

Esperion Therapeutics, Inc.  
Form 424B5  
August 10, 2017

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Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-208701

**Prospectus Supplement**

(to Prospectus dated January 19, 2016)

**3,100,000 Shares**

**Common Stock**

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Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 3,100,000 shares of our common stock, par value \$0.001 per share.

Our common stock is quoted on The NASDAQ Global Market under the symbol "ESPR." On August 9, 2017, the last reported sale price of our common stock on The NASDAQ Global Market was \$50.54 per share.

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**Investing in our securities involves a high degree of risk. Before buying any shares you should read the discussion of material risks of investing in our securities in "Risk Factors" beginning on page S-10.**

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	<b>Per Share</b>		<b>Total</b>
Public offering price	\$ 49.00	\$	151,900,000
Underwriting discounts and commissions <sup>(1)</sup>	\$ 2.94	\$	9,114,000
Proceeds to us (before expenses)	\$ 46.06	\$	142,786,000

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<sup>(1)</sup> See "Underwriting."

We have granted a 30-day option to the underwriters to purchase up to 465,000 of additional shares of our common stock (15% of the shares sold).

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the shares is expected to be made on or about August 15, 2017.

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**Jefferies**

**Cowen**

**UBS Investment  
Bank**

**JMP Securities**

**Stifel**

**Needham &  
Company**

The date of this prospectus supplement is August 9, 2017

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Esperion Therapeutics, Inc. and other trademarks or service marks of Esperion Therapeutics appearing in this prospectus supplement and the accompanying prospectus are the property of Esperion Therapeutics. This prospectus supplement and the accompanying prospectus may refer to brand names, trademarks, service marks or trade names of other companies and organizations, and those brand names, trademarks, service marks and trade names are the property of their respective holders.

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

On December 22, 2015, we filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-3 (File No. 333-208701) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on January 19, 2016. Under this shelf registration process, we may, from time to time, sell up to \$250.0 million in the aggregate of common stock, preferred stock, debt securities, warrants and/or units in any combination.

This prospectus supplement describes the specific terms of an offering of shares of our common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part, the accompanying prospectus, provides more general information. If the information in this prospectus supplement is inconsistent with the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement.

We and the underwriters have not authorized anyone to provide you with any information or to make any representations other than those included or incorporated by reference in this prospectus supplement and the accompanying prospectus and any relevant free writing prospectus. If you receive any information not authorized by us, we and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, such information. We are not making an offer to sell the shares of common stock in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus or any relevant free writing prospectus is accurate as of any date other than its respective date.

It is important for you to read and consider all of the information contained in this prospectus supplement and the accompanying prospectus in making your investment decision. We include cross-references in this prospectus supplement and the accompanying prospectus to captions in these materials where you can find additional related discussions. The table of contents in this prospectus supplement provides the pages on which these captions are located. You should read both this prospectus supplement and the accompanying prospectus, together with the additional information described in the sections entitled "Where You Can Find More Information" and "Incorporation by Reference" of this prospectus supplement, before investing in our common stock.

We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Our principal executive offices are located at 3891 Ranchero Drive, Suite 150, Ann Arbor, MI 48108, and our telephone number is (734) 887-3903. Our website address is [www.esperion.com](http://www.esperion.com). The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement or the accompanying prospectus.

Unless the context otherwise requires, "Esperion," the "company," "we," "us," "our" and similar names refer to Esperion Therapeutics, Inc.

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**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement and the accompanying prospectus, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue," and similar expressions, or the negative of these terms. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus supplement and the accompanying prospectus, and in particular those factors referenced in the section "Risk Factors."

