

PROSPECTUS

8,000,000 Shares



Common Stock

This is Omthera Pharmaceuticals' initial public offering. We are selling 8,000,000 shares of our common stock.

Currently, no public market exists for the shares. The shares will trade on the NASDAQ Global Market under the symbol "OMTH."

We are an "emerging growth company" under federal securities laws and, as such, will be subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 9 of this prospectus.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ 8.00	\$ 64,000,000
Underwriting discounts and commissions(1)	\$.56	\$ 4,480,000
Proceeds, before expenses, to us	\$ 7.44	\$ 59,520,000

(1) We refer you to "Underwriting" beginning on page 121 of this prospectus for additional information regarding total underwriter compensation.

The underwriters may also exercise their option to purchase up to an additional 1,200,000 shares of our common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Certain of our existing stockholders will purchase an aggregate of 2,087,500 shares of our common stock in this offering at the initial public offering price.

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

The shares will be ready for delivery on or about April 16, 2013.

BofA Merrill Lynch

Barclays

Leerink Swann

Stifel

Piper Jaffray

The date of this prospectus is April 11, 2013.

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You should rely only on the information contained in this prospectus or in any free writing prospectus we file with the Securities and Exchange Commission. We and the underwriters have not authorized anyone to provide you with information different from that contained in this prospectus or any free writing prospectus. We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under “Risk Factors” and our financial statements and notes thereto that appear elsewhere in this prospectus. Unless otherwise indicated herein, the terms “we,” “our,” “us,” “Omthera,” or “the Company” refer to Omthera Pharmaceuticals, Inc.

Omthera Pharmaceuticals, Inc.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of new therapies for abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular disease. Epanova, currently our sole product candidate, is a late-stage, novel, omega-3 free fatty acid composition that meaningfully reduces triglycerides, improves other key lipid parameters and is expected to increase patient convenience with 2-gram once-a-day dosing with or without meals. Epanova is a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with eicosapentaenoic acid, or EPA, docosahexaenoic acid, or DHA, and docosapentaenoic acid being the most abundant forms of omega-3 fatty acids. We have completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova. In 2012 we reported positive results from our Phase III EVOLVE and ESPRIT trials, both of which were conducted under Special Protocol Assessment, or SPA, agreements with the U.S. Food and Drug Administration, or FDA. Based on our clinical experience to date, we expect to submit a New Drug Application, or NDA, with the FDA in mid-2013 to commercialize Epanova in the United States for the treatment of patients with triglyceride levels greater than or equal to 500 mg/dL, or severe hypertriglyceridemia. We expect to build a U.S.-based sales and marketing infrastructure to support a launch of Epanova in patients with severe hypertriglyceridemia and anticipate initially targeting specialists, cardiologists and primary care physicians who are the top prescribers of lipid-regulating therapies.

The EVOLVE trial demonstrated in patients with severe hypertriglyceridemia that Epanova 2-, 3- and 4-gram doses administered once daily significantly reduced triglyceride levels and improved other lipid parameters and other markers of cardiovascular risk. In addition, the ESPRIT trial demonstrated Epanova’s efficacy as an adjunct to a low-fat diet and statin therapy for the further reduction of non-HDL-Cholesterol, or non-HDL-C, and triglycerides in high cardiovascular risk patients with triglyceride levels above 200 mg/dL and less than 500 mg/dL, or high triglycerides.

Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglyceride-rich lipoproteins are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure and nephrotic syndrome.

We own exclusive worldwide rights to develop and commercialize Epanova through a licensing agreement with Chrysalis Pharma AG, or Chrysalis. Epanova is currently protected by issued patents that we license from Chrysalis that run until at least 2025, and by pending patent applications, including applications that we jointly own with Chrysalis, that run to 2033 in the United States and other major pharmaceutical markets. We believe that one of the issued U.S. patents protecting Epanova as of the date of potential NDA approval may be eligible for patent term extension for a period of up to five years. In addition, we believe Epanova may also be eligible to obtain new chemical entity, or NCE,

status from the FDA, which could provide up to a five-year regulatory exclusivity that could further strengthen Epanova's exclusivity in the first five years after approval. Epanova is delivered in a patent-protected capsule, with a patent-protected coating designed to maximize bioavailability and tolerability.

Currently, there are several marketed prescription omega-3 fatty acids approved for sale as anti-dyslipidemics in the United States, Europe and Japan. Lovaza, which is sold in the United States, Europe and Japan, is an omega-3 ethyl-ester comprised of EPA and DHA and is indicated for the treatment of severe hypertriglyceridemia in twice-daily doses of two 1-gram capsules or once-a-day dose of four 1-gram capsules. In addition, Vascepa and Epedel are two approved omega-3 ethyl-ester forms of EPA that are sold in the United States and Japan, respectively. Based on currently marketed products, we estimate the total prescription omega-3 market generated over \$2 billion in sales worldwide in 2012. We believe that there will be increased growth in the prescription omega-3 market based on the expected introduction, and resulting increased promotion and awareness, of new prescription omega-3 products, as well as the emergence of new clinical data regarding the efficacy of omega-3s on cardiovascular health.

Epanova's free fatty acid form of omega-3 differentiates it from competitors and we believe this distinction leads to numerous clinical advantages. In clinical studies, Epanova demonstrated improved, predictable absorption characteristics and bioavailability compared to Lovaza. Our Phase II ECLIPSE trial compared the bioavailability of Epanova and Lovaza and demonstrated that Epanova's free fatty acid form is less reliant on meal-fat content for optimal absorption than Lovaza's ethyl-ester omega-3 form, which required a high-fat meal for optimal absorption. This study also demonstrated that Epanova patients on a low-fat diet exhibited four times higher blood plasma levels of EPA and DHA relative to Lovaza. Additional benefits of Epanova's improved bioavailability include once-a-day dosing, reduced pill burden and accompanying heightened patient compliance as Epanova's 2-gram dose displays a similar efficacy to both Lovaza's and Vascepa's 4-gram dosages in reducing triglycerides. Epanova's lower starting 2-gram dosage provides physicians the opportunity to titrate to 4 grams should greater triglyceride reduction be necessary. Moreover, improved blood plasma levels of EPA and DHA have been shown to lead to decreased cardiovascular risk.

After commercially launching Epanova in the severe hypertriglyceridemia indication, we will consider pursuing the development and commercialization of Epanova in combination with statins as a therapy for non-HDL-C and triglyceride reduction in high cardiovascular risk patients with high triglycerides, as well as other indications. Under the SPA for our ESPRIT study, we are able to submit a supplemental NDA for an indication for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy after we obtain approval for Epanova for patients with severe hypertriglyceridemia and are substantially underway with a cardiovascular outcomes study. While we do not intend to immediately pursue such an outcomes study and, therefore, be able to submit a supplemental NDA for this indication, we will review our strategy with respect to this second indication in light of Epanova's commercial success in severe hypertriglyceridemia and our ability to find a suitable pharmaceutical partner to enter into a development and commercial collaboration.

We believe that based on Epanova's favorable clinical profile, as demonstrated in our Phase III ESPRIT and EVOLVE studies, we are well-positioned to capture a meaningful share of the overall prescription omega-3 market in the United States, which we expect will expand following increased promotion and emerging clinical data.

We were incorporated in November 2008 and have funded our operations since inception through private placements of our common stock, issuance of convertible preferred stock and short-term loans and government grants.

Our Strategy

Our goal is to build a specialty pharmaceutical company focused on new therapies for dyslipidemia and cardiovascular disease. Key elements of our strategy to achieve this goal include:

- obtain U.S. regulatory approval for Epanova for the severe hypertriglyceridemia indication;
- establish in-house sales and marketing capabilities to effectively commercialize Epanova in the United States;
- pursue additional indications for Epanova beyond severe hypertriglyceridemia with a strategic partner;
- pursue partnerships to broadly commercialize Epanova outside the United States; and
- strengthen our patent portfolio and other means of protecting exclusivity.

Selected Risk Factors

Our business is subject to many risks and uncertainties of which you should be aware before you decide to invest in our common stock. These risks are discussed more fully under “Risk Factors” in this prospectus. Some of these risks include:

- we currently have no commercial products, and we have not received regulatory approval for, nor have we generated commercial revenue from, any products;
- we depend entirely on the success of Epanova. If we are unable to obtain required regulatory approvals of, commercialize, obtain and maintain patent protection for or gain sufficient market acceptance of Epanova, or experience significant delays in doing so, our business will be materially harmed and our ability to generate revenue will be materially impaired;
- we face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- we have not yet formed a sales or marketing organization to commercialize Epanova and a failure to do so successfully will adversely affect our efforts to become profitable;
- we may be unable to maintain and protect our proprietary intellectual property assets, which could impair our commercial opportunities;
- if we fail to obtain the capital necessary to fund our operations, we may be unable to commercialize Epanova in the United States for treatment of severe hypertriglyceridemia or pursue Epanova for other indications and we could be forced to share our rights to commercialize Epanova with third parties on terms that may not be favorable to us;
- we have incurred significant losses since our inception and, as of December 31, 2012, we had an accumulated deficit of \$64.6 million. We expect to incur substantial losses for the foreseeable future and may never achieve or maintain profitability; and
- our independent registered public accounting firm has issued a going concern opinion, which could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of

specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Also, we have irrevocably elected to “opt out” of the exemption for the delayed adoption of certain accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Company and Other Information

We were incorporated under the laws of the State of Delaware in November 2008. Our principal executive office is located at 707 State Road, Princeton, New Jersey 08540, and our telephone number is (908) 741-4399. Our website address is www.omthera.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

We own and license from a third party various U.S. federal trademark registrations and applications, and unregistered trademarks, including the following marks referred to in this prospectus: *Omthera*[™], our corporate logo and *Epanova*[®]. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the [®] and [™] symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

THE OFFERING

Common stock offered by us	8,000,000 shares
Common stock to be outstanding after this offering	24,414,868 shares
Option to purchase additional shares .	The underwriters have an option to purchase a maximum of 1,200,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus
Use of Proceeds	We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$57.5 million, or \$66.4 million if the underwriters fully exercise their option to purchase additional shares, based on the initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to obtain marketing approval and prepare for the U.S. commercial launch of Epanova for the treatment of severe hypertriglyceridemia and for working capital and other general corporate purposes. See "Use of Proceeds."
NASDAQ Global Market symbol	OMTH
Risk Factors	You should read "Risk Factors" beginning on page 9 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in shares of our common stock.

Certain of our existing stockholders will purchase an aggregate of 2,087,500 shares of our common stock in this offering at the initial public offering price. The shares purchased by these investors will be subject to lock-up restrictions described in "Shares Eligible for Future Sale."

The number of shares of common stock to be outstanding after this offering is based on 16,414,868 shares outstanding as of December 31, 2012 and excludes:

- 1,179,906 shares of common stock issuable upon exercise of outstanding options as of December 31, 2012 at a weighted average exercise price of \$2.86 per share (of which options to acquire 451,610 shares of common stock are vested as of December 31, 2012);
- up to 97,656 shares of common stock issuable to Hercules Technology Growth Capital, Inc. upon exercise of a warrant at \$6.40 per share, which will remain outstanding after this offering unless earlier exercised, based on the initial public offering price per share of \$8.00; and
- 1,218,375 shares of our common stock reserved for future issuance under our 2013 Stock Option and Incentive Plan, which will become effective in connection with this offering.

Except as otherwise indicated, all information in this prospectus:

- gives effect to a 1-for-1.3953 reverse stock split of our common stock effected on April 1, 2013, prior to the effectiveness of this offering;
- gives effect to our amended and restated certificate of incorporation, which we will file immediately prior to the completion of this offering;

- gives effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 10,625,847 shares of our common stock upon the completion of this offering;
- gives effect to the issuance of 2,228,925 shares of common stock upon the conversion of all outstanding principal and interest accrued on our convertible promissory notes and the issuance of 549,995 shares of common stock upon the automatic net exercise of outstanding warrants to purchase capital stock, in each case upon the closing of this offering, based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013; and
- assumes no exercise by the underwriters of their option to purchase up to an additional 1,200,000 shares of our common stock in this offering.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statements of operations data for the years ended December 31, 2011 and 2012 from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

The unaudited pro forma balance sheet data set forth below give effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 10,625,847 shares of our common stock and (ii) the automatic net exercise of outstanding warrants and the conversion of all outstanding principal and interest accrued on our convertible promissory notes into common stock, based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013. The unaudited pro forma as adjusted balance sheet data set forth below give further effect to our issuance and sale of 8,000,000 shares of our common stock in this offering at an initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and estimated offering expenses payable by us.

	Year Ended December 31,		Period From November 19, 2008 (Inception) through December 31, 2012
	2011	2012	2012
	(In thousands, except share and per share data)		
Statements of Operations Data:			
Operating expenses:			
Research and development	\$ 21,210	\$ 22,673	\$ 48,133
General and administrative	3,722	4,916	10,875
Total operating expenses	24,932	27,589	59,009
Loss from operations	(24,932)	(27,589)	(59,009)
Total other income (expense)	(2)	22	(611)
Net loss	(24,934)	(27,568)	(59,620)
Dividends on preferred stock, not declared	(2,864)	(4,160)	(7,415)
Beneficial conversion charge	—	(5,000)	(5,000)
Net loss attributable to common stockholders	\$ (27,798)	\$ (36,728)	\$ (72,035)
Net loss per share, basic and diluted	\$ (22.73)	\$ (19.20)	
Weighted average shares outstanding, basic and diluted	1,222,794	1,912,421	
Pro forma information(1)			
Pro forma net loss per share, basic and diluted (unaudited)	\$ (3.14)	\$ (3.08)	
Pro forma weighted average shares outstanding, basic and diluted (unaudited)	8,873,640	11,939,170(2)	

- (1) The calculations for the unaudited pro forma net loss per common share, basic and diluted, assume the conversion of all our outstanding shares of convertible preferred stock into shares of our common stock.
- (2) Excludes the assumed conversion to common stock of our convertible promissory notes and warrants to purchase capital stock, in each case upon closing of this offering.

As of December 31, 2012

	Actual	Pro forma(3)	Pro forma as adjusted
	(In thousands)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 2,505	\$ 20,105	\$ 77,625
Working capital	(2,816)	14,784	72,304
Total assets	3,008	20,608	78,128
Preferred stock	55,777	—	—
Deficit accumulated during the development stage	(64,620)	(64,851)	(64,851)
Total stockholders' (deficit) equity	(58,251)	15,126	72,646

(3) Pro forma cash and cash equivalents, working capital and total assets includes approximately \$17.6 million as a result of the conversion of our convertible promissory notes into common stock.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this prospectus, including our financial statements and related notes, before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. The risks below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See “Cautionary Note Regarding Forward-Looking Statements” in this prospectus.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend entirely on the success of Epanova, which is still in clinical development. If we are unable to generate revenues from Epanova in any indication, our ability to create shareholder value will be limited.

We have no drug products that have been approved by the U.S. Food and Drug Administration, or FDA. Our only product candidate is Epanova, for which we have not yet filed a New Drug Application, or NDA, and for which we must still complete development activities and seek and receive regulatory approval prior to commercial launch. We do not have any other product candidates in development; therefore our business currently depends entirely on the successful development, regulatory approval and commercialization of Epanova, which may never occur.

We have invested, and expect to continue to invest, a significant portion of our time and financial resources in the development of Epanova in an initial indication as an adjunct therapy to low-fat diet for patients with triglyceride levels greater than or equal to 500 mg/dL, or severe hypertriglyceridemia, for which we have completed one Phase III clinical trial, our EVOLVE Phase III study. The FDA has confirmed via a Special Protocol Assessment, or SPA, agreement that the design and size of this single study is adequate to support regulatory approval on the basis of effectiveness for patients with severe hypertriglyceridemia. The FDA's agreement to an SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA. After commercially launching Epanova in the severe hypertriglyceridemia indication, we will consider pursuing the development and commercialization of Epanova in combination with statins as a therapy for non-HDL-Cholesterol, or non-HDL-C, and triglyceride reduction in high cardiovascular risk patients with levels of triglycerides above 200 mg/dL and less than 500 mg/dL, or high triglycerides, as well as other indications.

