14.13 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (except payment of money obligations), to the extent that such failure or delay is caused by or results from causes which are enforceable and irresistible, potentially including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

**14.14 Independent Parties.** It is expressly agreed that Esperion and Otsuka shall be independent contractors and that the relationship between Esperion and Otsuka shall not constitute a partnership, joint venture or agency. Esperion shall not have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on Otsuka, without the prior written consent of Otsuka, and Otsuka shall not have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on Esperion without the prior written consent of Esperion.

**14.15 Performance by Affiliates.**

**14.15.1 Use of Affiliates.** Each Party acknowledges and accepts that the other Party may exercise its rights and perform its obligations under this Agreement either directly or through one or more of its Affiliates. A Party's Affiliates will have the benefit of all rights (including all licenses) of such Party under this Agreement. Accordingly, in this Agreement "Otsuka" will be interpreted to mean "Otsuka or its Affiliates" and "Esperion" will be interpreted

to mean “Esperion or its Affiliates” where necessary to give each Party’s Affiliates the benefit of the rights provided to such Party in this Agreement; provided, however, that in any event each Party will remain responsible for the acts and omissions, including financial liabilities, of its Affiliates.

**14.15.2 Future Acquisition of a Party or its Business.** Notwithstanding Section 14.15.1 (Use of Affiliates) or anything to the contrary in this Agreement, in the event of an acquisition of a Party or its business by a Third Party (an “**Acquirer**”) after the Effective Date, whether by merger, asset purchase or otherwise, as to any such Acquirer, the non-acquired Party shall not obtain rights, licenses, options or access to any Patent Rights, Know-How, product candidates or products that are held by the Acquirer or any Affiliate of the Acquirer that becomes an Affiliate of the acquired Party as a result of such acquisition (but excluding the acquired Party), that were not generated through any use or access to the Know-How or Patent Rights of the acquired Party, or that are not used by the acquired Party in connection with a Licensed Product.

**14.15.3 Acquired Programs.**

(a) Notwithstanding Section 14.15.1 (Use of Affiliates) or anything to the contrary in this Agreement, in the event of either (a) an acquisition of a Party or its business after the Effective Date by an Acquirer whether by merger, asset purchase or otherwise, or (b) an acquisition by a Party after the Effective Date of the business or assets of a Third Party, whether by merger, asset purchase or otherwise, that includes any program(s) of the acquired Third Party that but for this Section 14.15.3 (Acquired Programs), would violate Section 10.4 (Exclusivity) (each such program, a “**Competing Program**,” and such acquired business or assets, an “**Acquired Business**”), then, in either case ((a) or (b)), the Acquirer or Acquired Business, and any Affiliate of the Acquirer or Acquired Business that becomes an Affiliate of the acquired or acquiring Party as a result of such acquisition (but excluding the acquired Party), shall not be subject to the restrictions in Section 10.4 (Exclusivity) as to: [\*\*\*].

(b) In addition, notwithstanding Section 14.15.1 (Use of Affiliates) or anything to the contrary in this Agreement, in the event of an acquisition by a Party after the Effective Date of an Acquired Business that includes a Competing Program that is the lead development program (if such Acquired Business has no commercial products) or lead commercial product (i.e. its product with the highest net sales) for such Acquired Business and its Affiliates, the acquiring Party (a) if Otsuka, [\*\*\*]; or (b) if Esperion, [\*\*\*].

**14.16 Binding Effect; No Third Party Beneficiaries.** As of the Effective Date, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective permitted successors and permitted assigns. Except as expressly set forth in this Agreement, no Person other than the Parties and their respective Affiliates and permitted assignees hereunder shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

**14.17 Counterparts.** The Agreement may be executed in two or more counterparts, including by facsimile or PDF signature pages or other electronic means, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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**[THE REMAINDER OF THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK]**

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

**OTSUKA PHARMACEUTICAL CO., LTD.**

**ESPERION THERAPEUTICS, INC.**

BY: [\*\*\*]

NAME: [\*\*\*]

TITLE: [\*\*\*]

BY: [\*\*\*]

NAME: [\*\*\*]

TITLE: [\*\*\*]

**OTSUKA PHARMACEUTICAL CO., LTD.**

BY: [\*\*\*]

NAME: [\*\*\*]

TITLE: [\*\*\*]

*Signature page to License and Collaboration Agreement*

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**Schedule 1.45**  
**Esperion Trademarks\***