This prospectus supplement and the accompanying prospectus contain forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- § our ability to obtain regulatory approval for the bempedoic acid / ezetimibe combination and bempedoic acid, including statements related to specific clinical studies or clinical observations that will be required for such approval;
- § our ability to achieve clinical or regulatory milestones with our existing cash resources;
- § the design, timing or outcome of our Phase 3 clinical program for the bempedoic acid / ezetimibe combination and bempedoic acid;
- § the design, timing or outcome of our cardiovascular outcomes trial, or CVOT, of bempedoic acid;
- § the design, timing or outcome of our other clinical studies of the bempedoic acid / ezetimibe combination or bempedoic acid;
- § our ability to recruit and enroll patients, particularly statin intolerant patients, in any ongoing or future clinical study;
- § our ability to replicate positive results from a completed clinical study in a future clinical study;
- § our ability to fund our development programs with existing capital or our ability to raise additional capital in the future;
- § the potential benefits, effectiveness or safety of the bempedoic acid / ezetimibe combination and bempedoic acid, as compared to statins and other low-density lipoprotein cholesterol, or LDL-C, lowering therapies, either those currently available or those in development;
- § our ability to respond and adhere to changes in regulatory requirements, including any requirement to conduct additional, unplanned clinical studies in connection with our pursuit of the bempedoic acid / ezetimibe combination or bempedoic acid as an LDL-C lowering therapy;

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guidelines relating to LDL-C levels and cardiovascular risk that are generally accepted within the medical community, including recent changes and any future changes to such guidelines;

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reimbursement policies, including any future changes to such policies or related government legislation, and their impact on our ability to market, distribute and obtain payment for the bempedoic acid / ezetimibe combination or bempedoic acid, if approved;

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the accuracy of our estimates of the size and growth potential of the LDL-C lowering market and the rate and degree of the bempedoic acid / ezetimibe combination or bempedoic acid's market acceptance, if approved;

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our ability to obtain and maintain intellectual property protection for the bempedoic acid / ezetimibe combination or bempedoic acid without infringing on the intellectual property rights of others;

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the loss of any of our key scientific or management personnel;

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our intention to seek to establish strategic relationships or partnerships; and

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our ability to compete with other companies that are, or may be, developing or selling products that may compete with the bempedoic acid / ezetimibe combination or bempedoic acid, if approved.

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**PROSPECTUS SUPPLEMENT SUMMARY**

*The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. Before you decide to invest in our securities, you should read the entire prospectus supplement and the accompanying prospectus carefully, including the risk factors and the financial statements and related notes included or incorporated by reference in this prospectus supplement and the accompanying prospectus.*

**Our Company**

**Overview**

We are the Lipid Management Company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies 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 therapies that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. Bempedoic acid and our lead product candidate, the bempedoic acid / ezetimibe combination, are targeted therapies that have been shown to significantly reduce elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

In the United States, 78 million people, or more than 20 percent of the population, have elevated LDL-C; an additional 73 million people in Europe also live with elevated LDL-C. It is estimated that 40 million patients in the United States are taking statins, with approximately 8.6 million of those patients requiring additional LDL-C lowering. Approximately 3.5 million U.S. patients are only able to tolerate less than the lowest approved daily starting dose of their statin and are therefore considered to be statin intolerant. It is estimated that approximately 3.3 million patients in Europe are statin intolerant and approximately 8.4 million patients require additional LDL-C lowering. Our mission as the Lipid Management Company is to provide patients and physicians with convenient, complementary, cost-effective, once-daily, oral therapies to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies.

**Recent Developments**

***Communications with FDA***

On June 26, 2017, we announced that the U.S. Food and Drug Administration, or FDA, recently confirmed the regulatory pathway to approval for the once-daily, oral combination pill of bempedoic acid 180 mg and ezetimibe 10 mg. Based on feedback from the FDA, we plan to initiate a single global pivotal Phase 3 bridging study (1002FDC-053) for the bempedoic acid / ezetimibe combination pill that will be conducted concurrently with the ongoing global pivotal Phase 3 program for bempedoic acid. The randomized, double-blind, placebo-controlled study is expected to enroll up to 350 patients with hypercholesterolemia and with atherosclerotic cardiovascular disease, or ASCVD, and/or heterozygous familial hypercholesterolemia, or HeFH, including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled. The goal of this study is to evaluate the efficacy and safety of the bempedoic acid / ezetimibe combination, a convenient, cost-effective, once-daily, oral pill. We expect to initiate 1002FDC-053 in the fourth quarter of 2017 and to report top-line results by the end of 2018, and intend to use positive results from this study to support our New Drug Application, or NDA, submission for the bempedoic acid / ezetimibe combination



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through the abbreviated 505(b)(2) pathway by the first quarter of 2019, and our Marketing Authorization Application, or MAA, submission for an LDL-C lowering indication by the first half of 2019.