We note that most drug candidates never reach the clinical development stage and even those that do reach clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. If we are unable to commercialize Epanova in one or more indications, our ability to create long-term shareholder value will be limited.

In addition, if there is not adequate demand for Epanova or the market for Epanova develops less rapidly than we anticipate, we may not have the ability to shift our resources to the development of alternative products. As a result, the limited range of products we intend to develop, currently only Epanova, could constrain our ability to generate revenues and achieve profitability.

If we are not able to obtain required regulatory approvals for Epanova, we will not be able to commercialize our only product candidate and our ability to generate revenue will be limited.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market Epanova in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for Epanova, including regulatory approval, are not successful for its planned indications, or if adequate demand for Epanova is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such approvals is uncertain and subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of Epanova's safety and efficacy;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other regulatory agencies for marketing approval;
- the dosing of Epanova in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to Epanova;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we have conducted to date or that any future trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or preclinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have not submitted an NDA or received regulatory approval to market Epanova in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission

of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Epanova may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for Epanova in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

Our SPA agreements with the FDA do not guarantee FDA approval of Epanova for the proposed indications.

An SPA agreement is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Our EVOLVE Phase III trial was conducted under an SPA with the FDA. Our ESPRIT Phase III trial was also conducted under an SPA with the FDA. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of these trials are adequate to support use of the studies as the primary basis for approval with respect to effectiveness for the indications studied. An SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no assurance that the FDA will not identify a scientific issue and deem either or both of our SPAs no longer binding. Moreover, any change to a study protocol after agreement with the FDA is reached can invalidate an SPA. If the FDA does not consider the applicable SPA to be binding during its review of our regulatory approval applications, or if the FDA determines that we did not follow the protocols that are subject to SPAs, the agency could assert that additional studies or data are required to support approval of the application.

Epanova is our only product candidate in development. If we fail to successfully commercialize Epanova, we may need to acquire additional product candidates and our business may be adversely affected.

We have never commercialized any product candidates and do not have any other compounds in clinical testing, pre-clinical testing, lead optimization or lead identification stages beyond Epanova. We cannot be certain that Epanova will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize Epanova as a treatment for severe hypertriglyceridemia, high triglycerides or any other indication, whether as a stand-alone therapy or in combination with other treatments, our business would be adversely affected. If this occurs, we may seek out opportunities to discover, develop, acquire or license additional promising product candidates or drug compounds to expand our product candidate pipeline beyond Epanova; however, this would constitute a significant change in our strategy and would likely require substantial

additional capital. We would also be exposed to numerous additional risks related to our ability to identify, select and acquire the right product candidates and products on terms that are acceptable to us, and there is no guarantee that we would be successful in these efforts.

Even if we receive regulatory approval for Epanova, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

The commercial success of Epanova in any indication for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of Epanova will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of prescription omega-3 products generally;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe Epanova and of the target patient population to try new therapies;
- efficacy of Epanova compared to competing products, including Lovaza, Vascepa and omega-3 dietary supplements;
- the introduction of any new products, including generic prescription omega-3 products, that may in the future become available to treat indications for which Epanova may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which Epanova may show utility;
- pricing and cost-effectiveness;
- the inclusion of prescription omega-3 products in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize Epanova successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render Epanova not commercially viable. For example, regulatory authorities may approve Epanova for fewer or more limited indications than we request, may not approve the price we intend to charge for Epanova, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve Epanova with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Any of the foregoing scenarios could materially harm the commercial prospects for Epanova.

If Epanova is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of Epanova may require significant resources and may never be successful. Even if we are able to demonstrate and maintain a competitive advantage over our competitors, if the market for prescription omega-3 treatments fails to achieve expected future growth or decreases, we may not generate sufficient revenue.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not succeed in commercializing Epanova.

At present, we have no sales personnel and a limited number of marketing personnel. We do not intend to begin to hire additional marketing personnel until the time of NDA submission and to establish our own sales organization in the United States until shortly prior to FDA approval of Epanova. Therefore, at the time of our anticipated commercial launch of Epanova, assuming regulatory approval of the drug by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Epanova in the United States.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize Epanova in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe Epanova;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing Epanova, which would adversely affect our business, operating results and financial condition.

Outside the United States, where we intend to commercialize Epanova by entering into collaboration agreements with pharmaceutical partners, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make Epanova obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy,

convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to Epanova. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and Abbott Laboratories, which currently markets Tricor and Trilipix (both fibrates) and Niaspan (niacin) for the treatment of high triglycerides and severe hypertriglyceridemia. In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation related to Lovaza in the United States. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. Generic versions of Lovaza from Apotex or other companies, if available, will also create greater market competition for our product. Amarin Corporation currently markets Vascepa, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia.

Other companies are also developing products that, if approved, will compete directly with Epanova. These companies that are in various stages of clinical development with omega-3 prescription therapies for the treatment of high triglycerides include Trygg Pharma AS (Phase III), Acasti Pharma Inc., a subsidiary of Neptune Technologies and Bioresources Inc. (Phase II), Resolvix Pharmaceuticals, Inc. (Phase I) and Catabasis Pharmaceuticals, Inc. (Phase I).

Epanova is designed to be a prescription-only omega-3 free fatty acid. Omega-3 fatty acids are also marketed by other companies as dietary supplements, which, unlike drugs, are not subject to FDA approval and therefore do not require a prescription and are not subject to pharmaceutical manufacturing standards. As a result, Epanova, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, Epanova will be a prescription-only omega-3 free fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as dietary supplements. Dietary supplements may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval, but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. We believe the pharmaceutical-grade purity of Epanova has a superior therapeutic profile to naturally occurring omega-3 fatty acids and the omega-3 in commercially available dietary supplements. However, we cannot be sure that physicians or consumers will view Epanova as superior. To the extent the price of Epanova is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of Epanova or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Epanova.

Even if we obtain marketing approval for Epanova, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Epanova could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with Epanova.

Even if we obtain U.S. regulatory approval of Epanova for an indication, the FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase IV clinical trials, and post-market surveillance to monitor safety and efficacy. Epanova will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if Epanova is approved for an indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for Epanova, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Epanova and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize Epanova and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for Epanova, restrict or regulate post-approval activities and affect our ability to profitably sell Epanova.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of Epanova, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for Epanova and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners.

Despite initiatives to invalidate the Health Care Reform Law, the U.S. Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Although there are legal challenges to the Health Care Reform Law in lower courts on other grounds, at this time it appears the implementation of the Health Care Reform Law will continue. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize Epanova in foreign markets for which we intend to rely on collaboration with third parties. If we commercialize Epanova in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers’ ability to obtain reimbursement for Epanova in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;

- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of Epanova could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If we market Epanova in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

We are, and will be, completely dependent on third parties to manufacture Epanova, and our commercialization of Epanova could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of Epanova or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in Epanova for use in our clinical trials or for commercial product, if any. As a result, we have entered into manufacturing and supply agreements with Ocean Nutrition Canada Limited, or ONC, and BioVectra Inc., or BioVectra, to manufacture and supply us with bulk API for clinical and commercial purposes. Our March 2012 agreement with ONC for the supply of bulk fish oil for Epanova includes requirements for: (i) a one-time payment of \$1.0 million due to ONC upon completion of FDA inspection of the site; (ii) a one-time payment of \$500,000 due to ONC upon shipment into commerce of the first commercial product; and (iii) us to purchase a certain percentage of our bulk fish oil from ONC. The ONC agreement has an initial term of ten years and will renew for one additional five year period in the event either party gives notice of renewal no later than 12 months prior to the expiration of such initial term. Our March 2012 agreement with BioVectra for the manufacture of the API for Epanova, includes requirements for: (i) construction of a 100 metric ton facility exclusively for the manufacture of the API for Epanova for an amount not to exceed \$5.0 million (of which we have paid approximately \$1.4 million as of December 31, 2012); and (ii) minimum annual purchase commitments. The BioVectra agreement has an initial term of five years from the date of commencement of commercial supply and will automatically renew for consecutive one year periods upon agreement between the parties no later than six months prior to the expiration of the then-current term. Our agreements with ONC and BioVectra are cancelable by us in the event Epanova does not receive regulatory approval or if we abandon commercialization due to market conditions.

In addition, we do not have the capability to encapsulate Epanova as a finished drug product for commercial distribution. Consequently, we have entered into an agreement with Catalent Pharma Solutions GmbH to supply us with finished product.

The facilities used by our contract manufacturers to manufacture Epanova must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to Epanova. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of Epanova or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market Epanova, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market Epanova, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to

comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market Epanova.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished Epanova product or should cease doing business with us, we could experience significant interruptions in the supply of Epanova or may not be able to create a supply of Epanova at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of Epanova might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply Epanova at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of Epanova if we decided to transfer the manufacture of Epanova to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of Epanova, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our current manufacturing and supply partners or any alternative service providers will be able to reduce the costs of commercial scale manufacturing of Epanova over time. If the manufacturing costs of Epanova remain at current levels, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Any termination or suspension of, or delays in the commencement or completion of, any necessary future studies of Epanova for any additional indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Under the SPA for our ESPRIT study, we are able to submit a supplemental NDA for an indication for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy after we obtain approval for Epanova for patients with severe hypertriglyceridemia and are substantially underway with a cardiovascular outcomes study. While we do not intend to immediately pursue such an outcomes study and, therefore, be able to submit a supplemental NDA for this indication, we will review our strategy with respect to this second indication in light of Epanova's commercial success in severe hypertriglyceridemia and our ability to find a suitable pharmaceutical partner to enter into a development and commercial collaboration. In the event we initiate such an outcomes study, delays in the commencement or completion of such study could significantly affect our product development costs. We do not know whether such study will begin or

will be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing Epanova being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing Epanova, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for Epanova in a future indication will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical

studies of Epanova, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of Epanova. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of Epanova could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

In the event we pursue an outcomes study for an indication for Epanova for the reduction of the risk of cardiovascular events in patients with high triglycerides in combination with statin therapy, or other clinical study for other indications, we will continue to be subject to risks related to clinical trials. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in our Phase III clinical trials for Epanova do not ensure that later clinical trials will produce similar results. We cannot assure you that the FDA will view the results as we do or that any future trials of Epanova for other indications will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for Epanova may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for Epanova for other indications. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

Further, we have limited experience conducting clinical trials, and a portion of the clinical trial data that we will use in support of any NDA we submit to the FDA for Epanova was conducted by our licensor in the development of Epanova for Crohn's disease. There can be no assurance that our clinical trials, including our EVOLVE and ESPRIT Phase III clinical trials, or the clinical trials conducted by our licensor, will demonstrate sufficient safety and efficacy for the FDA to approve Epanova for severe hypertriglyceridemia, as an adjunct therapy to low-fat diet and statins for patients with high triglycerides or any other indication that may be specified in an NDA submission.

We expect that we will rely on third parties to conduct any future clinical trials for Epanova. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize Epanova and our business could be substantially harmed.

In the event we conduct any future clinical trials for Epanova for any indication, we expect to enter into agreements with third-party CROs to provide monitors for and to manage data for our ongoing clinical programs. We would rely heavily on these parties for execution of clinical studies for Epanova and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs would not relieve us of our regulatory responsibilities. We and our CROs would be required to comply with cGCPs, which are

regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we would design the clinical trials for Epanova, we expect that the CROs would conduct all of the clinical trials. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of Epanova for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or Epanova. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize Epanova. As a result, our financial results and the commercial prospects for Epanova in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market Epanova will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which Epanova is sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell Epanova profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;

- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Risks Related to Our Financial Position and Need for Capital

We have a limited operating history and have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. The likelihood of success of our business plan must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Therefore, we expect to incur expenses without corresponding revenues until we are able to obtain regulatory approval and subsequently sell Epanova in significant quantities. We have been engaged in developing Epanova since 2009. To date, we have not generated any revenue from Epanova, and we may never be able to obtain regulatory approval for the marketing of Epanova in any indication. Further, even if we are able to commercialize Epanova or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net loss for the year ended December 31, 2012 was \$27.6 million. As of December 31, 2012, we had an accumulated deficit of \$64.6 million.

Assuming we obtain FDA approval, we expect that our expenses will increase as we prepare for the commercial launch of Epanova. We also expect that our research and development expenses will continue to increase in the event we pursue FDA approval for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses may be increasing. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2012 with respect to this uncertainty. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Epanova, but this product candidate cannot be marketed for any indication until regulatory approvals have been obtained. Meaningful revenues will likely not be available until, and unless, Epanova or any future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur. If we successfully complete this offering, based upon our currently-expected level of operating expenditures, we expect to be able to fund our operations for at least the next

months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

If we fail to obtain the capital necessary to fund our operations, we may be unable to commercialize Epanova in the United States for treatment of severe hypertriglyceridemia or pursue Epanova for other indications and we could be forced to share our rights to commercialize Epanova with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our development and commercialization efforts for Epanova. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to Epanova with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Based on our current operating plans, and after giving effect to the receipt of the net proceeds of this offering, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next 12 months. Our cash and cash equivalents were \$2.5 million at December 31, 2012. We raised an additional \$17.6 million in February 2013 through the issuance and sale of convertible promissory notes and warrants. Depending on the status of regulatory approval or, if approved, commercialization of Epanova, as well as the progress we make in selling Epanova, we may require additional capital to fund operating needs thereafter. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for Epanova or otherwise expand more rapidly than we presently anticipate.

Raising additional capital may cause dilution to our existing stockholders or restrict our operations.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. The sale of additional equity or debt securities, if convertible, could result in the issuance of additional shares of our capital stock and could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our common stock to fall.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned by or licensed to us). The patent applications for Epanova may never be approved by

U.S. or foreign patent offices and the existing patents and patent applications relating to Epanova and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies. For example, one of the two patents covering Epanova's time-release coating is undergoing reexamination by the U.S. Patent and Trademark Office, and a third party has requested that the U.S. Patent and Trademark Office order a reexamination of the other of the two patents covering Epanova's time-release coating. Although we do not expect that an adverse decision in the foregoing reexamination matters will have a material adverse effect on our business, any determination during reexamination that claims of these patents are unpatentable, or a determination that narrowing of the patent claims is necessary to overcome the prior art, or a determination in a future proceeding that claims of other patents owned by or licensed to us are unpatentable, could deprive us of exclusionary rights that are important for the successful commercialization of Epanova or any other product candidates that we may develop. In Europe, the patent covering the composition of Epanova's gelatin capsule was opposed after grant, but successfully upheld during Opposition Proceedings. Two of the three Opponents have filed a Notice of Appeal seeking to overturn the judgments previously rendered in favor of patentability by both the Examining Division and the Opposition Division of the European Patent Office. If this patent is invalidated on appeal, our intellectual property position will be weakened and our business could be significantly harmed.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to Epanova, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensor will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

We depend on Chrysalis Pharma AG, or Chrysalis, to protect a significant portion of our proprietary rights. Chrysalis may be primarily or wholly responsible for the maintenance of patents and prosecution of patent applications relating to important areas of our business. If Chrysalis fails to adequately maintain, prosecute or protect these patents or patent applications, we may have the right to take further action on our own to protect our technology. However, we may not be successful or have adequate resources to do so. Any failure by Chrysalis or by us to protect our intellectual property rights could significantly harm our business and prospects.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Our research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our proprietary and licensed technology and other confidential information, our ability and that of our licensor to receive patent protection and our ability to protect valuable information owned or licensed by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we or our licensor fails to obtain or maintain patent protection or trade secret protection for Epanova or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We also rely on the trademarks we license from Chrysalis to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or Chrysalis will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Epanova is covered by patents and will be marketed under trademarks that are not owned by us but are instead licensed to us by a third party.