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**Schedule 2.1.2**

**Initial Development Plan for Initial Product**

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### **Schedule 7.3**

#### **Press Releases**

##### **Esperion Press Release:**

##### **Esperion Announces Agreement with Otsuka Pharmaceutical Co., Ltd. for Development and Commercialization of NEXLETOL™ (bempedoic acid) and NEXLIZET™ (bempedoic acid and ezetimibe) Tablets in Japan**

- *Esperion to Receive \$60 Million Upfront Payment –*
  - *Up to \$510 Million in Total Milestones –*
  - *Substantial Tiered Royalties –*
- *Combines Esperion’s Expertise in Lipid Management with Otsuka’s Deep Cardiovascular Drug Development and Commercialization Expertise in Japan –*

ANN ARBOR, Mich., Apr. 20, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: EPR) today announced that they have entered into a collaboration agreement with Otsuka Pharmaceutical Co., Ltd. for the development and commercialization of NEXLETOL and NEXLIZET tablets in Japan. Both medicines were recently approved in both the US and EU.

The collaboration advances the commitment of both companies to provide cost-effective, oral, once-daily, non-statin LDL-cholesterol (LDL-C) lowering medicines for hypercholesterolemia patients in Japan. This development and commercialization collaboration combines Esperion’s expertise in lipid management with Otsuka’s deep cardiovascular drug development and commercialization expertise in Japan.

Under the terms of the agreement, Esperion will grant Otsuka exclusive rights to NEXLETOL and NEXLIZET tablet development and commercialization in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all Japan-specific development costs associated with the program. Esperion estimates this amount to total up to \$100 million over the next few years. Esperion will receive an upfront cash payment of \$60 million as well as up to an additional \$450 million in total development and sales milestones. Esperion will also receive tiered royalties from 15 percent to 30 percent on net sales in Japan.

“We are thrilled to partner with Otsuka, one of the leading pharmaceutical companies in Japan. Otsuka shares our vision of the potential for convenient oral, once-daily, non-statin LDL-C lowering medicines to help hypercholesterolemia patients in Japan,” said Tim Mayleben, president and chief executive officer of Esperion. “Otsuka’s history of successfully commercializing cardiovascular medicines in Japan, and overlapping healthcare provider targets make this a highly synergistic collaboration. This collaboration continues the evolution of Esperion to a truly global research and development driven commercial pharmaceutical company and further validates the global value of our medicines.”

Makoto Inoue, president and representative director of Otsuka Pharmaceutical commented, “We aspire to become an indispensable company for patients, physicians and others around the world. If approved

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in our home market of Japan, bempedoic acid will represent another step forward in our fulfillment of that aspiration.”

### **Esperion Therapeutics**

Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit [www.esperion.com](http://www.esperion.com) and follow us on Twitter at [www.twitter.com/EsperionInc](https://www.twitter.com/EsperionInc).

### **Esperion Therapeutics' Commitment to Patients with Hyperlipidemia**

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack and stroke. In the U.S., 96 million people, or more than 37 percent of the adult population, have elevated LDL-C. There are approximately 18 million people in the U.S. living with elevated levels of LDL-C despite taking maximally tolerated lipid-modifying therapy — including individuals considered statin averse — leaving them at high risk for cardiovascular events.<sup>1</sup> In the United States, more than 50 percent of atherosclerotic cardiovascular disease (ASCVD) patients and heterozygous familial hypercholesterolemia (HeFH) patients who are not able to reach their guideline recommended LDL-C levels with statins alone need less than a 40 percent reduction to reach their LDL-C threshold goal.<sup>2</sup>

Esperion's mission as the Lipid Management Company is to deliver oral, once-daily medicines that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

### **Forward-Looking Statements**

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the clinical development and commercialization plans for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of expanded indications for their effect on cardiovascular events, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet in the European Union. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, delays or failures in Esperion's clinical development and commercialization plans, or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, that Otsuka is able to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe fixed dose combination tablet, the impact of COVID-19 on our business, clinical activities and commercial development plans, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of

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the date hereof, and Esperion disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

#### **References**

- (1) Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.
- (2) Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.

#### **Otsuka Press Release** (English Version):

### **Otsuka Enters into Licensing Agreement in Japan for Bempedoic Acid, a Treatment for Hypercholesterolemia**

Otsuka Pharmaceutical Co., Ltd. and Esperion Therapeutics, Inc. (headquartered in Michigan, U.S.) announce a licensing agreement in which Otsuka acquires from Esperion exclusive development and commercialization rights in Japan for bempedoic acid (chemical name).

Bempedoic acid, designed by Esperion, has a novel mechanism of action that inhibits cholesterol and fatty acid synthesis pathways by acting on ATP (adenosine triphosphate-citrate lyase, an enzyme that breaks down citric acid in the liver).