On March 20, 2017, we announced that the FDA recently confirmed that our LDL-C lowering program is adequate to support approval of bempedoic acid for an LDL-C lowering indication. Based on the successful completion of the global pivotal Phase 3 LDL-C lowering program we plan to submit our NDA for an LDL-C lowering indication by the first quarter of 2019 and our MAA for an LDL-C lowering indication by the first half of 2019. The proposed product label would include specific language for use of bempedoic acid as an adjunct to maximally tolerated statin therapy in patients with hypercholesterolemia, specifically those at high CVD risk with ASCVD and/or HeFH, who require additional LDL-C lowering.

In addition, our interactions with the FDA also addressed the ongoing CLEAR Outcomes CVOT for bempedoic acid in patients with hypercholesterolemia who are at high risk of CVD and who are only able to tolerate less than the lowest approved starting dose of a statin and can be considered statin intolerant. For purposes of the CVOT, we reached an agreement with the FDA that the following definition of statin intolerance is acceptable: "the inability to tolerate two or more statins, one at the lowest approved daily starting dose, due to an adverse effect," as defined in CLEAR Outcomes. The lowest approved daily starting statin doses include an average daily dose of <5 mg rosuvastatin, <10 mg of atorvastatin, <10 mg simvastatin, <20 mg lovastatin, <40 mg pravastatin, <40 mg fluvastatin and <2 mg of pitavastatin. Additionally, patients and investigators will provide written confirmation that the patient is statin intolerant and that the patient is aware of the benefits of statins in reducing the risk of cardiovascular events and death.

***Clinical Development Updates***

*1002-038 Phase 2 efficacy and safety study of the bempedoic acid / ezetimibe combination plus atorvastatin in patients with hypercholesterolemia*

On August 8, 2017, we announced top-line results from the Phase 2 clinical study (1002-038), also known as the triplet oral therapy study. The six-week, Phase 2, randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of bempedoic acid 180 mg, ezetimibe 10 mg and atorvastatin 20 mg (the "bempedoic acid / ezetimibe combination plus atorvastatin", or "Combo + Statin"), versus placebo, in patients with hypercholesterolemia. The primary objective of the study is to assess the LDL-C lowering efficacy of the bempedoic acid / ezetimibe combination plus atorvastatin versus placebo. Secondary objectives include assessing the percent of treated patients achieving a reduction in LDL-C levels of  $\geq 50\%$ , the percent of treated patients reaching LDL-C levels of  $< 70$  mg/d, assessment of the effect of the bempedoic acid / ezetimibe combination plus atorvastatin therapy on additional lipid and cardiometabolic risk markers, including total cholesterol, apolipoprotein B, or apoB, non-high-density lipoprotein-cholesterol, or non-HDL-C, and high-sensitivity C-reactive protein, or hsCRP, and assessment of the safety and tolerability of the bempedoic acid / ezetimibe combination plus atorvastatin therapy, including muscle-related adverse events, or AEs. Prior to randomization, patients were washed out of all lipid-lowering therapies for six weeks. 43 patients received the bempedoic acid / ezetimibe combination

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plus atorvastatin and 20 patients received placebo. While analyses of the complete efficacy and safety results from 100-038 are ongoing, the top-line results are summarized as follows:

**LDL-Cholesterol Percent Change from Baseline to Week 6 Endpoint**

Treatment Group	Number of Patients	LDL-C	LDL-C	Percent Change from Baseline	
		Baseline Mean (SD) mg/dL	Week 6 Endpoint Mean (SD) mg/dL	LS Mean (SE)	P Value
Combo + Statin	41	154 (18)	56 (17)	64% (1.7)	<0.001
Placebo	20	156 (14)	152 (27)	3% (3.34)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