We have an exclusive worldwide license under certain patents and know-how to develop and commercialize Epanova within a specified field of use pursuant to our license agreement with Chrysalis. We also have a limited license to use the EPANOVA trademark under this agreement. The limitation on our field of use may prevent us from developing and commercializing Epanova in other fields. Additionally, our license is subject to termination for breach of its terms, and therefore our rights may only be available to us for as long as Chrysalis agrees that our development and commercialization activities are sufficient to meet the terms of the license. If this license is terminated and we are not able to negotiate another agreement with Chrysalis for use of its patents, know-how and trademarks, we will not be able to manufacture and market Epanova, which would adversely affect our business prospects and financial condition.

Epanova may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to our proprietary or licensed technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of Epanova or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that our licensor or we may be required to license in order to research, develop or commercialize Epanova, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development or commercialization delays;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent Epanova from being marketed. Any patent-related legal action

against our licensor, our collaborators or us claiming damages and seeking to enjoin commercial activities relating to Epanova or our processes could subject us to potential liability for damages and require our licensor or us to obtain a license to continue to manufacture or market Epanova or any future product candidates. We cannot predict whether we or our licensor would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign Epanova or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing Epanova or a future product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of omega-3 fatty acids, which resulted in the filing of many patent applications related to this research. We are aware of third-party U.S. patents, and corresponding foreign counterparts, that contain broad claims related to methods of using these general types of compounds, which may be construed to include potential uses of Epanova or any future product candidates. If we or our licensor were to challenge the validity of these or any issued U.S. patent in court, we or our licensor would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that, in order to prevail, we or our licensor would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we or our licensor were to challenge the validity of these or any issued U.S. patent in an administrative trial before the Patent Trial and Appeal Board in the U.S. Patent and Trademark Office, we or our licensor would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our or our licensor's favor on questions of infringement, validity or enforceability.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for Epanova, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of Epanova, one or more of the U.S. patents we license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

General Company-Related Risks

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2012, we employed 14 employees. As our development and commercialization plans and strategies develop, we expect to need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize Epanova and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. While we have employment agreements with certain of our employees, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Gerald L. Wisler, our President and Chief Executive Officer, may have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Epanova.

We face a potential risk of product liability as a result of the clinical testing of Epanova and will face an even greater risk if we commercialize Epanova or any other future product. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims

may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Epanova. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Epanova or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize Epanova; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$7.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the NASDAQ Global Market, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and

internal control over financial reporting and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We estimate that we will annually incur approximately \$1.0 million to \$3.0 million in expenses in response to these requirements. We also estimate that the expenses we will incur in completing this offering, not including the underwriting discount, will be approximately \$2.0 million.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the SEC. However, for as long as we remain an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. We will incur substantial accounting expense and expend significant management efforts to comply with these requirements. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with these requirements in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the NASDAQ Global Market, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions contemplated by this offering.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax exempt rate and the value of the company’s stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that the transactions described in this offering, either on a standalone basis or when combined with future transactions, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383. As of December 31, 2012, we have estimated approximately \$45.1 million of U.S. federal and state net operating loss carryforwards may be at risk of loss due to possible prior ownership changes and approximately \$45.1 million of U.S. federal and state net operating loss carryforwards may be at risk of limitation in the event of a future ownership change.

Risks Related to Our Common Stock

An active trading market for our common stock may not develop, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although our common stock has been approved for listing on NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock was determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

We expect that our stock price may fluctuate significantly.

Prior to this offering, you could not buy or sell our common stock publicly. An active public market for our common stock may not develop or be sustained after the completion of this offering. We negotiated and determined the initial public offering price with the underwriters based on several factors. This price may vary from the market price of our common stock after this offering. You may be unable to sell your shares of common stock at or above the initial offering price. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- any delay in filing our intended NDAs for Epanova and any adverse development or perceived adverse development with respect to the FDA's review of those NDAs, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- our failure to commercialize Epanova or develop and commercialize additional indications;
- unanticipated efficacy, safety or tolerability concerns related to the use of Epanova;
- regulatory actions with respect to Epanova or our competitors' products;
- inability to obtain adequate product supply for any approved indication for Epanova or inability to do so at acceptable prices;
- adverse results or delays in our clinical trials;
- results of clinical trials of our competitors' products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and any future international commercialization partners;
- changes in laws or regulations applicable to Epanova or any future product candidates, including but not limited to clinical trial requirements for approvals;

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the NASDAQ Global Market and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Our principal stockholders will exercise significant control over our company.

Immediately after this offering, assuming no shares are purchased in this offering by our existing stockholders, New Enterprise Associates and Sofinnova Partners, our largest stockholders, will beneficially own, in the aggregate, shares representing approximately 48.1% of our outstanding capital stock. New Enterprise Associates and Sofinnova Partners will purchase an aggregate of 1,250,000 shares of our common stock in this offering at the initial public offering price. After giving effect to the purchase of such shares in this offering by these existing stockholders, based on the initial public offering price of \$8.00 per share and the closing of this offering on April 16, 2013, New Enterprise Associates and Sofinnova Partners will beneficially own an aggregate of 12,998,042 shares or 53.2% (50.7% if the underwriters' option to purchase additional shares is exercised in full) of our common stock outstanding after this offering. Although we are not aware of any voting arrangements that will be in place among these stockholders following this offering, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This

concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline significantly and could decline below the initial public offering price. Based on shares outstanding as of December 31, 2012, and including the effect of the conversion of our convertible promissory notes and the net exercise of outstanding warrants into shares of our common stock, upon the completion of this offering, we will have outstanding 24,414,868 shares of common stock, assuming no exercise of outstanding options. Of these shares, 5,893,750 shares of common stock, plus any shares sold pursuant to the underwriters' option to purchase additional shares, will be immediately freely tradable, without restriction, in the public market. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. may, in their sole discretion, permit our officers, directors, employees and current stockholders to sell shares prior to the expiration of the lock-up agreements. Moreover, a relatively small number of our shareholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

After the lock-up agreements pertaining to this offering expire and based on shares outstanding as of December 31, 2012 and including the effect of the conversion of our convertible promissory notes and the net exercise of outstanding warrants into shares of our common stock, an additional 18,521,118 shares will be eligible for sale in the public market. In addition, the 1,179,906 shares subject to outstanding options under our stock option plans and the 1,218,375 shares reserved for future issuance under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of this offering, holders of approximately 13.4 million shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We will have broad discretion in how we use the proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering to obtain marketing approval and prepare for the U.S. commercial launch of Epanova for the treatment of severe hypertriglyceridemia, for working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.

Provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated by-laws, which will be effective upon the completion of this offering, may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors;
- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated by-laws: and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

The affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class, is necessary to amend or repeal the above provisions that are contained in our amended and restated certificate of incorporation. In addition, absent approval of our board of directors, our amended and restated by-laws may only be amended or repealed by the affirmative vote of the holders of at least 75% of our shares of capital stock entitled to vote.

In addition, upon the closing of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law, which limits business combination transactions with stockholders of 15% or more of our outstanding voting stock that our board of directors has not approved. These provisions and other similar provisions make it more difficult for stockholders or potential acquirers to acquire us without negotiation. These provisions may apply even if some stockholders may consider the transaction beneficial to them.

As a result, these provisions could limit the price that investors are willing to pay in the future for shares of our common stock. These provisions might also discourage a potential acquisition proposal or tender offer, even if the acquisition proposal or tender offer is at a premium over the then current market price for our common stock.

We are an “emerging growth company” and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less

active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We have never paid dividends on our capital stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have not paid dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

Investors in this offering will pay a higher price than the book value of our common stock.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. You will incur immediate and substantial dilution of \$5.04 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the initial public offering price of \$8.00 per share. In the past, we issued restricted stock, options and warrants to acquire common stock at prices significantly below the assumed initial public offering price. To the extent any outstanding options or warrants are ultimately exercised, you will sustain further dilution.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, 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 in this prospectus include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our ability to obtain and maintain regulatory approval of Epanova for any indication, and the labeling under any approval we may obtain;
- regulatory developments in the United States and foreign countries;
- our plans to develop and commercialize Epanova;
- our ability, or the ability of potential collaboration partners, to obtain third-party reimbursement for Epanova;
- the successful development of our sales and marketing capabilities;
- the size and growth of the potential markets for Epanova and our ability to serve those markets;
- the rate and degree of market acceptance of Epanova for any indication;
- the success of competing products that are or become available;
- our plans to enter into contracts with suppliers and manufacturers;
- the performance of third-party manufacturers;
- our ability to obtain additional financing;
- our ability to obtain and maintain intellectual property protection for our proprietary assets; and
- the loss of key scientific or management personnel.

In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable 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 which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and elsewhere in this prospectus. 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. You should read this prospectus and the documents that we reference

in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$57.5 million, or \$66.4 million if the underwriters fully exercise their option to purchase additional shares, based on the initial public offering price of \$8.00 per share and after deducting estimated underwriting discounts and estimated offering expenses payable by us.

We currently anticipate that we will use a substantial portion of the net proceeds received by us to obtain marketing approval and prepare for the U.S. commercial launch of Epanova for the treatment of severe hypertriglyceridemia, and the balance for working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. We currently expect to allocate approximately \$30.0 million to \$35.0 million of the proceeds to development costs in preparation of our NDA for Epanova as well as costs to increase capacity and validate the manufacturing process at our suppliers and build inventory for commercial launch, and approximately \$20.0 million to \$25.0 million of the proceeds to marketing and direct selling efforts.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the factors described under “Risk Factors” in this prospectus. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering.

Pending these uses, we intend to invest the net proceeds in high-quality, investment-grade, short-term fixed income instruments which include corporate, financial institution, federal agency or U.S. government obligations.

DIVIDEND POLICY

We have never declared or paid dividends on our capital stock. We do not anticipate paying any dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2012:

- on an actual basis;
- on a pro forma basis to reflect: (i) the conversion of all of our outstanding convertible preferred stock into an aggregate of 10,625,847 shares of common stock upon the completion of this offering and (ii) the automatic net exercise of outstanding warrants and the conversion of all outstanding principal and interest accrued on our convertible promissory notes into common stock, based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013; and
- on a pro forma as adjusted basis to reflect the pro forma adjustments listed above and the sale of 8,000,000 shares of common stock by us in this offering at an initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and estimated offering expenses payable by us.

You should read this table in conjunction with the sections of this prospectus entitled “Use of Proceeds,” “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	As of December 31, 2012		
	Actual	Pro forma(1)	Pro forma as adjusted
	(In thousands, except share data)		
Cash and cash equivalents	\$ 2,505	\$ 20,105	\$ 77,625
Series A Preferred Stock \$0.001 par value; 4,694,375 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	\$ 6,388	\$ —	—
Series B Preferred Stock \$0.001 par value; 10,131,879 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	49,389	—	—
Common Stock \$0.001 par value; 22,000,000 shares authorized, 3,010,101 shares issued and outstanding, actual; 22,000,000 shares authorized, 16,414,868 shares issued and outstanding, pro forma; 120,000,000 shares authorized and 24,414,868 shares issued and outstanding, pro forma as adjusted	3	16	24
Additional paid-in capital	6,365	79,961	137,473
Accumulated deficit	(64,620)	(64,851)	(64,851)
Total capitalization	\$ (2,475)	\$ 15,126	\$ 72,646

(1) Pro forma cash and cash equivalents includes approximately \$17.6 million as a result of the conversion of our convertible promissory notes into common stock.

The table above does not include:

- 1,179,906 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2012, with a weighted average exercise price of \$2.86 per share; and
- 1,218,375 shares of our common stock reserved for future issuance under our 2013 Stock Option and Incentive Plan.

DILUTION

If you invest in our common stock, your investment will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after completion of this offering.

Our historical net tangible book value as of December 31, 2012, was approximately \$(58.6) million, or \$(19.46) per share, based on 3,010,101 shares of common stock outstanding as of December 31, 2012. Historical net tangible book value per share is determined by dividing our total tangible assets less total liabilities and convertible preferred stock by the actual number of outstanding shares of our common stock. Our pro forma net tangible book value as of December 31, 2012 was approximately \$14.8 million, or approximately \$0.90 per share, based on 16,414,868 shares of common stock outstanding after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 10,625,847 shares of our common stock upon the completion of this offering and (ii) the issuance of shares of common stock upon the conversion of all outstanding principal and interest accrued on our convertible promissory notes and the issuance of shares of common stock upon the automatic net exercise of outstanding warrants to purchase capital stock, in each case upon the closing of this offering, based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the pro forma number of shares of common stock outstanding before giving effect to this offering.

After giving effect to our sale of 8,000,000 shares of common stock in this offering based on an initial public offering price of \$8.00 per share, less estimated underwriting discounts and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2012 would have been \$2.96 per share. This represents an immediate increase in pro forma net tangible book value per share of \$2.06 to existing stockholders and immediate dilution in pro forma net tangible book value of \$5.04 per share to new investors purchasing our common stock in this offering at the initial public offering price. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the assumed initial public offering price per share paid by a new investor. The following table illustrates the per share dilution without giving effect to the over-allotment option granted to the underwriters:

Initial public offering price per share	\$ 8.00
Historical net tangible book value per share as of December 31, 2012	\$(19.46)
Increase per share due to the conversion of all shares of convertible preferred stock, conversion of all outstanding principal and interest accrued on our convertible promissory notes and the automatic net exercise of outstanding warrants	<u>20.36</u>
Pro forma net tangible book value per share as of December 31, 2012	0.90
Increase per share attributable to new investors	<u>2.06</u>
Pro forma net tangible book value per share after the offering	<u>2.96</u>
Dilution per share to new investors	<u>\$ 5.04</u>

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be \$3.17 per share. This represents an increase in pro forma as adjusted net tangible book value of \$0.21 per share to

existing stockholders and dilution in pro forma as adjusted net tangible book value of \$4.83 per share to new investors.

The following table summarizes as of December 31, 2012, the number of shares of our common stock purchased from us, the total cash consideration paid to us and the average price per share paid to us by existing stockholders and by new investors in this offering at the initial public offering price of \$8.00 per share, before deducting estimated underwriting discounts and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	16,414,848	67.2%	\$ 73,618,551	53.5%	\$ 4.48
New investors	8,000,000	32.8	64,000,000	46.5	8.00
Total	<u>24,414,868</u>	<u>100.0%</u>	<u>\$137,618,551</u>	<u>100.0%</u>	\$ 5.64

The discussion and tables above assume no exercise of the underwriters' option to purchase additional shares. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders will be further reduced to 64.1% of the total number of shares of our common stock to be outstanding after the offering, and the number of shares of our common stock held by investors participating in the offering will be further increased to 35.9% of the total number of shares of our common stock to be outstanding after the offering.

Certain of our existing stockholders will purchase an aggregate of 2,087,500 shares of our common stock in this offering at the initial public offering price. The foregoing discussion and tables do not reflect any purchases by these existing stockholders. After giving effect to the purchase of shares in this offering by these existing stockholders, based on the initial public offering price of \$8.00 per share, our existing stockholders will hold 75.9% (72.3% if the underwriters option to purchase additional shares is exercised in full) of our common stock outstanding after this offering.