It is a once-daily, oral therapeutic agent for hypercholesterolemia that was developed for patients who cannot take statins due to side effects or whose LDL cholesterol levels do not decrease sufficiently when taking statins or other lipid-lowering therapies. Manufacturing and marketing approvals for bempedoic acid have been obtained in the U.S. and Europe.

Under the terms of the agreement, Otsuka will pay Esperion a one-time payment of USD 60 million, as well as milestones in accordance with achievement of development and sales goals. Otsuka will conduct future clinical trials in Japan and bear the costs. Otsuka will have exclusive marketing rights in Japan and will pay royalties to Esperion based on sales levels.

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**Schedule 10.2.2**

**Existing Esperion Patent Rights**

[\*\*\*]

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**1<sup>ST</sup> AMENDMENT**  
**TO THE**  
**LICENSE AND COLLABORATION AGREEMENT**

**by and between**

**DAIICHI SANKYO EUROPE GMBH**

**and**

**ESPERION THERAPEUTICS, INC.**

**June 18, 2020**

THIS 1<sup>st</sup> AMENDMENT to the LICENSE AND COLLABORATION AGREEMENT (this “**1<sup>st</sup> Amendment**”), entered into as of June 18, 2020 (the “**1<sup>st</sup> Amendment Effective Date**”), is entered into by and between Daiichi Sankyo Europe GmbH, a corporation organized and existing under the laws of Germany (“**DSE**”) and Esperion Therapeutics, Inc., a corporation organized and existing under the laws of the state of Delaware (“**Esperion**”).

Reference is hereby made to the License and Collaboration Agreement by and between DSE and Esperion, dated effective as of January 2, 2019, as amended from time to time (the “**LCA**”), and the Manufacturing and Supply Agreement by and between DSE and Esperion, dated effective as of July 30, 2019, as amended from time to time (the “**Supply Agreement**”). Capitalized terms not otherwise defined in this 1<sup>st</sup> Amendment shall have the meanings set forth in the LCA. DSE and Esperion are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

The Parties hereby agree to amend the LCA as of the 1<sup>st</sup> Amendment Effective Date as follows:

1. Commercial Milestone Payment. Section 9.3 (Commercial Milestones) of the LCA requires DSE to pay Esperion a One Hundred and Fifty Million United States dollars (\$150,000,000) commercial milestone payment upon the First Commercial Sale of a Licensed Product in the DSE Territory (the “**Commercial Milestone Payment**”). DSE and Esperion hereby agree that, notwithstanding anything in Section 9.3 (Commercial Milestones) of the LCA, DSE shall not be required to pay Esperion the Commercial Milestone Payment, provided DSE has paid Esperion the Regulatory Approval Transfer Payment set forth in paragraph 2 of this 1<sup>st</sup> Amendment.
  2. Regulatory Approval Transfer Payment. In consideration of the transfer by Esperion, acting through its representative FGK Representative Service GmbH, to DSE of the Regulatory
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Approval listed in **Exhibit A** to this 1<sup>st</sup> Amendment, DSE hereby agrees to pay to Esperion a one-time, non-creditable, non-refundable, non-reimbursable payment in the amount of One Hundred and Fifty Million United States dollars (\$150,000,000) (the “**Regulatory Approval Transfer Payment**”). The Parties acknowledge and agree that prior to the 1<sup>st</sup> Amendment Effective Date, Esperion, acting through its representative FGK Representative Service GmbH, transferred to DSE the Regulatory Approval listed in **Exhibit A** to this 1<sup>st</sup> Amendment. As such, following the 1<sup>st</sup> Amendment Effective Date, Esperion shall within three (3) calendar days of the 1<sup>st</sup> Amendment Effective Date, invoice DSE for the Regulatory Approval Transfer Payment, and DSE shall pay Esperion the Regulatory Approval Transfer Payment no later than June 29, 2020, which payment shall be made in accordance with and subject to Sections 9.8 (Late Payments), 9.9 (Taxes) and 9.11 (Payment) of the LCA.