**hsCRP Nonparametric Analysis**

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline	
			Median Change	P Value
Combo + Statin	41	1.94	48%	<0.001
Placebo	19	1.64	3%	

## mITT population

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After six weeks of treatment with the bempedoic acid / ezetimibe combination plus atorvastatin, the primary endpoint of the study, LDL-C levels were lowered by 64% (p<0.001), with an average reduction of 3% for patients dosed with placebo. The maximal effect on LDL-C lowering was seen at 3 weeks into the study.

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95% of patients treated with the bempedoic acid / ezetimibe combination plus atorvastatin achieved an LDL-C reduction of  $\geq 50\%$ . 90% of the treated patients with the bempedoic acid / ezetimibe combination plus atorvastatin achieved an LDL-C level of < 70 mg/dL.

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hsCRP, a marker of the underlying inflammation associated with CVD, was reduced by 48% (p<0.001=0.26) for patients dosed with the bempedoic acid / ezetimibe combination plus atorvastatin after six weeks of therapy, versus a 3% reduction with placebo.

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Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid / ezetimibe combination plus atorvastatin.

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Discontinuation rates for the bempedoic acid / ezetimibe combination plus atorvastatin were low and comparable to placebo. There were no increases (repeated and confirmed) in liver function tests or levels of creatine kinase, or CK, an enzyme associated with muscle damage. Elevations in liver function tests and CK have been observed with use of statins.

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*1002-038 Study Design.* This multi-center, randomized, double-blind, placebo-controlled, parallel group Phase 2 study consisted of two periods. Patients initially underwent screening at Week-6 (Visit S1). Eligible patients began washout of all LDL-C lowering drugs and nutritional supplements at least five weeks prior to randomization. Patients returned at Week-1 (Visit S2) for lipid and/or other assessments. At Week 0

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(Visit T1), 63 patients were randomized in a ratio of 2:1 to receive either the bempedoic acid /ezetimibe combination plus atorvastatin or placebo once daily for 6 weeks.

*1002-038 Study Population.* 63 patients were enrolled and randomized, of whom 80% were Caucasian and 64% were female, and the average age of all patients was 61 years.

*1002-038 Safety and Tolerability Profile.* The bempedoic acid / ezetimibe combination plus atorvastatin appeared to be safe and well tolerated and produced no increases in AEs. Rates of discontinuation due to an adverse event were low. There were no reported serious adverse events in the study. Rates of muscle-related AEs for the bempedoic acid / ezetimibe combination plus atorvastatin were similar to those seen with placebo. There were no elevations (repeated and confirmed) in liver function tests or in CK.

	<b>Number (%) of Patients</b>	
	<b>Combo + Statin</b>	<b>Placebo</b>
	<b>N=43</b>	<b>N=20</b>
<b>Overview of SAEs and Discontinuations</b>		
Any AEs	15 (35%)	7 (35%)
Serious AE(s)		
Total Related AEs	8 (18.6%)	2 (10%)
Study Drug Discontinuation due to AE(s)	3 (7%)	1 (5%)

**Safety and Tolerability Overview of Muscle-Related Adverse Events (AEs)**

	<b>Number (%) of Patients</b>	
	<b>Combo + Statin</b>	<b>Placebo</b>
	<b>N=43</b>	<b>N=20</b>
<b>Muscle-Related Treatment Emergent Adverse Events (AEs)</b>		
Any Potential Muscle AEs	7 (16.3%)	6 (30%)
Related Potential Muscle AEs	2 (4.7%)	2 (10%)
Discontinuation due to Muscle-related AE	1 (2.3%)	1 (5%)

**Corporate Information**

We were founded in January 2008 by former executives of and investors in the original Esperion Therapeutics, Inc., a biopharmaceutical company, which was primarily focused on the research and development of therapies to regulate high-density lipoprotein cholesterol, or HDL-cholesterol. After successfully completing a Phase 2a clinical study with its synthetic HDL-cholesterol therapy ETC-216, the original Esperion was acquired by Pfizer Inc. in 2004. Bempedoic acid was first discovered at the original Esperion and we subsequently acquired the rights to the product from Pfizer in 2008.