The above discussion and tables are based on 3,010,101 shares of common stock issued and outstanding as of December 31, 2012 and also reflects (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 10,625,847 shares of our common stock upon the completion of this offering and (ii) the issuance of shares of common stock upon the conversion of all outstanding principal and interest accrued on our convertible promissory notes and the issuance of shares of common stock upon the automatic net exercise of outstanding warrants to purchase capital stock, in each case upon the closing of this offering, based on the initial public offering price per share of \$8.00 and the closing of the offering on April 16, 2013, and excludes:

- 1,179,906 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2012, with a weighted average exercise price of \$2.86 per share; and
- 1,218,375 shares of our common stock reserved for future issuance under our 2013 Stock Option and Incentive Plan.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

You should read the selected financial data presented below in conjunction with our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus and financial statements and the related notes included elsewhere in this prospectus. The selected financial data presented below under the heading “Statements of Operations Data” for the years ended December 31, 2011 and 2012 and the selected financial data presented below under the heading “Balance Sheet Data” as of December 31, 2011 and 2012, have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,		Period From November 19, 2008 (Inception) through December 31, 2012
	2011	2012	2012
	(In thousands, except share and per share data)		
Statements of Operations Data:			
Operating expenses:			
Research and development	\$ 21,210	\$ 22,673	\$ 48,134
General and administrative	3,722	4,916	10,875
Total operating expenses	24,932	27,589	59,009
Loss from operations	(24,932)	(27,589)	(59,009)
Total other income (expense)	(2)	22	(611)
Net loss	(24,934)	(27,568)	(59,620)
Dividends on preferred stock, not declared	(2,864)	(4,160)	(7,415)
Beneficial conversion charge	—	(5,000)	(5,000)
Net loss attributable to common stockholders	\$ (27,798)	\$ (36,728)	\$(72,035)
Net loss per share, basic and diluted	\$ (22.73)	\$ (19.20)	
Weighted average shares outstanding, basic and diluted	1,222,794	1,912,421	
 Pro forma information(1)			
Pro forma net loss per share, basic and diluted (unaudited)	\$ 3.14	\$ (3.08)	
Pro forma weighted average shares outstanding, basic and diluted (unaudited)	8,873,640	11,939,170(2)	

- (1) The calculations for the unaudited pro forma net loss per common share, basic and diluted, assume the conversion of all our outstanding shares of convertible preferred stock into shares of our common stock as if the conversion had occurred at the beginning of the period presented, or the issuance date, if later.
- (2) Excludes the assumed conversion to common stock of our convertible promissory notes and warrants to purchase capital stock, in each case upon closing of this offering.

	As of December 31,	
	2011	2012
	(In thousands)	
Balance Sheet Data:		
Cash and cash equivalents	\$10,869	\$ 2,505
Working capital	14,347	(2,816)
Total assets	18,556	3,008
Preferred stock	45,792	55,777
Deficit accumulated during the development stage	(32,052)	(64,620)
Total stockholders’ deficit	(31,414)	(58,252)

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 together with our financial statements and the related notes and the other financial information included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly those under "Risk Factors." Dollars in tabular format are presented in thousands, except per share data, or otherwise indicated.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of new therapies for abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular disease. Epanova, currently our sole product candidate, is a novel, late-stage, omega-3 free fatty acid composition that meaningfully reduces triglycerides, improves other key lipid parameters and is expected to increase patient convenience with 2-gram once-a-day dosing with or without meals. Epanova is a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with eicosapentaenoic acid, or EPA, docosahexaenoic acid, or DHA, and docosapentaenoic acid being the most abundant forms of omega-3 fatty acids. We have completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova. In 2012 we reported positive results from our Phase III EVOLVE and ESPRIT trials, both of which were conducted under Special Protocol Assessment, or SPA, agreements with the U.S. Food and Drug Administration, or FDA. Based on our clinical experience to date, we expect to submit a New Drug Application, or NDA, with the FDA in mid-2013 to commercialize Epanova in the United States for the treatment of patients with triglyceride levels greater than or equal to 500 mg/dL, or severe hypertriglyceridemia. We expect to build a U.S.-based sales and marketing infrastructure to support a launch of Epanova in patients with severe hypertriglyceridemia and anticipate to initially target specialists, cardiologists and primary care physicians who are the top prescribers of lipid-regulating therapies.

We own exclusive worldwide rights to develop and commercialize Epanova through a licensing agreement with Chrysalis Pharma AG, or Chrysalis. Epanova is currently protected by issued patents that we license from Chrysalis that run until at least 2025, and by pending patent applications, including applications that we jointly own with Chrysalis, that run to 2033 in the United States and other major pharmaceutical markets. In addition, we believe Epanova may also be eligible to obtain new chemical entity, or NCE, status from the FDA, which could provide up to five years of marketing exclusivity for Epanova. One of the issued U.S. patents protecting Epanova as of the date of NDA approval may also be eligible for patent term extension for a period of up to five years. Analogous patent term extension and regulatory exclusivity may be available in Europe and various other major pharmaceutical markets. Epanova is delivered in a patent-protected capsule, with a patent-protected coating designed to maximize bioavailability and tolerability.

After commercially launching Epanova in the severe hypertriglyceridemia indication, we will consider pursuing the development and commercialization of Epanova in combination with statins as a therapy for non-HDL-C and triglyceride reduction in high cardiovascular risk patients with high triglycerides, as well as other indications. Under the SPA for our ESPRIT study, we are able to submit a supplemental NDA for an indication for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy after we obtain approval for Epanova for patients with severe hypertriglyceridemia and are substantially underway with a cardiovascular outcomes study. While we do not intend to immediately pursue such an outcomes study

and, therefore, be able to submit a supplemental NDA for this indication, we will review our strategy with respect to this second indication in light of Epanova's commercial success in severe hypertriglyceridemia and our ability to find a suitable partner to enter into a development and commercial collaboration.

Since our inception in 2008, we have devoted substantially all of our resources to developing Epanova, building our intellectual property portfolio, developing the supply chain, business planning, raising capital, and providing general and administrative support for these operations. To date, we have funded our operations primarily through sales of convertible preferred stock and convertible promissory notes. From inception through December 31, 2012, we have received net proceeds of \$55.1 million from such sales.

We are a development stage company and have not generated any revenues. We have never been profitable and, from inception to December 31, 2012, our losses from operations have been \$59.0 million. Our net loss was \$27.6 million and \$24.9 million for the years ended December 31, 2012 and 2011, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities to seek regulatory approval and commercialization of Epanova. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. 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 negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

In February 2013, we issued \$17.6 million aggregate principal amount of convertible promissory notes to existing and new investors. In connection with the notes, we issued to the investors warrants to purchase shares of our capital stock up to 25% of the principal amount of the notes divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. See "Liquidity and Capital Resources—February 2013 Note and Warrant Issuance" for additional details regarding this transaction.

Financial Operations Overview

Revenue

To date, we have not generated any revenues. In the future, we may generate revenue from the sales of Epanova. If we fail to complete the development of Epanova, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of Epanova, which include:

- employee-related expenses, including salaries and stock-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials; and
- costs associated with clinical activities and regulatory operations.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, 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.

The table below summarizes our direct research and development expenses by program for the periods indicated. 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 trials. We have been developing Epanova and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate costs related to acquiring and manufacturing clinical trial materials, salaries, stock-based compensation, employee benefit, or other indirect costs related to our research and development function to specific programs. Those expenses are included in “Other” in the table below.

	Year Ended December 31,	
	2011	2012
	(In thousands)	
Direct research and development expense by program		
EVOLVE	\$ 6,597	\$ 2,923
ESPRIT	3,803	6,368
ECLIPSE	188	15
Preclinical	2,719	490
Development milestones	—	2,419
Other	<u>\$ 7,903</u>	<u>\$10,458</u>
Total research & development	<u>\$21,210</u>	<u>\$22,673</u>

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

We have completed pharmacokinetic (ECLIPSE and ECLIPSE II) and Phase III (EVOLVE and ESPRIT) clinical studies to investigate the safety and efficacy of Epanova. In 2012, we reported positive results from our Phase III studies and based on our clinical experience to date, we expect to submit an NDA with the FDA in mid-2013 to commercialize Epanova in the United States for the treatment of patients with triglyceride levels greater than or equal to 500 mg/dl, or severe hypertriglyceridemia, in mid-2014.

Although the clinical development program for Epanova is essentially complete, the product is subject to a number of risks including, but not limited to:

- the uncertainty of the timing and outcome of regulatory review of Epanova;
- the possibility that the emergence of competing technologies and products and other adverse market developments could impede our commercial efforts; and
- the requirement that the facilities used by our contract manufacturers to manufacture Epanova must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

We will continue to incur development costs in preparation of our NDA for Epanova as well as costs to increase capacity and validate the manufacturing process at our suppliers and build inventory for commercial launch.

The estimated costs expected to be incurred for the activities noted above through commercial launch are between \$30.0 million and \$35.0 million, which we expect to fund with the anticipated proceeds from this offering.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. Other general and administrative expenses include facility costs, communication expenses, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in 2013 due to many factors, the most significant of which include:

- increased personnel expenses as we prepare for the commercialization of Epanova, including costs for market research, sales force preparation and development of information management systems; the extent of such increases will depend in large part upon the timing of our NDA approval for Epanova; and
- increased expenses related to becoming a publicly-traded company, including increased legal and accounting services, stock registration and printing fees, addition of new headcount to support compliance and communication needs, and increased insurance premiums.

Other Income

Other income is comprised of interest income earned on cash, cash equivalents and available for sale securities and gain on the sale of available for sale securities.

Net Operating Losses and Tax Carryforwards

As of December 31, 2012, we had approximately \$45.1 million of federal and state net operating loss carryforwards. We also potentially have federal and state research and development tax credits which would offset future taxable income. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. As of December 31, 2012, all of our net operating losses were fully offset by a valuation allowance.

Bridge Note Interest Expense

Bridge note interest expense is comprised of interest expense on our 8% interest rate bridge note, or Bridge Note, in the amount of \$2.5 million. In connection with the issuance of the Bridge Note, we issued warrants equal to 25% of the principal amount of the Bridge Note.

Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. 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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other 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. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with preclinical development activities; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. Based on historical experience, actual results have not been materially different from our estimates.

Stock-Based Compensation

Described below is the methodology we have utilized in measuring stock-based compensation expense. Following the consummation of this offering, stock option values will be determined based on the quoted market price of our common stock, at the time of grant.

Since our inception in 2008, we have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, 718 “Accounting for Stock Based Compensation,” which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Compensation expense is recognized, on a straight-line basis, over the vesting period of the award. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the price volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Many of these assumptions are highly subjective. Because we are a privately-held company with a limited operating history, we utilize data from several peer companies to estimate expected stock price volatility and the expected term of our options. We selected peer companies from the biopharmaceutical industry with similar characteristics to us, including stage of product development, market capitalization, number of employees and therapeutic focus. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

The following table summarizes the weighted average assumptions we used in our Black-Scholes calculations:

	Year Ended December 31,	
	2011	2012
Employee stock options:		
Risk-free interest rate	1.97%	0.61%
Expected dividend yield	0%	0%
Expected volatility	80%	80%
Expected term (years)	6.25	6.25

The following table summarizes the allocation of our stock compensation expense:

	Year Ended December 31,	
	2011	2012
	(In thousands)	
Research and development	\$186	\$400
General and administrative	178	323
Total	<u>\$364</u>	<u>\$723</u>

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest.

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined contemporaneously by our board of directors based on valuation estimates provided by management.

We utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, “Valuation of Privately-Held Company Equity Securities Issued as Compensation,” to estimate the fair value of our common stock. The methodologies included (1) for options granted during the period September 2011 to March 2012, an option pricing method to estimate our underlying equity value, and a probability-weighted expected return methodology (PWERM) that determined an estimated value under an initial public offering, or IPO, scenario and a sale scenario and (2) for options granted in September 2012, a PWERM that determined an estimated value under IPO and sale scenarios. Each valuation methodology includes estimates and assumptions that require our judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to completing an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of our common stock at each valuation date.

Key variables used in applying the option pricing method are as follows:

- the prices of our convertible preferred stock sold to or exchanged between outside investors in arm’s length transactions and the rights, liquidation preferences and privileges included in the convertible preferred stock as compared to those of our common stock;
- volatility—we estimated volatility based on comparison to volatility of publicly-traded comparable companies;
- time to liquidity—We estimated time to a liquidity event based on the forecasted time to significant clinical development or regulatory event for Epanova that we believed could lead to an IPO or other type of liquidation event for our stockholders;
- risk-free interest rate—We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a liquidation event for our stockholders; and
- discounts for lack of marketability—Because we were a privately held company at the time of the valuations, shares of our common stock were illiquid and, as such, warrant a discount in value from their estimated “marketable” price. We estimated the discount factor for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model.

The following table presents the grant dates and related exercise prices of stock options granted to our employees and our board of directors from inception through December 31, 2012, prior to the closing of our initial public offering, along with the corresponding exercise price for each grant and the fair value per share utilized to calculate stock-based compensation expense.

<u>Grant Date</u>	<u>Number of Shares Underlying Options Granted</u>	<u>Exercise Price per Share</u>	<u>Common Stock Fair Value per Share on Grant Date</u>	<u>Per Share Weighted Average Fair Value of Options</u>
4/7/10	311,811	\$ 0.33	\$ 0.33	\$ 0.31
12/16/10	125,419	\$ 0.56	\$ 0.56	\$ 0.46
9/7/11	710,370	\$ 2.08	\$ 2.08	\$ 1.69
11/16/11	103,920	\$ 2.08	\$ 2.08	\$ 1.69
3/2/12	44,247	\$ 2.08	\$ 2.08	\$ 1.44
9/14/12	81,884	\$15.36	\$15.36	\$10.58
10/31/12	28,667	\$15.36	\$15.36	\$10.58

At December 31, 2012, options to purchase 1,179,906 shares of our common stock were outstanding. The aggregate intrinsic value of these options was \$10,260,419 based on the initial public offering price of \$8.00 per share.

The discussion below highlights the methodology and assumptions utilized to value our stock options granted during the period September 2011 to March 2012, which was calculated using an income-based approach. The following table summarizes the significant assumptions utilized for each of the valuation scenarios used to determine the fair value of our common stock during this period.

	Liquidity Scenario		
	Private	Future IPO	M&A
Probability weighting	50%	15%	35%
Volatility	80%	NA	NA
Risk-free interest rate	0.09%	NA	NA
Discount for lack of marketability	10%	10%	10%
Probability-weighted expected return methodology (PWERM)	\$2.08		

On February 28, 2011, we raised \$31.3 million in a funding round in which we sold shares of our 8% Series B cumulative convertible preferred stock, or Series B Preferred Stock, led by a new investor, New Enterprise Associates, and including our existing investor, Sofinnova Partners. In March 2011, we initiated a pivotal Phase III clinical trial (EVOLVE) for Epanova for patients with severe hypertriglyceridemia. In August 2011, we initiated a second Phase III trial (ESPRIT) for Epanova in patients with triglyceride levels above 200 mg/dL and less than 500 mg/dL currently on statin therapy. At the time, we were planning for Epanova to be commercially available within the next 24 months. Also, as we expected to receive data from our EVOLVE study in the first quarter of 2012, we were positioning to plan for a potential sale in the middle of 2012. We were also developing plans to prepare for an IPO within one year.

Given these developments, it was necessary to incorporate multiple scenarios into the analysis to reflect several potential outcomes, since we had progressed to the point where a possible exit event was becoming more foreseeable. The first scenario assumed that we stayed private. In this first scenario, a discounted cash flow, or DCF, analysis was utilized to arrive at an equity valuation, based on our projections through 2025 and an appropriate rate of return of 45%, which was derived utilizing observed venture capital financing rates. It was concluded that an investor would require a return on equity at the first stage of development level. For the stay-private scenario, we determined enterprise value by calculating the sum of the present values of the explicitly projected cash flows through 2025, present value of horizon value and cash as of the valuation date. Then the option pricing model was used to allocate the equity value amongst our various equity classes, deriving a control level fully marketable value per share of our common stock.