3. Territory Expansion.

- a. DSE Territory. The definition of “**DSE Territory**” set forth in Section 1.35 of the LCA is hereby amended to include Turkey.
  - b. Regulatory Approval. Notwithstanding anything in Sections 3.1 (Ownership of Regulatory Filings) and 3.2 (Responsibility for Regulatory Matters) of the LCA, solely with respect to Turkey, DSE’s designated Affiliate in Turkey shall be solely responsible, at its sole cost and expense, for all regulatory matters relating to such Licensed Product in Turkey, including obtaining Regulatory Approval for such Licensed Product in Turkey.
  - c. Additional Right of Termination. If DSE fails to Commercialize, directly or indirectly through its Affiliate, the Licensed Product set forth in Schedule 1.77 of the LCA in Turkey within [\*\*\*] following the date of receipt of Pricing and Reimbursement Approval, then either Party may upon written notice to the other Party terminate the LCA with respect to Turkey and the provisions of Sections 13.3.1 (Consequences of Termination or Expiration of this Agreement) and 13.4 (Special Consequences of Certain Terminations) shall apply with respect to such termination, *mutatis mutandis*.
  - d. Royalty Payments. Notwithstanding anything in Section 9.4.1 (Royalty Rates) of the LCA, solely with respect to Turkey, the royalty rate applicable to the Net Sales of Licensed Product in Turkey shall [\*\*\*] of the aggregate Net Sales of Licensed Product in Turkey. For clarity, Net Sales of Licensed Product in Turkey shall count as Net Sales for the purposes of determining the royalty rate tiers set forth in Section 9.4.1 (Royalty Rates) of the LCA and triggering the commercial milestone payments set forth in Section 9.3 (Commercial Milestones) of the LCA.
  - e. Pricing. With respect to each Licensed Product that may be subject to global price referencing affecting markets outside Turkey (but other than with respect to Europe), DSE shall develop a “Turkey pricing strategy” for submission to Esperion. For clarity, DSE shall determine all pricing of Licensed Product in the Field in the
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DSE Territory (including Turkey), and Esperion shall not have the right to direct, control, or approve DSE's pricing of Licensed Product in the Field in the DSE Territory (including Turkey).

4. Right to Manufacture. Within [\*\*\*] following the 1<sup>st</sup> Amendment Effective Date, the Parties shall negotiate in good faith and enter into an amendment to the Supply Agreement pursuant to which DSE, if required by applicable Laws to Manufacture the Licensed Product in Turkey, shall purchase from Esperion API (as defined in the Supply Agreement) for use by DSE to Manufacture Licensed Product in Turkey solely for subsequent Commercialization in Turkey at a price equal to [\*\*\*]. For clarity, neither DSE nor its Affiliates or Third Party contract manufacturing organizations shall have the right to: (a) [\*\*\*]; (b) [\*\*\*]; or (c) [\*\*\*].
  5. Confidentiality. The provisions of Section 7.1 (Nondisclosure Obligation) of the LCA are hereby incorporated into this 1<sup>st</sup> Amendment by reference and shall apply to this 1<sup>st</sup> Amendment, *mutatis mutandis*.
  6. Assignment. This 1<sup>st</sup> Amendment may not be assigned, nor may any right or obligation hereunder be assigned, by either Party without the prior written consent of the other Party, except that either Party may assign this 1<sup>st</sup> Amendment, and its rights and obligations hereunder, without the other Party's prior written consent together with an assignment of the LCA in accordance with Section 14.2 (Assignment) of the LCA.
  7. Miscellaneous. The provisions of Sections 14.3 (Governing Law), 14.4 (Jurisdiction), 14.5 (Entire Agreement; Amendment), 14.11 (Notices) and 14.17 (Counterparts) of the LCA are hereby incorporated into this 1<sup>st</sup> Amendment by reference and shall apply to this 1<sup>st</sup> Amendment, *mutatis mutandis*.
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IN WITNESS WHEREOF, the Parties have caused this 1<sup>st</sup> Amendment to be duly executed by their respective duly authorized officers as of the 1<sup>st</sup> Amendment Effective Date.

**ESPERION THERAPEUTICS, INC.**

BY: /s/ [\*\*\*]  
NAME: [\*\*\*]  
TITLE: [\*\*\*]

**DAIICHI SANKYO EUROPE GMBH**

BY: /s/ [\*\*\*]  
NAME: [\*\*\*]  
TITLE: [\*\*\*]

BY: /s/ [\*\*\*]  
NAME: [\*\*\*]  
TITLE: [\*\*\*]

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**Exhibit A**

**Regulatory Approval**

[\*\*\*]

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**Certification**

I, Tim M. Mayleben certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2020, of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Tim M. Mayleben  
\_\_\_\_\_  
Tim M. Mayleben  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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**Certification**

I, Richard B. Bartram, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2020, of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Richard B. Bartram

Richard B. Bartram

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of Esperion Therapeutics, Inc. (the "Company") for the period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of Esperion Therapeutics, Inc., hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to my knowledge as of the date hereof:

- 1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2020

/s/ Tim M. Mayleben

Tim M. Mayleben  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ Richard B. Bartram

Richard B. Bartram  
*Chief Financial Officer*  
*(Principal Financial Officer and Principal Accounting Officer)*

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