Our principal executive offices are located at 3891 Ranchero Drive, Suite 150, Ann Arbor, MI 48108 and our telephone number is (734) 887-3903. Our website address is [www.esperion.com](http://www.esperion.com).

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**The Offering**

Common stock offered by us	3,100,000 shares of common stock.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 465,000 additional shares of common stock.
Common stock to be outstanding after this offering	25,693,162 shares of common stock (or 26,158,162 shares of common stock if the underwriters exercise their option to purchase additional shares in full).
Use of Proceeds	We intend to use the net proceeds from this offering to continue to fund the CLEAR Outcomes CVOT for patients with hypercholesterolemia with ASCVD and/or HeFH, or who are at high risk for CVD, and who are only able to tolerate less than the lowest approved daily starting doses of a statin and can be considered statin intolerant; support the NDA and MAA submission activities and our operations through regulatory approvals for LDL-C lowering indications for the bempedoic acid / ezetimibe combination pill and bempedoic acid; support pre-commercial launch activities for the bempedoic acid / ezetimibe combination pill and bempedoic acid; initiate development activities for a reformulated tablet of bempedoic acid for nonalcoholic steatohepatitis, or NASH, indications; and for working capital and general corporate and administrative expenses. See "Use of Proceeds" on page S-42.
Risk Factors	This investment involves a high degree of risk. You should read the description of risks set forth under "Risk Factors" beginning on page S-10 of this prospectus supplement or otherwise incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to purchase our securities.
NASDAQ Global Market Symbol	"ESPR"
The number of shares of our common stock to be outstanding immediately after this offering is based on 22,593,162 shares outstanding as of June 30, 2017, and does not include:	

- § 452,434 shares of common stock issuable upon the exercise of outstanding options under our 2008 Incentive Stock Option and Restricted Stock Plan with a weighted-average exercise price of \$2.28 per share, as of June 30, 2017;
- § 3,813,422 shares of common stock issuable upon the exercise of outstanding options and vesting of restricted stock units under our Amended and Restated 2013 Stock Option and Incentive Plan with a weighted-average exercise price of \$29.77 per share, as of June 30, 2017;
- § 102,000 shares of common stock issuable upon the exercise of outstanding options under our 2017 Inducement Equity Plan with an exercise price of \$37.31 per share, as of June 30, 2017;
- § 155,582 shares of common stock reserved for future issuance under our Amended and Restated 2013 Stock Option and Incentive Plan, as of June 30, 2017;

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648,000 shares of common stock reserved for future issuance under our 2017 Inducement Equity Plan, as of June 30, 2017;  
and

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256,590 shares of common stock issuable upon the exercise of warrants with a weighted-average exercise price of \$7.25 per  
share, as of June 30, 2017.

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**RISK FACTORS**

*Investing in our common stock involves risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described below. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K, and included in our Quarterly Reports for the fiscal quarters ended March 31, 2017 and June 30, 2017, which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section above entitled "Cautionary Statement Regarding Forward-Looking Statements."*

**Risks Related to our Business and the Clinical Development and Commercialization of Our Product Candidates**

**We depend almost entirely on the success of two product candidates, the bempedoic acid / ezetimibe combination pill and bempedoic acid, which are in Phase 3 clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, our product candidates.**