The other two scenarios, IPO and sale, assumed we would sell for a certain amount or were worth a certain amount upon IPO, and then we determined a present value for our common stock based on that value. The same value was assumed for a sale or IPO in these two other scenarios and this value was determined by calculating the value upon a hypothetical liquidity event in one year and discounting that value to the present at an appropriate rate of return. For the IPO or sale scenarios, a somewhat lower level of risk would be expected given that we continued to make progress in our clinical trials and would be progressing toward a liquidity event. In this scenario, a return on equity of 35% was selected. For the IPO or sale scenarios, we determined enterprise value by calculating the sum of the present values of the explicitly projected cash flows through 2025, present value of horizon value and estimated cash one year from the valuation date. This analysis was then compared to data on the values of pre-revenue pharmaceutical companies as a reasonableness test.

The values from the three scenarios were then assigned a weight, based on the probability estimate for each scenario. Then, an appropriate discount for lack of marketability was deducted from this fully marketable value to arrive at the fair market value per share of our common stock. A key factor driving the discount is the expected time to a liquidity event. The longer the expected holding period, the greater the discount for lack of marketability, all other factors being equal. A minority shareholder could realize a return through some liquidity event such as the sale of our company and the distribution of the proceeds. However, a minority shareholder could not unilaterally force such an action. Given our progress toward a sale or IPO, a potential liquidity event was estimated to potentially be twelve months away. This factor would support a lack of marketability but one significantly lower than for a private company with no expectations regarding a sale or IPO.

From a quantitative standpoint, the Black-Scholes and Finnerty Model put option models were used to estimate a theoretical discount for lack of marketability. The put option calculations (both the Black-Scholes and Finnerty model) resulted in discounts ranging from 6% to 12%. Based on quantitative calculations and a review of the qualitative factors and consideration of restricted stock studies, a discount for lack of marketability of 10% was selected.

The discussion below highlights the methodology and assumptions utilized to value our stock options granted in September 2012 and October 2012, which was calculated using a combination of an income-based approach and a market-based approach. The following table summarizes the significant assumptions utilized for each of the valuation scenarios used to determine the fair value of our common stock during this period.

	Liquidity Scenario			
	M&A (Base)	M&A (Upside)	Future IPO (Base)	Future IPO (Upside)
Probability weighting	50%	10%	30%	10%
Discount for lack of marketability	10%	10%	10%	10%
PWERM	\$15.36			

Following the previous valuation, the following significant events occurred:

- in late April 2012, we received positive results from our pivotal Phase III EVOLVE clinical trial, which demonstrated in patients with severe hypertriglyceridemia that Epanova 2-, 3- and 4-gram once-a-day significantly reduced triglyceride levels and improved other lipid parameters as well as other markers of cardiovascular risk. The EVOLVE trial also demonstrated clinical efficacy of 2 grams once-a-day of Epanova that was comparable to the clinical efficacy demonstrated in third-party studies for 4 grams once-a-day of other prescription omega-3 products; and
- in July 2012, we received positive results from our Phase III ESPRIT clinical trial, which supported the efficacy of Epanova as an adjunct to low-fat diet and statin therapy for further reduction of non-HDL-C and triglyceride levels in patients with high triglycerides and at high risk for cardiovascular disease. Epanova yielded clinically and statistically significant reductions in non-HDL-C and triglycerides.

In light of the events noted above, four possible scenarios were considered for this valuation: two sale scenarios and two IPO scenarios. The sale scenarios assumed that we would be sold within the next six months. The two IPO scenarios assumed that we would execute an IPO in one year. In the base sale and IPO scenarios, we utilized a DCF analysis to arrive at an equity value for our company, based on our projections through 2025 and an appropriate rate of return at which to discount these cash flows of 28%, which was derived utilizing observed venture capital financing rates and reflects the median rate of return for early stage companies. Our cost of capital, as a reasonableness check, was

also developed using the capital asset pricing model. For the Base sale scenario, we determined enterprise value by calculating the sum of the present values of the explicitly projected cash flows through 2025 and the present value of the horizon value six months from the valuation date. For the Base IPO scenario, the sum of the present values of the explicitly projected cash flows through 2025 and the present value of the horizon value one year from the valuation date.

For the Upside sale scenario and the Upside IPO scenario, we utilized a market-based approach that considered the enterprise values of comparable biotechnology companies in a similar stage of development as ours, based on market data from recent IPOs and M&A transactions.

For each exit event value, a value that would be allocated to our common stock upon a sale or IPO was determined and present values were then estimated. These values from the four scenarios were then assigned a weight based on our probability estimate for each scenario. Then, an appropriate discount for lack of marketability was then deducted from this fully marketable value to arrive at the fair value per share of our common stock. As the factors underlying our determination of an appropriate discount did not change from the previous valuation, we used a discount for lack of marketability of 10%.

We believe the difference between our estimate of the fair value of our common stock of \$15.36 in October 2012 and the price for this offering is attributable to our use of updated market conditions in the determination of the initial public offering price after consultation with the managing underwriters for this offering. We note that, as is typical in IPOs, the price range for this offering was not derived using a formal determination of fair value, but was determined by us in consultation with the underwriters. Among the factors that were considered in setting this range were the following:

- an analysis of the typical valuation ranges seen in recent initial public offerings for companies in our industry;
- the general condition of the securities markets and the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies; and
- assumptions regarding the demand for our common stock and the public trading market for pharmaceutical companies such as us.

Beneficial Conversion

When we issue a debt or equity security that is convertible into common stock at a discount from the fair value of the common stock at the date the debt or equity security counterparty is legally committed to purchase such a security, or the Commitment Date, a beneficial conversion charge is measured and recorded on the Commitment Date for the difference between the fair value of our common stock and the effective conversion price of the convertible debt or equity security. If the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the convertible debt or equity security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the convertible debt or equity security. The amount allocated to the beneficial conversion feature is presented as a discount or reduction to the related debt security or as an immediate charge to earnings available to common stockholders for convertible preferred stock instruments that are convertible by the stockholders at any time.

In connection with the issuance of the Series B Preferred Stock on July 24, 2012, we recorded a beneficial conversion charge representing the difference between the conversion price and the fair value of our common stock as of the Commitment Date. The intrinsic value was in excess of the proceeds at the commitment date; therefore, the beneficial conversion charge was limited to the proceeds of approximately \$5.0 million.

Emerging Growth Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Results of Operations

Comparison of Years Ended December 31, 2012 and 2011

	Year Ended December 31,		Increase (Decrease)
	2011	2012	
	(In thousands)		
Expenses:			
Research and development	\$ 21,210	\$ 22,673	\$1,353
General and administrative	<u>3,722</u>	<u>4,916</u>	<u>1,194</u>
Operating loss	(24,932)	(27,589)	2,547
Other income (expense):			
Interest expense, net	(67)	—	(67)
Other income	<u>65</u>	<u>22</u>	<u>(43)</u>
Net loss	<u><u>\$(24,934)</u></u>	<u><u>\$(27,568)</u></u>	<u><u>\$2,523</u></u>

Research and development expenses. Research and development expense for the year ended December 31, 2012 was \$22.7 million, compared to \$21.2 million for the year ended December 31, 2011, an increase of \$1.5 million. The increase in research and development expense was primarily due to higher manufacturing costs for commencement of process validation work in connection with preparation for the NDA filing and development of the supply chain.

General and administrative expenses. General and administrative expenses for the year ended December 31, 2012 was \$4.9 million, compared to \$3.7 million for the year ended December 31, 2011, an increase of \$1.2 million. The increase in general and administrative expense was primarily attributable to higher personnel costs as a result of additional headcount to support company growth.

Interest expense, net. Interest expense for the year ended December 31, 2012 was \$0 compared to \$67,222 for the year ended December 31, 2011, a decrease of \$67,222. Our Bridge Notes (and related convertible preferred stock warrants) were converted to Series B Preferred Stock in February 2011 and no new debt was incurred. Accordingly, there was no interest expense in 2012.

Other income. Other income for the year ended December 31, 2012 was \$21,784 compared to \$64,868 for the year ended December 31, 2011, a decrease of \$43,084. Interest income was related to interest earned on our cash, cash equivalents and short-term investments. The decrease was due primarily to a lower average short-term investment balance.

Liquidity and Capital Resources

We have funded our operations since inception through private placements of our common stock, issuance of convertible preferred stock and convertible promissory notes and to a limited extent, short-term loans and government grants. As of December 31, 2012, we have raised a total of \$55.1 million from sales of our equity securities.

At December 31, 2012, we had cash, cash equivalents and short-term investments totaling \$2.5 million. We invest our cash equivalents and short-term investments in highly liquid, interest-bearing investment-grade and government securities in order to preserve principal.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year Ended December 31,	
	2011	2012
	(In thousands)	
Cash used in operating activities	\$(22,331)	\$(24,944)
Cash provided by (used in) investing activities	\$ (6,790)	\$ 6,595
Cash provided by (used in) financing activities	\$ 36,214	\$ 9,985
Net increase (decrease) in cash and cash equivalents	<u>\$ 7,093</u>	<u>\$ (8,364)</u>

Operating Activities

We have incurred significant costs in the area of research and development, including CRO fees, manufacturing, regulatory and other clinical trial costs, as our product was being developed. However, we will have increased development costs in preparation of the NDA for Epanova as well as costs to validate the manufacturing process at our suppliers and build inventory for commercial launch. With the wind down of our Phase III studies, clinical development expenses are expected to decline. We also expect our general and administrative expenses to increase as we expand our administrative and business development activities and prepare for commercial launch. The increase in cash used in operating activities for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily due to higher manufacturing costs in connection with process validation work and development of the supply chain.

Investing Activities

Investing activities include primarily net purchases of marketable securities with the proceeds received from our issuances of convertible preferred stock. It also includes expenditures for any property, plant and equipment and related costs.

The increase of \$13.4 million in cash provided by investing activities for the year ended December 31, 2012, compared to the year ended December 31, 2011 results from higher net sales/maturities of short-term investments to fund operations.

Financing Activities

Cash provided by financing activities in 2011 are due to the issuance of 7,963,002 shares of our Series B Preferred Stock for net proceeds of \$36.2 million. The cash provided by financing activities in the year ended December 31, 2012 is the result of the sale and issuance of 2,041,296 shares of our Series B Preferred Stock for net proceeds of \$10.0 million.

February 2013 Note and Warrant Issuance

In February 2013, we issued \$17.6 million aggregate principal amount of 8% secured convertible promissory notes due February 15, 2014 to existing and new investors. In the event of a default under the notes, the interest rate will be increased from 8% to 15%. The principal balance and all accrued and unpaid interest due on the notes will be converted into shares of our capital stock upon the earliest to occur of the following:

- upon the closing of an initial public offering either with gross proceeds to us of at least \$50.0 million or which has been approved by our board of directors (including the representatives from Sofinnova Partners and New Enterprise Associates), the notes will automatically convert into shares of our common stock at a per share price equal to the price to the public for common stock issued in the initial public offering;
- upon the completion of an equity financing other than an initial public offering as noted above and at the election of the holders of the notes, the notes will convert into shares of the securities issued in the equity financing at the per share price of the securities issued in such equity financing;
- in the absence of an initial public offering on or before February 15, 2014, and at the election of the holders of the notes, the notes will convert into shares of our Series B Preferred Stock or into a more recent class of our equity securities; or
- upon a sale of our company, transfer of all or substantially all of our assets, or the voluntary or involuntary liquidation, dissolution or winding up of our company, and at the election of the holders of the notes, the notes will become due and payable at three times the outstanding principal amount or will convert into Series B Preferred Stock.

In connection with the convertible promissory notes, we issued warrants to purchase shares of our capital stock up to 25% of the principal amount of the convertible promissory notes divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. The warrants are exercisable upon the earliest occurrence of the events described above and expire on February 15, 2023. The warrants automatically net exercise for shares of our common stock upon the closing of our initial public offering. We expect to record the promissory notes at fair value and the warrants as liabilities. Upon issuance, we expect to record interest expense as the difference between the fair value of the notes and warrants and the actual proceeds received. The warrants will be “marked-to-market” at each reporting period.

March 2013 Loan Agreement

In March 2013, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., or Hercules, pursuant to which Hercules has agreed to provide us with a term loan facility of up to \$12.5 million. We may draw down on the facility in two tranches of at least \$5.0 million each commencing on March 29, 2013 and ending September 30, 2013. Under the terms of the loan and security agreement, the term loan will bear interest at a floating yearly rate equal to the higher of either (i) 9.50%, or (ii) the sum of (A) 9.50% plus (B) the prime rate as reported in the Wall Street Journal minus 3.25%. The loan is secured by all of our assets, excluding intellectual property. If we borrow any amounts under the facility, we will be required to make interest only payments through the end of 2013, which may be extended to July 1, 2014 if we receive, on or before January 1, 2014, net cash proceeds of at least \$50.0 million from the issuance of equity securities or other net upfront payments from investors reasonably acceptable to Hercules, referred to as an Equity Event. Thereafter, the loan will be repaid in thirty equal monthly installments of principal and interest. All outstanding amounts, including principal and interest, will be due and payable in full on July 1, 2016, which will be extended to January 1, 2017 if we complete an Equity Event on or before January 1, 2014. To date, we have not borrowed any amounts under the loan facility.

In connection with the loan and security agreement, we agreed to issue to Hercules, effective April 1, 2013, a warrant to purchase a number of shares of our common stock initially equal to 78,125 shares of common stock (which will increase to 97,656 shares if we draw down on the term loan facility) at an exercise price of \$6.40 per share, based on the initial public offering price per share of \$8.00. If we do not complete an initial public offering on or before September 30, 2013, the warrant will be exercisable for shares of our Series B Preferred Stock or shares of a subsequent class of preferred stock, subject to certain conditions. The warrant will expire upon the earlier of April 1, 2020 or five years after the completion of our initial public offering.

We intend to account for the warrant as a liability and account for it at fair value. Subsequently, the warrant will be “marked-to-market” at each reporting date with a corresponding charge (credit) recognized in our Statements of Operations.

Funding Requirements and Other Liquidity Matters

Epanova is still in clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for Epanova for the currently planned or any additional indication;
- establish a sales and marketing infrastructure to commercialize Epanova in the United States;
- seek to identify additional indications for Epanova;
- maintain, leverage and expand our intellectual property portfolio;
- acquire or in-license other products and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of Epanova, and the extent to which we may enter into collaborations with pharmaceutical partners for development and commercialization of Epanova, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of Epanova. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of Epanova;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for Epanova;
- the revenue, if any, received from commercial sales of Epanova;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. 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, 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, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or Epanova or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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 Epanova that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2012 that will affect our future liquidity:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(In thousands)				
Operating leases	\$ 399	\$ 208	\$191	—	—
Construction commitment	3,600	3,600	—	—	—
Development milestone	—	2,000	—	—	—
Total	<u>\$3,999</u>	<u>\$5,808</u>	<u>\$191</u>	<u>—</u>	<u>—</u>

In November 2009, we entered into an exclusive license agreement with PVT Polyver Trust AG (now known as Chrysalis Pharma AG), as successor-in-interest to Tillotts Pharma AG, to develop and commercialize Epanova. Under the license agreement with Chrysalis, we retain the worldwide rights to Epanova and are subject to certain developmental and regulatory milestone payments as well as royalty payments upon commercialization. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of patients with severe hypertriglyceridemia total approximately \$9.5 million. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of patients with high triglycerides total approximately \$15.0 million. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of atrial fibrillation, heart failure or cardiovascular indications for patients with type II diabetes total approximately \$10.0 million. We are also required to pay Chrysalis a tiered royalty for the first 15 years of commercial sales of Epanova that ranges from approximately 7% to up to 12% based on net sales of the product. These royalties are subject to up to a 50% reduction upon certain events relating to the commercialization of competing generic products. As of December 31, 2012, we have paid approximately \$400,000 as a result of the completion of a development milestone. In addition, we accrued \$2.0 million as of December 31, 2012 related to the achievement of a development milestone, which was included in the table above upon our receipt of an invoice from Chrysalis for payment to be made in the second quarter of 2013. However, in March 2013, we and Chrysalis amended the license agreement such that this \$2.0 million development milestone will now be due and payable upon the initiation of an outcomes study for the reduction of high triglycerides. Because we have not initiated an outcomes study and are under no obligation to conduct such a study at this time, the milestone payment is no longer due to Chrysalis and we will reduce this liability during the first quarter of 2013. The remaining milestones are not included in the table above since we were unable to estimate the timing or likelihood of us achieving the milestones.