The bempedoic acid / ezetimibe combination pill and bempedoic acid are our only product candidates in clinical development, and our business depends almost entirely on their successful clinical development, regulatory approvals and commercialization. We currently have no drug products for sale and may never be able to develop marketable drug products. The bempedoic acid / ezetimibe combination and bempedoic acid will require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence their commercialization. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical studies that the product candidate is safe and effective for use in each target indication. This process can take many years and require the expenditure of substantial resources beyond the proceeds we have raised, and may include post-marketing studies and surveillance, including a Risk Evaluation and Mitigation Strategy, or REMS program. Of the large number of drugs in development in the U.S., only a small percentage successfully complete the approval process at the FDA, EMA or any other foreign regulatory agency, and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that the bempedoic acid / ezetimibe combination and bempedoic acid or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market our product candidates in the U.S. or Europe until we receive approval of an NDA from the FDA, a MAA from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA or MAA for the bempedoic acid / ezetimibe combination to treat patients with hypercholesterolemia, we intend to initiate and complete the global pivotal Phase 3 bridging study (1002FDC-053) in addition to the global pivotal Phase 3 LDL-C lowering program for bempedoic acid, to support an NDA submission for an LDL-C lowering indication. As a condition to submitting an NDA or MAA for bempedoic acid to treat patients with hypercholesterolemia, we have currently completed eight Phase 2 clinical studies and expect to complete the global pivotal Phase 3 LDL-C lowering efficacy and safety studies to support an NDA submission for an LDL-C lowering indication,

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and to complete the CLEAR Outcomes CVOT to support an NDA submission for a CVD risk reduction indication.

Additionally, we currently intend to submit NDAs in tandem for the bempedoic acid / ezetimibe combination and for bempedoic acid for LDL-C lowering indications by the first quarter of 2019 if we successfully complete our Phase 3 bridging study and Phase 3 LDL-C lowering program, based on the FDA's recent guidance that these programs are adequate to support approval of an LDL-C lowering indication. However, there is no guarantee that the FDA will view results from our Phase 3 bridging study or global pivotal Phase 3 LDL-C lowering program alone as sufficient to support approval of an LDL-C lowering indication for the bempedoic acid / ezetimibe combination or bempedoic acid. In the event that FDA determines LDL-C lowering is no longer a surrogate endpoint for initial approval of the bempedoic acid / ezetimibe combination or bempedoic acid in the future, we would plan to submit our NDA for bempedoic acid with a proposed indication of CV risk reduction in statin intolerant patients on the basis of a completed and successful CLEAR Outcomes CVOT, which would include the results of the global pivotal Phase 3 LDL-C lowering program, by 2022. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of the bempedoic acid / ezetimibe combination pill and bempedoic acid for many reasons, including, among others:

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the FDA, EMA or any other regulatory authorities may change their approval policies or adopt new regulations, including with respect to whether LDL-C lowering is a surrogate endpoint for initial approval of the bempedoic acid / ezetimibe combination or bempedoic acid;

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the FDA, EMA or any other regulatory authorities may change their approval policies for an LDL-C lowering indication for the bempedoic acid / ezetimibe combination or bempedoic acid if there is a shift in the future standard-of-care for statin intolerant patients with hypercholesterolemia;

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we may not be able to demonstrate that the bempedoic acid / ezetimibe combination and bempedoic acid are safe and effective in treating patients with hypercholesterolemia to the satisfaction of the FDA, EMA or any other regulatory agency;

§

the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;

§

the magnitude of the treatment effect must also be clinically meaningful along with the drug's safety for a favorable benefit/risk assessment by the FDA, EMA or any other regulatory agency;

§

the FDA, EMA or any other regulatory agency may change in the future the number, design, size, duration, patient enrollment criteria, exposure of patients, or conduct or implementation of our clinical studies;

§

the FDA, EMA or any other regulatory agency may require that we conduct additional clinical studies;

§

the FDA, EMA or any other regulatory agency may not approve the formulation, specifications or labeling of the bempedoic acid / ezetimibe combination or bempedoic acid;

§

the clinical research organizations, or CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

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the FDA, EMA or any other regulatory agency may find the data from preclinical studies and clinical studies insufficient to demonstrate that the clinical and other benefits of the bempedoic acid / ezetimibe combination or bempedoic acid outweigh the safety risks;



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the FDA, EMA or any other regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical studies;