In March 2012, we entered into an agreement with Ocean Nutrition Canada Limited, or ONC, for the supply of bulk fish oil for Epanova. The agreement includes requirements for: (i) a one-time

payment of \$1.0 million due to ONC upon completion of FDA inspection of the site; (ii) a one-time payment of \$500,000 due to ONC upon shipment into commerce of the first commercial product; and (iii) us to purchase a certain percentage of our bulk fish oil from ONC. The amount included in item (i) is not included in the table above since we were unable to estimate the timing or likelihood of ONC achieving the milestone. The agreement is cancelable by us in the event the product does not receive regulatory approval or if we abandon commercialization due to market conditions and, therefore, items (ii) and (iii) are not included in the table above.

In March 2012, we entered into an agreement with BioVectra Inc. for the manufacture of the active pharmaceutical ingredient, or API, for Epanova. The agreement includes requirements for: (i) construction of a 100 metric ton facility exclusively for the manufacture of the API for Epanova for an amount not to exceed \$5.0 million (of which we have paid approximately \$1.4 million as of December 31, 2012); and (ii) minimum annual purchase commitments. We have included \$3.6 million in the table above for the remaining estimated costs to complete construction since it is reasonably likely we will incur the expenditure. The agreement is cancelable by us in the event the product does not receive regulatory approval or if we abandon commercialization due to market conditions and, therefore, item (ii) is not included in the table above.

In February 2013, we entered into an agreement with Croda Europe Limited, or Croda, for the supply of API for Epanova. The agreement includes requirements for: (i) payment of development fees of \$800,000 in 2013 and (ii) minimum annual purchase commitments. The agreement is cancelable by us in the event the product does not receive regulatory approval or if we abandon commercialization within twelve months of regulatory approval. No payment or fee amounts have been included in the Contractual Obligations and Commitments table above because this contract was executed after December 31, 2012.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Recently Issued Accounting Pronouncements

During May 2011, an accounting standard update regarding fair value measurement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. This standard update also changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The standard is effective for interim and annual periods beginning after December 15, 2011. The adoption of this standard update did not have a significant impact on our financial statements.

Quantitative and Qualitative Disclosures about Market Risk

Our cash and cash equivalents as of December 31, 2012 consisted primarily of cash and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

BUSINESS

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of new therapies for abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular disease. Epanova, currently our sole product candidate is a novel, late-stage omega-3 free fatty acid composition that meaningfully reduces triglycerides, improves other key lipid parameters and is expected to increase patient convenience with 2-gram once-a-day dosing with or without meals. Epanova is a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with eicosapentaenoic acid, or EPA, docosahexaenoic acid, or DHA, and docosapentaenoic acid being the most abundant forms of omega-3 fatty acids. We have completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova. In 2012, we reported positive results from our Phase III EVOLVE and ESPRIT trials, both of which were conducted under Special Protocol Assessment, or SPA, agreements with the U.S. Food and Drug Administration, or FDA. Based on our clinical experience to date, we expect to submit a New Drug Application, or NDA, with the FDA in mid-2013 to commercialize Epanova in the United States for the treatment of patients with triglyceride levels greater than or equal to 500 mg/dL, or severe hypertriglyceridemia. We expect to build a U.S.-based sales and marketing infrastructure to support a launch of Epanova in patients with severe hypertriglyceridemia and anticipate to initially target specialists, cardiologists and primary care physicians who are the top prescribers of lipid-regulating therapies.

The EVOLVE trial demonstrated in patients with severe hypertriglyceridemia that Epanova 2-, 3- and 4-gram doses administered once daily significantly reduced triglyceride levels and improved other lipid parameters and other markers of cardiovascular risk. In addition, the ESPRIT trial demonstrated Epanova's efficacy as an adjunct to a low-fat diet and statin therapy for the further reduction of non-HDL-Cholesterol, or non-HDL-C, and triglycerides in high cardiovascular risk patients with triglyceride levels above 200 mg/dL and less than 500 mg/dL, or high triglycerides.

We own exclusive worldwide rights to develop and commercialize Epanova through a licensing agreement with Chrysalis Pharma AG, or Chrysalis. Epanova is currently protected by issued patents that we license from Chrysalis that run until at least 2025, and by pending patent applications, including applications that we jointly own with Chrysalis, that run to 2033 in the United States and other major pharmaceutical markets. We believe that one of the issued U.S. patents protecting Epanova as of the date of NDA approval may be eligible for patent term extension for a period of up to five years. In addition, we believe Epanova may also be eligible to obtain new chemical entity, or NCE, status from the FDA, which could provide up to a five-year regulatory exclusivity that could further strengthen Epanova's exclusivity in the first five years after commercialization. Analogous patent term extension and regulatory exclusivity may be available in Europe and various other major pharmaceutical markets. Epanova is delivered in a patent-protected capsule, with a patent-protected coating designed to maximize bioavailability and tolerability.

Currently, there are several marketed prescription omega-3 fatty acids approved for sale as anti-dyslipidemics in the United States, Europe and Japan. Lovaza, which is sold in the United States, Europe and Japan, is an omega-3 ethyl-ester comprised of EPA and DHA and is indicated for the treatment of severe hypertriglyceridemia in twice-daily doses of two 1-gram capsules or once-a-day dose of four 1-gram capsules. In addition, Vascepa and Epadel are two approved omega-3 ethyl-ester forms of EPA that are sold in the United States and Japan, respectively. Based on currently marketed products, we estimate the total prescription omega-3 market generated over \$2 billion in sales worldwide in 2012. We believe that there will be increased growth in the prescription omega-3 market based on the expected introduction, and resulting increased promotion and awareness, of new

prescription omega-3 products, as well as the emergence of new clinical data regarding the efficacy of omega-3s on cardiovascular health.

Epanova's free fatty acid form of omega-3 differentiates it from competitors and we believe this distinction leads to numerous clinical advantages. In clinical studies, Epanova demonstrated improved, predictable absorption characteristics and bioavailability compared to Lovaza. Our Phase II ECLIPSE trial compared the bioavailability of Epanova and Lovaza and demonstrated that Epanova's free fatty acid form is less reliant on meal-fat content for optimal absorption than Lovaza's ethyl-ester omega-3 form, which required a high-fat meal for optimal absorption. This study also demonstrated that Epanova patients on a low-fat diet exhibited four times higher blood plasma levels of EPA and DHA relative to Lovaza. Additional benefits of Epanova's improved bioavailability include once-a-day dosing, reduced pill burden and accompanying heightened patient compliance as Epanova's 2-gram dose displays a similar efficacy to both Lovaza's and Vascepa's 4-gram dosages in reducing triglycerides. Epanova's lower starting 2-gram dosage provides physicians the opportunity to titrate to 4 grams should greater triglyceride reduction be necessary. Moreover, improved blood plasma levels of EPA and DHA have been shown to lead to decreased cardiovascular risk.

After commercially launching Epanova in the severe hypertriglyceridemia indication, we will consider pursuing the development and commercialization of Epanova in combination with statins as a therapy for non-HDL-C and triglyceride reduction in high cardiovascular risk patients with high triglycerides, as well as other indications. Under the SPA for our ESPRIT study, we are able to submit a supplemental NDA for an indication for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy after we obtain approval for Epanova for patients with severe hypertriglyceridemia and are substantially underway with a cardiovascular outcomes study. Upon successful completion of this outcomes study, we would anticipate seeking additional approval for Epanova to reduce the risk of cardiovascular events. While we do not intend to immediately pursue such an outcomes study and, therefore, be able to submit a supplemental NDA for this indication, we will review our strategy with respect to this second indication in light of Epanova's commercial success in severe hypertriglyceridemia and our ability to find a suitable pharmaceutical partner to enter into a development and commercial collaboration.

We believe that based on Epanova's favorable clinical profile, as demonstrated in our Phase III ESPRIT and EVOLVE studies, we are well-positioned to capture a meaningful share of the overall prescription omega-3 market in the United States, which we expect will expand following increased promotion and emerging clinical data.

Our Strategy

Our goal is to build a specialty pharmaceutical company focused on new therapies for dyslipidemia and cardiovascular disease. Key elements of our strategy to achieve this goal include:

- *Obtain U.S. regulatory approval for Epanova for the severe hypertriglyceridemia indication.* Based on the positive results of our pivotal Phase III EVOLVE study of Epanova for the treatment of severe hypertriglyceridemia, we intend to submit an application for marketing approval by the FDA under our SPA in mid-2013.
- *Establish in-house sales and marketing capabilities to effectively commercialize Epanova in the United States.* Subject to receiving marketing approval, we plan to leverage our management team's expertise in commercializing innovative therapeutic products to build a focused, in-house sales and marketing organization to establish relationships with specialists, cardiologists and primary care physicians who comprise the top prescribers of lipid-regulating therapies.

- *Pursue additional indications for Epanova beyond severe hypertriglyceridemia with a strategic partner.* We intend to seek a partner to pursue approval of Epanova for additional indications beyond severe hypertriglyceridemia. These indications may include mixed dyslipidemia (low levels of HDL-Cholesterol, or HDL-C, and elevated levels of triglycerides, with or without elevated levels of LDL-Cholesterol, or LDL-C), indications to reduce the risk of cardiovascular events and fixed-dose combinations with statins or other approved products. Approval of these indications would greatly expand our target patient population.
- *Pursue partnerships to broadly commercialize Epanova outside the United States.* As we continue to advance Epanova toward regulatory approval in the United States, we are also investigating collaborations with pharmaceutical partners for regulatory approval and commercialization of Epanova in key geographies outside the United States.
- *Strengthen our patent portfolio and other means of protecting exclusivity.* We intend to continue to explore opportunities presented by the disclosure of the existing patent applications and to file new applications to continue to broaden our intellectual property portfolio relating to Epanova. In addition, the potential to obtain NCE status from the FDA for the omega-3 free fatty acid composition of the active ingredient in Epanova could provide market exclusivity for up to five years, in parallel with our patent protection. We also intend to explore additional life cycle management opportunities for Epanova.

Background

Hypertriglyceridemia and Cardiovascular Disease Market Overview

Hypertriglyceridemia refers to a condition in which patients have levels of triglycerides in their blood above 200 mg/dL, and severe hypertriglyceridemia refers to a condition involving levels of triglycerides equal to or above 500 mg/dL. Triglycerides are fats that are carried in the blood, together with cholesterol within lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease. Hypertriglyceridemia is due to both genetic and environmental factors. Environmental factors include obesity, sedentary lifestyle and high-caloric diets. Hypertriglyceridemia is also associated with comorbid conditions such as diabetes, chronic renal failure and nephrotic syndrome.

The prevalence of hypertriglyceridemia is rapidly increasing in the United States and throughout the world, correlating with the increasing incidence of obesity. Of the over 100 million patients with dyslipidemia in the United States, it is estimated that over 40 million are diagnosed with hypertriglyceridemia and over four million are diagnosed with severe hypertriglyceridemia. A recent National Health and Nutrition Examination Survey of dyslipidemia in the United States indicated that, while LDL-C levels have actually declined since the last National Health and Nutrition Examination Survey analysis, the percentage of patients with severe hypertriglyceridemia has risen sharply along with the dramatic increases in obesity. The National Cholesterol Education Program, or NCEP, Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol recommends that the first priority for the management of severe hypertriglyceridemia be triglyceride reduction to decrease the risk of pancreatitis. In addition, severe hypertriglyceridemia is also associated with markedly increased risk for cardiovascular disease and recent studies have demonstrated that elevated triglyceride levels can be regarded as an independent risk factor for cardiovascular disease related events such as myocardial infarction, ischemic heart disease and ischemic stroke.

Cardiovascular disease has been linked to a range of lipid disorders (LDL-C, HDL-C, triglycerides and non-HDL-C) collectively referred to as dyslipidemia. Historically, low HDL-C (commonly referred to as “good” cholesterol) and high LDL-C (commonly referred to as one of the components of “bad” cholesterol) levels were generally considered the determining risk factors for cardiovascular disease, resulting in therapeutic strategies designed primarily to manage cholesterol

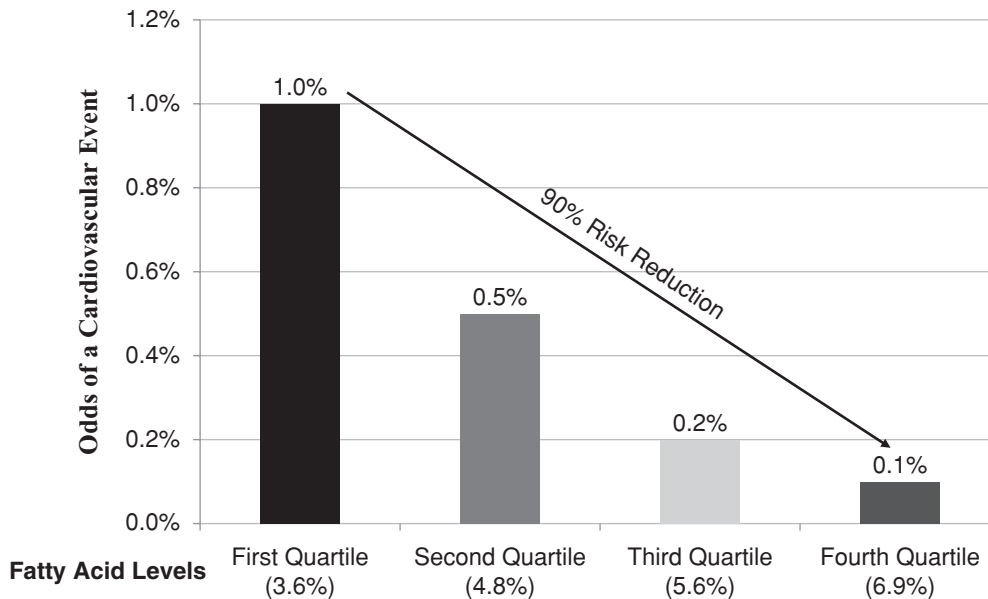
levels. However, recent investigations conclude that non-HDL-C (total cholesterol minus HDL-C) is a superior predictor of risk for cardiovascular disease compared to LDL-C, and when LDL-C and non-HDL-C levels are discordant, the risk appears to follow non-HDL-C. Non-HDL-C is a measure of the cholesterol and triglycerides carried by all apolipoprotein B-containing lipoproteins, including very low-density lipoprotein, or VLDL, chylomicron, intermediate density lipoprotein, LDL (including small, dense LDL), and lipoprotein. In addition, as obesity continues to become an increasing concern in United States, there is less focus on LDL-C and an emerging clinical consensus to also treat elevated concentrations of triglycerides that contribute to the total non-HDL-C which makes up all the “bad cholesterol.” A recent meta-analysis by Sarwar et al. included 29 prospective studies and was the largest and most comprehensive epidemiological assessment of the association between triglyceride values and cardiovascular disease risk in Western populations (262,525 participants; 10,158 cases). A combined analysis of the 29 studies yielded an adjusted odds ratio of 1.72 (72% higher risk) for the patients with triglyceride levels greater than or equal to 200 mg/dL compared to those with normal triglyceride levels. The conclusion of the study is that there is a strong and highly significant association between triglyceride value and cardiovascular disease risk.

Currently Available Treatment Options

The dramatic rise in obesity over the last 20 years has led to a concomitant increase in triglyceride levels among the population, and therefore has resulted in a shift in the clinical awareness of the critical role that high triglyceride levels have as a predictor of cardiovascular events. Accordingly, the introduction of new drugs and novel mechanisms of action to lower the risk of cardiovascular events by addressing complicated lipid profiles in their entirety, including elevated triglycerides, has become a priority. The initial treatment recommendation for patients with dyslipidemia is typically a low-fat diet. Dyslipidemia is also treated with statins, which account for approximately 80% of all prescriptions. However, statins alone are primarily used for reducing blood levels of LDL-C and appear to have only modest effects on triglyceride levels. Recognizing that statins alone are not effective triglyceride lowering drugs, the NCEP panel recommends the use of more focused therapies to lower triglyceride levels in patients with severe hypertriglyceridemia. Fibrates, omega-3 fatty acids and niacin are all used to lower triglyceride levels. In patients with severe hypertriglyceridemia, first-line drug therapy is often a prescription omega-3 or fibrate. Prescription omega-3 has been shown to reduce triglyceride levels in the range of 26-52%. In 2012, U.S. sales of branded fibrates were approximately \$1.1 billion.

The cardioprotective efficacy of omega-3 fatty acids is well-established, and, therefore, the American Heart Association recommends increased intake of fish enriched with omega-3 fatty acids. Omega-3 products have anti-thrombotic and anti-inflammatory effects that have proven to inhibit atherosclerosis in animal models as well as reduce the rate of adverse cardiovascular events in humans. Omega-3 fatty acids, particularly those with concentrated levels of EPA and DHA, have been demonstrated in multiple clinical trials to lower serum concentrations of triglycerides and non-HDL-C. In a study published in the *New England Journal of Medicine*, increased levels of EPA and DHA in red blood cells directly correlated with significant reductions in cardiovascular health risks.

Relationship Between EPA+DHA Levels and Cardiovascular Risk



In a subgroup analysis of the Japan EPA Lipid Intervention Study, in which 18,645 hypercholesterolemic patients randomly received EPA plus a statin or statin control, patients with baseline triglycerides >150 mg/dL and HDL-C <40 mg/dL receiving EPA plus a statin (7,503 patients) had a 53% ($p=0.043$) reduced risk of cardiovascular disease compared to a statin alone (7,478 patients). In addition, the GISSI trial randomly assigned 11,324 survivors of recent myocardial infarction to receive omega-3 polyunsaturated fatty acids (1 gram per day), vitamin E (300 mg per day), both, or neither (the control group) for 3.5 years. Among the patients who received omega-3 fatty acids alone, as compared with the control group, there was a 15% reduction in the composite primary end point of death, nonfatal myocardial infarction, or nonfatal stroke ($p<0.02$), with a 20% reduction in the rate of death from any cause ($p<0.01$) and a 45% reduction in the rate of sudden death ($p<0.001$).

A prescription omega-3 fatty acid approved for use as an anti-dyslipidemic is marketed as Lovaza in the United States, Omacor, Seacor, Eskim, Esapent and Zodin in Europe and Lotriga in Japan. Lovaza, which is comprised of omega-3 ethyl-ester comprised of EPA and DHA, is indicated for the treatment of severe hypertriglyceridemia in twice-daily doses of two 1-gram capsules or once-a-day dose of four 1-gram capsules. In the 12 months ended December 31, 2012, an aggregate of approximately 5.2 million prescriptions for Lovaza had been dispensed in the United States, representing an 8% year-over-year decline in prescriptions. Lovaza currently represents approximately 2.5% of total anti-dyslipidemic prescriptions in the United States, with reported U.S. sales of nearly \$1.0 billion in the 12 months ended December 31, 2012. Worldwide sales of Lovaza/Omacor were nearly \$1.4 billion in the 12 months ended September 30, 2012. A second ethyl-ester prescription omega-3, marketed as Vascepa, was approved in the United States in July 2012. Vascepa is an omega-3 ethyl-ester form of EPA. In addition, a third ethyl-ester prescription omega-3 product, which also consists solely of EPA, is marketed as Epadel in Japan. Epadel reported sales in Japan of approximately \$500 million in the 12 months ended February 28, 2012. Based on currently marketed products, we estimate the total prescription omega-3 market generated over \$2 billion in sales worldwide in 2012. We believe that there will be increased growth in the prescription omega-3 market in conjunction with the expected introduction, and resulting increased promotion and awareness, of new prescription omega-3 products, as well as the emergence of new clinical data regarding the efficacy of omega-3 on cardiovascular health.

Current estimates indicate that fewer than 4% of adults in the United States with hypertriglyceridemia receive prescription medication to lower triglyceride levels, representing a continuing serious unmet medical need. The currently available treatment options have significant limitations in the treatment of hypertriglyceridemia which we believe Epanova can address. The use of fibrates has been shown to possess a risk of abnormal increases in liver enzymes and creatinine (a marker of kidney function) and, when combined with a statin, rhabdomyolysis (muscle breakdown). Niacin has not proven particularly effective for use in lowering triglycerides and is considered difficult to tolerate, due to the potential for severe flushing in patients. Although many dietary supplements containing fish oils or other omega-3 fatty acid formulations are currently available on the market, they have lower concentrations of active ingredient and are not approved to treat hypertriglyceridemia. In addition, absorption of ethyl-ester forms of currently available prescription omega-3 fatty acids requires the breakdown of fats by pancreatic enzymes that are produced in response to the consumption of high-fat meals. As a low-fat diet is typically a critical component for the treatment of patients with severe hypertriglyceridemia, these ethyl-ester formulations have demonstrated poor absorption and bioavailability relative to those formulated as free fatty acids.

We believe that Epanova, with its excellent bioavailability, unique ratios of omega-3 free fatty acids, increased plasma concentrations of EPA and DHA compared to Lovaza, once-a-day dosing convenience, excellent safety profile and efficacy in reducing triglyceride levels, is well-positioned to address this unmet medical need and become a standard of care in the treatment of hypertriglyceridemia. We believe that Epanova also has the potential to replace fibrates due to its demonstrated clinical efficacy and more favorable safety profile. Furthermore, we believe that Epanova in combination with statins could become a standard of care in patients with mixed dyslipidemia with a prescribing and commercial advantage favoring products with a once per day dosing convenience similar to statins.

Epanova

Overview

Epanova contains EPA and DHA in their free fatty acid form at a total concentration of 50-60% EPA and 15-25% DHA along with other potentially active omega-3 fatty acids stored in a patent-protected capsule with a patent-protected coating designed to maximize bioavailability and tolerability. Free fatty acids are the chemical form in which essential fatty acids, such as EPA and DHA, are absorbed in the digestive tract. The active ingredient of Epanova is a complex mixture of concentrated omega-3 free fatty acids purified from crude marine fish oil and are, therefore, of natural origin. Our strategy is to initially develop and commercialize Epanova in the United States as a prescription monotherapy as an adjunct to low-fat diet in patients for the reduction of triglyceride levels greater than or equal to 500 mg/dL, or severe hypertriglyceridemia.

The present Epanova formulation is the result of the further development of a drug originally intended to serve as treatment of Crohn's disease, which ultimately proved safe but ineffective for treatment of Crohn's disease. Before halting internal development and licensing its rights to the drug formulation to us, Tillotts Pharma AG (the predecessor entity to Chrysalis) conducted two large pivotal Phase III trials in 762 randomized patients with Crohn's disease in both the European Union and North America.

We have completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova. Epanova has demonstrated improved absorption characteristics and bioavailability as compared to Lovaza, an ethyl-ester formulation of omega-3. Ethyl-ester forms of omega-3s require enzymatic breakdown prior to absorption, with the extent of absorption dependent upon the stimulation of pancreatic enzyme production, often instigated by the co-ingestion of high-fat meals. Unlike ethyl-ester forms of omega-3 fatty acids, such as Lovaza and Vascepa, the free fatty acid

form can easily cross the intestinal wall without enzymatic breakdown allowing more predictable and consistent absorption at lower doses independent of meal-fat content.

Our pharmacokinetic clinical program ECLIPSE, which consisted of two studies comparing the bioavailability of Epanova and Lovaza, showed that the absorption of the ethyl-ester form found in other concentrated omega-3 compounds is significantly impacted by the fat content of meals, whereas the absorption of the free fatty acid form of Epanova does not appear to be constrained by this food effect. We expect that, based on this demonstrated improved bioavailability, Epanova would yield either similar efficacy with a lower daily dosage (i.e. two 1-gram capsules, once per day) or improved triglyceride lowering efficacy at doses comparable to existing omega-3 products currently on the market or approved for marketing (i.e. twice-daily doses of two 1-gram capsules or once-a-day dose of four 1-gram capsules for Lovaza).

Our Phase III program consisted of two clinical studies designed to further investigate the potential safety and efficacy of Epanova in patients with dyslipidemia: our pivotal Phase III EVOLVE trial (Epanova for Lowering Very high triglyceridEs); and our Phase III ESPRIT trial (Epanova combined with a Statin in Patients with hyperTriglycerIdemia to reduce non-HDL cholestTerol). In April 2012, we announced results from our pivotal Phase III EVOLVE clinical trial. The primary endpoint of the trial, conducted with patients with severe hypertriglyceridemia, was the percentage change in triglycerides from baseline to week 12 and secondary endpoints were the changes in other lipoproteins. The EVOLVE trial demonstrated that the free fatty-acid form of omega-3 fatty acids in the 2-gram dose of Epanova produced significantly improved blood levels of EPA and DHA that, in turn, led to significant decreases in triglyceride levels and non-HDL-C. In November 2012, we announced the results from our Phase III ESPRIT clinical trial in which Epanova demonstrated efficacy as an adjunct to a low-fat diet and statin therapy for the further reduction of non-HDL-C and triglyceride levels in patients with high triglycerides and high risk for cardiovascular disease. These results are comparable to the results found in third-party studies of other FDA-approved ethyl-ester omega-3 prescription products. The results of our EVOLVE and ESPRIT Phase III trials provide statistically significant evidence that Epanova reduces triglycerides and non-HDL-C and improves other lipid parameters.

We obtained an SPA agreement with the FDA for both our EVOLVE and ESPRIT studies. An SPA is an agreement with the FDA that the proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval, if the trial demonstrates sufficiently favorable efficacy results, safety profiles and benefit/risk of a treatment. Based on our clinical experience to date, we expect to submit an NDA with the FDA in mid-2013 pursuant to the provisions of Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, or FDCA, to commercialize Epanova for severe hypertriglyceridemia. Accordingly, we do not expect that any FDA approval of Epanova will be affected by any regulatory exclusivity granted to currently approved prescription omega-3 products under the Hatch-Waxman amendments to the FDCA. After commercially launching Epanova in the severe hypertriglyceridemia indication, we will consider pursuing the development and commercialization of Epanova in combination with statins as a therapy for non-HDL-C and triglyceride reduction in high cardiovascular risk patients with levels of triglycerides above 200 mg/dL and less than 500 mg/dL, as well as other indications. Under the SPA for our ESPRIT study, we are able to submit an NDA for an indication for Epanova for the reduction of non-HDL-C and triglycerides in patients with high triglycerides in combination with statin therapy after we obtain approval for Epanova for patients with severe hypertriglyceridemia and are substantially underway with a cardiovascular outcomes study. While we do not intend to immediately pursue such an outcomes study and, therefore, be able to submit a supplemental NDA for this indication, we will review our strategy with respect to this second indication in light of Epanova's commercial success in severe hypertriglyceridemia and our ability to find a suitable pharmaceutical partner to enter into a development and commercial collaboration.

Market Research

In December 2012, we completed a commissioned market research survey with participation of 177 physicians (consisting of 101 primary care physicians and 76 cardiologists or endocrinologists) who are high prescribers of Lovaza. Overall, most physicians mentioned at least one aspect that they felt is lacking from current treatment of severe hypertriglyceridemia and high triglycerides, particularly when it comes to efficacy in lowering triglyceride levels and efficacy in reaching target values. Most physicians felt that there is room for newer, more efficacious triglyceride-lowering therapies. Some physicians felt that there is room for improvement with therapies that have fewer side effects and better tolerability. In addition, the survey found that the majority of physicians believed that non-HDL-C is either as important or more important than LDL-C. Many also believed that raising HDL-C is important. Two of the key drivers of prescribing behavior consistent across primary care physicians and specialists for severe hypertriglyceridemia patients were “lowers triglycerides and raises HDL-C” and “lowers triglycerides and non-HDL-C.” This analysis also shows that primary care physicians tended to place additional value on variables associated with simplicity of use for patients with severe hypertriglyceridemia, such as once-a-day dosing (also for high triglycerides), bioavailability due to formulation and the ability to take the therapy with or without a meal. After reviewing the product profile, physicians responded favorably to the use of Epanova in the treatment of both severe hypertriglyceridemia and high triglycerides, with over three quarters of the physicians surveyed having a net positive reaction based, in part, on Epanova’s efficacy and product profile in comparison to other drugs.

Differentiating Factors of Epanova

We believe that the following key attributes differentiate Epanova from other prescription omega-3 based products currently marketed or in development and demonstrate its potential to become a best-in-class anti-dyslipidemic for the treatment of severe hypertriglyceridemia:

Unique free fatty acid formulation provides improved, predictable absorption and bioavailability. Unlike ethyl-ester omega-3 fatty acid formulations, Epanova does not require enzymatic breakdown in the small intestine before it can be adequately absorbed. These enzymes are secreted in the intestine in response to dietary fats. Therefore, ethyl-ester omega-3 fatty acids are not optimally absorbed unless they are taken with a high-fat meal, which is contraindicated in patients with hypertriglyceridemia. Because Epanova is less reliant on meal-fat content for optimal absorption, it has significantly greater bioavailability than the ethyl-ester form under the recommended low-fat diet conditions.

Only prescription omega-3 fatty acid with a once-daily 2-gram dosage that meaningfully reduces triglycerides and improves other key lipid parameters. We believe that the once-daily 2-gram dosage of Epanova produces changes in triglycerides and non-HDL-C that are comparable to the twice-daily Vascepa 4-gram dosage (2 grams, twice daily) and the once- or twice-daily Lovaza 4-gram dosage (2 grams, twice daily or 4 grams, once daily). The reduced daily pill burden associated with Epanova (two capsules) compared to both Lovaza and Vascepa (four capsules) is anticipated to offer improved convenience and patient compliance. This is particularly important when considering that many patients suffering from severe hypertriglyceridemia have other conditions that require treatment with multiple once-daily medications, such as statins and anti-hypertensives.

Only prescription omega-3 fatty acid approved with a range of doses for improved triglyceride management. To date physicians only have one FDA-approved dosage (4 grams/day) available to treat patients with severe hypertriglyceridemia with both Lovaza and Vascepa, and the labeling of these products does not permit an increase in the dosage for further triglyceride lowering. Epanova is expected to be approved with both a 2-gram and 4-gram dosage, enabling

physicians to start with a 2-gram dosage and increase to a 4-gram dosage if further triglyceride lowering is required.

Epanova provides improved plasma levels of EPA and DHA, which have been shown to decrease risks associated with cardiovascular events. Epanova's improved bioavailability also drives improved blood plasma levels of EPA and DHA relative to competitors. For instance, in our Phase II ECLIPSE pharmacokinetic study comparing Epanova's 4-gram dose to Lovaza's 4-gram dose, Epanova patients on a low-fat diet demonstrated four times higher plasma levels of EPA and DHA. Precedent omega-3 outcome studies have shown a correlation between high plasma levels of EPA and DHA and the reduction of cardiovascular risk. As such, to the extent we decide to pursue a cardiovascular outcomes study, we believe the likelihood of success would be greater than competitors utilizing ethyl-ester forms of EPA.