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the FDA, EMA or any other regulatory agency may not accept data generated at our clinical study sites;

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if our NDAs, if and when submitted, are reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our applications or may recommend that the FDA require, as a

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condition of approval, additional preclinical studies or clinical studies, limitations in approved labeling or distribution and use restrictions;

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the FDA, EMA or any other regulatory agency may require the development of a REMS as a condition of approval or post-approval; or

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the FDA, EMA or any other regulatory agency may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market the bempedoic acid / ezetimibe combination and bempedoic acid. Moreover, because our business is almost entirely dependent upon these product candidates, any setback in our pursuit of its regulatory approval would have a material adverse effect on our business and prospects.

The development and approvals required for the approval of the bempedoic acid / ezetimibe combination pill are substantially identical to those for bempedoic acid, and the risks relating to the clinical development and approval of bempedoic acid apply equally to the bempedoic acid / ezetimibe combination pill. The FDA accepted our submission of an IND application for the bempedoic acid / ezetimibe combination in the second quarter of 2016 and we completed a bioavailability study. We announced the clinical development and regulatory plans for the bempedoic acid / ezetimibe combination in June 2017. Any failure in our development of bempedoic acid would materially and adversely affect our ability to develop, seek approval for and commercialize the bempedoic acid / ezetimibe combination pill for the planned indications. In addition, even if bempedoic acid succeeds in its clinical development and is approved for one or more indications, there can be no assurance that the bempedoic acid / ezetimibe combination pill would be developed successfully and approved for the same indications or at all, and vice versa.

**Failures or delays in the completion of our global pivotal Phase 3 efficacy and safety studies, our planned global pivotal Phase 3 bridging study for the bempedoic acid / ezetimibe combination or our CLEAR Outcomes CVOT for bempedoic acid could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.**

In January 2016, we commenced our global pivotal Phase 3 long-term safety and tolerability study (Study 1). We initiated our three remaining global pivotal Phase 3 LDL-C lowering efficacy studies and the CLEAR Outcomes CVOT in December 2016. We do not know whether our ongoing clinical studies will be completed on schedule, if at all. We plan to initiate our global pivotal Phase 3 bridging study for the bempedoic acid / ezetimibe combination by the fourth quarter of 2017. We do not know whether this study will be commenced or completed on schedule. Successful completion of such clinical studies and, if required by the FDA due to a change in regulatory policy, our CLEAR Outcomes CVOT, are likely prerequisites to submitting an initial NDA to the FDA, MAA to the EMA or a similar application to any other foreign regulatory authorities from whom we seek to obtain approval and, consequently, the ultimate approval and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid. The commencement and completion of clinical studies can be delayed or prevented for a number of reasons, including, among others:

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the FDA, EMA or any other regulatory authority may not agree to the study design or overall program;

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the FDA, EMA or any other regulatory authority may place a clinical study on hold;

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delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

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inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies;

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difficulties or delays obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site or sites;



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challenges in recruiting and enrolling patients to participate in clinical studies or in our CLEAR Outcomes CVOT, including the size and nature of the patient population, the proximity of patients to clinical sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs, including PCSK9 inhibitors, for similar indications;

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severe or unexpected drug-related side effects experienced by patients in a clinical study, including instances of muscle pain or weakness or other side effects;

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reports from preclinical or clinical testing of other cardiometabolic therapies that raise safety or efficacy concerns; and

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difficulties retaining patients who have enrolled in a clinical study but may be prone to withdraw due to rigors of the study, lack of efficacy, side effects, personal issues or loss of interest.

Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA, the EMA, the IRBs at the sites where the IRBs are overseeing a clinical study, a data safety monitoring committee, or DMC, overseeing the clinical study at issue or any other regulatory authorities due to a number of factors, including, among others:

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failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;

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inspection of the clinical study operations or study sites by the FDA, EMA or any other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;

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unforeseen safety issues;

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changes in government regulations or administrative actions;

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problems with clinical supply materials; and

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lack of adequate funding to continue the clinical study.

**Positive results from completed Phase 1 and**