Our Clinical Experience

We have completed our clinical development program for the submission of an NDA for Epanova for the treatment of severe hypertriglyceridemia. Epanova has a long clinical track record involving 2,156 patients in ten different studies. This includes two large pivotal Phase III trials in 762 randomized patients with Crohn's disease conducted by Tillotts Pharma AG (the predecessor entity to Chrysalis). We believe that the combination of safety data from our clinical trials and the prior Crohn's disease studies of Epanova has resulted in the largest pool of safety data of any prescription omega-3 compound on the market or in development. Overall this 2,156 patient safety data has shown Epanova to have a positive safety and tolerability profile, with most adverse events being mild, transient and gastrointestinal related.

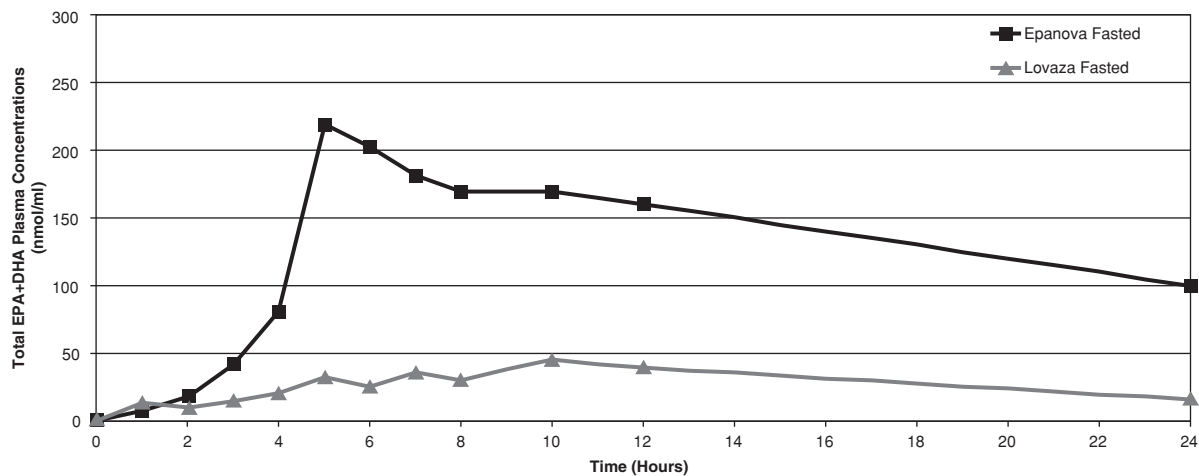
We engaged contract research organizations to provide monitors for and to manage data for each of the studies listed below. Our Phase II ECLIPSE and Phase III EVOLVE studies were conducted by Radiant Development; our Phase III ESPRIT study was conducted by Medpace, Inc.; and our Phase I ECLIPSE II study was conducted by Celerion.

Phase II ECLIPSE Study

In January 2011, we reported the results of our Phase II ECLIPSE (Epanova Compared to Lovaza In a Pharmacokinetic Single-dose Evaluation) study. The primary objective of this 54 subject, randomized, open-label, four-way cross-over pharmacokinetics study in normal healthy adults was to compare the bioavailability of the omega-3 fatty acids EPA and DHA in plasma after a single 4-gram dose of Epanova compared to a single 4-gram dose of Lovaza in the fasted state and after a high-fat meal. Bioavailability was determined by the ln-transformed area under the plasma concentration versus time curve (AUC_{0-t}) for baseline-adjusted Total EPA, Total DHA and Total EPA+DHA levels during a 24-hour post-dose interval. Data from the ECLIPSE study showed that Epanova provided significantly greater bioavailability under all dosing conditions as compared to Lovaza. Specifically, Epanova demonstrated baseline adjusted Total EPA+DHA levels 4 times higher than Lovaza when subjects were dosed in the fasted state (2650.16 versus 661.95 nmol/mL, respectively; p<0.0001) and 1.3 times higher than Lovaza after a high-fat meal (4,604.02 versus 3,589.4 nmol/mL, respectively; p<0.0001). In the fasted state, Epanova demonstrated a 9.5-fold increase in bioavailability of EPA over Lovaza (465.37 versus 48.85 µg/mL, respectively; p<0.0001) and a 1.6-fold increase over Lovaza in EPA in subjects consuming a high-fat meal (1088.94 versus 673.04 µg/mL, respectively; p<0.0001). The NCEP ATP III guidelines recommend that patients with severe hypertriglyceridemia adhere to a low-fat diet; therefore, Epanova has an additional therapeutic advantage over Lovaza due to Epanova's improved

bioavailability. There were no serious adverse events and a single 4-gram dose of Epanova was well-tolerated.

Total EPA+DHA: Single Dose Epanova Versus Lovaza Under Fasting Conditions

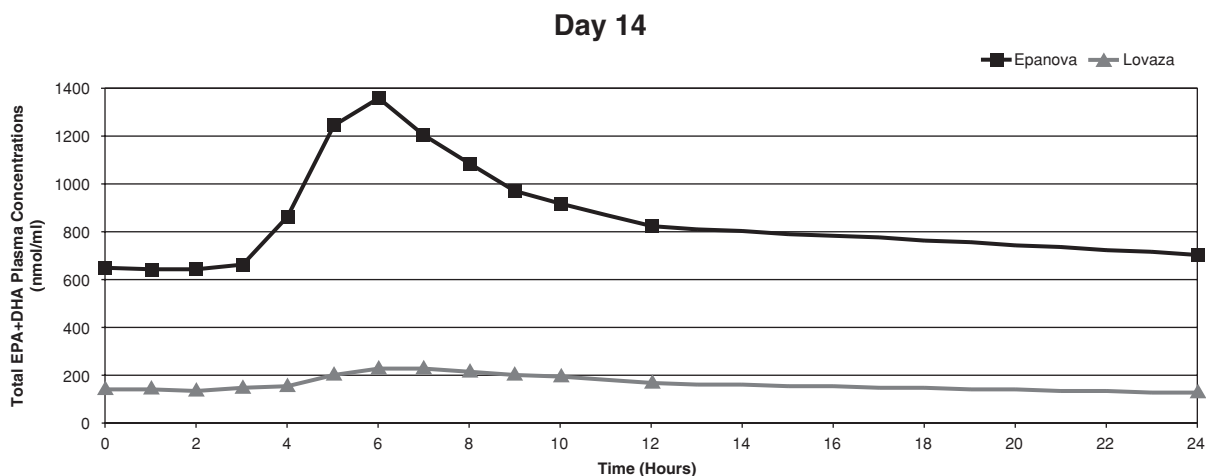


Phase I ECLIPSE II Study

In January 2012, we reported the results of our Phase I ECLIPSE II study. While the primary objective of this open-label, 2-cohort, parallel design pharmacokinetics study in 52 normal healthy adults was to evaluate the effect of multiple doses of Epanova on the single-dose pharmacokinetics and pharmacodynamics of warfarin (an anticoagulant), a secondary objective of this study was to compare the systemic exposure of Total EPA+DHA following multiple-dose administration of Epanova compared to multiple-dose administration of Lovaza under low-fat meal conditions.

Twenty-six subjects were enrolled in the first cohort and received a single dose of warfarin without Epanova followed by a second single dose of warfarin after 14 days repeat dosing with Epanova. Twenty-six subjects were enrolled in the second cohort and were administered a 4-gram dose of Lovaza each day for 14 days. All doses of Epanova and Lovaza were administered 30 minutes after a low-fat breakfast. In this study, the bioavailability comparison was determined by the ln-transformed area under the plasma concentration versus time curve ($AUC_{0-\tau}$) during a 24-hour interval for EPA and DHA (baseline-adjusted). Data from ECLIPSE II showed that after 14 days of dosing, systemic exposure to baseline-adjusted Total EPA, Total DHA and Total EPA+DHA was markedly greater following multiple-dose administration of Epanova than following multiple-dose administration of Lovaza. The overall exposure ($AUC_{(0-\tau)}$) was approximately seven-fold higher for Total EPA, three-fold higher for Total DHA and six-fold higher for Total EPA+DHA with Epanova than with Lovaza.

Total EPA+DHA: Multiple Dose Epanova Versus Lovaza on a Low-Fat Meal



The Epanova 4-gram dose also produced greater reduction in triglycerides (-26% median percent change from baseline) compared to the 4-gram dose of Lovaza (-9% median percent change from baseline) in this normal healthy population with a median baseline triglyceride level of 144 mg/dL. Additionally, once-daily 4-gram doses of Epanova had no effect on the pharmacokinetics and pharmacodynamics of a single 25 mg dose of warfarin. There were no serious adverse events in this study and co-administration of a single 25 mg dose of warfarin with a 4-gram dose of Epanova (following multiple daily dose administration) appeared to be safe and well-tolerated.

Phase III EVOLVE Study

In 2012, we reported positive results from our pivotal Phase III EVOLVE clinical trial, which demonstrated in patients with severe hypertriglyceridemia that Epanova 2-, 3- and 4-gram once-a-day significantly reduced triglyceride levels (26%, 24% and 31%, respectively) and improved other lipid parameters as well as other markers of cardiovascular risk. The EVOLVE trial also demonstrated clinical efficacy of 2 grams once-a-day of Epanova that was comparable to the clinical efficacy demonstrated in third-party studies for 4 grams once-a-day of other prescription omega-3 products. The EVOLVE trial was a 12-week, multi-center, randomized, double-blind, placebo-controlled (olive oil) study evaluating the efficacy and safety of three doses of Epanova in 399 patients with fasting triglyceride levels of ≥ 500 mg/dL and $< 2,000$ mg/dL (with or without statin therapy). Subjects in the trial were randomized into four equal groups: Epanova 2 grams/day; Epanova 3 grams/day; Epanova 4 grams/day; or olive oil placebo 4 caps/day. The primary endpoint of the trial was the percentage change in triglyceride levels from baseline to week 12. The secondary endpoints were percentages changes in non-HDL-C and HDL-C.

In addition, all three Epanova doses (2 grams, 3 grams and 4 grams daily) demonstrated statistically significant reductions of 8%, 6% and 10%, respectively, in the secondary efficacy endpoint of non-HDL-C compared to a 2% increase with olive oil. The Epanova treatments also demonstrated lipid lowering in other parameters consistent with the primary and secondary endpoints: Total

Cholesterol decreased -5% to -8% and VLDL-Cholesterol, or VLDL-C, decreased -26% to -33% .

Parameter	EPANOVA 2 N=100			Difference from OO	EPANOVA 3 N=101			Difference from OO	EPANOVA 4 N=99			Difference from OO	Olive oil (OO) N=99		
	BL	EOT	%Δ		BL	EOT	%Δ		BL	EOT	%Δ		BL	EOT	%Δ
Triglycerides	717	554	-26^{**}	-22	715	561	-24^*	-20	655	511	-31^{***}	-27	686	642	-4
Non-HDL-C	205	209	-8^*	-10	215	197	-6^*	-8	225	211	-10^{**}	-12	215	217	+2
VLDL-C	123	98	-27^{**}	-18	124	94	-26^*	-17	126	87	-33^{***}	-24	125	113	-9
TC/HDL-C	8.8	8.1	-12^*	-12	8.8	8.0	-8	-8	9.0	8.3	-13^{**}	-13	8.8	8.3	-0.3
TC	241	233	-6^*	-9	244	231	-5	-8	254	247	-8^{**}	-11	246	244	+3
ApoC-III	25	21	-11^*	-13	26	21	-12^{**}	-14	25	21	-14^{***}	-16	24	26	+2
HDL-C	27	29	+7	+5	28	28	+3	+1	29	29	+6	+4	29	30	+2
LDL-C	77	93	$+19^{**}$	+16	81	95	+14	+11	90	110	$+19^{***}$	+16	78	86	+3

BL = Baseline (mg/dL); except TC/HDL-C, where all values are %; % Change = LS Mean Percent Change from Baseline; Difference = EPANOVA % Change – Olive Oil % Change; p-value generated from ANCOVA model that includes terms for treatment, baseline value as covariate p-value $* < 0.05$, $** < 0.01$, $*** < 0.001$

The EVOLVE safety analyses demonstrated a positive safety profile for the 2-gram, 3-gram and 4-gram daily dosing with Epanova that was consistent with previously reported trials of omega-3 interventions. There were no apparent differences among the Epanova dosing groups in the patterns of occurrence for overall adverse events, and while gastrointestinal events were reported more frequently with Epanova than olive oil, most were considered mild or moderate in severity. There were no significant differences between treatment groups or from baseline in vital signs or ECG parameters including a thorough evaluation of the QTc interval. The successful lowering of triglyceride levels with all three doses and clinically comparable efficacy between the 2-gram and 4-gram daily dosing demonstrated by Epanova in the EVOLVE trial suggest that a 2-gram daily dose of Epanova will be an effective dose for patients with severe hypertriglyceridemia.

Phase III ESPRIT Study

In November 2012, we announced positive results from our Phase III ESPRIT clinical trial, which supported the efficacy of Epanova as an adjunct to low-fat diet and statin therapy for further reduction of non-HDL-C and triglyceride levels in patients with high triglycerides and high risk for cardiovascular disease. The ESPRIT study was a randomized, double-blind, placebo-controlled, parallel group study to assess the efficacy and safety of Epanova in combination with statins in 647 subjects with high triglycerides. The primary endpoint was to evaluate the efficacy of adding Epanova (2-gram or 4-gram daily) to statin monotherapy for lowering non-HDL-C. Secondary endpoints were to evaluate the safety of the Epanova and statin combination therapies, and to evaluate the effects of the combination therapies on other lipids and lipoproteins. Following an initial six-week washout and diet stabilization period during which subjects discontinued use of any non-statin lipid-lowering therapies that could be stopped, continued their current statin regimen and followed a low-fat diet, subjects with a fasting triglyceride level of above 200 mg/dL and less than 500 mg/dL were randomized in a 1:1:1 ratio to receive either double-blinded Epanova (2-gram or 4-gram daily) or a matching olive oil placebo (4-gram daily) for six weeks, without regard to meals. Both the 2-gram and 4-gram once-a-day dose of Epanova yielded clinically and statistically significant reductions in non-HDL-C and triglycerides. The non-HDL-C reduction with the 2-gram dose of Epanova was 4%, which is consistent with the non-HDL-C reduction observed with a doubling of the dose of a statin. There was a 7% reduction in non-HDL-C in patients taking Epanova 4-gram once a day. Triglyceride reductions of 15% and 21%

were observed with 2-gram and 4-gram once-a-day dose of Epanova, respectively. All reductions in non-HDL-C and triglycerides were statistically significant.

Parameter	EPANOVA 2 N=209			Difference from OO	EPANOVA 4 N=207			Difference from OO	Olive oil (OO) N=211		
	BL	EOT	%Δ		BL	EOT	%Δ		BL	EOT	%Δ
Non-HDL-C	139	133	-4*	-3	135	129	-7***	-6	132	134	-0.91
Triglycerides	265	222	-15***	-9	265	215	-21***	-15	269	260	-6
HDL-C	38	39	+3	+1	37	38	+3	+1	38	38	+2
VLDL-C	42	37	-14**	-8	43	33	-21***	-15	42	41	-6
TC/HDL-C	5	5	-5	-3	5	4	-7***	-5	5	5	-2
TC	177	174	-2*	-2	170	167	-4***	-4	174	174	+0.48
ApoC-III	15	14	-8	-4	15	13	-13***	-10	15	14	-3
LDL-C	92	95	+5*	+4	91	92	+1	0	87	91	+1

BL = Baseline (mg/dL); EOT = End of treatment (mg/dL) except TC/HDL-C, where all values are %; %Δ = LS Mean Percent Change from Baseline; Difference = EPANOVA % Change – Olive oil % Change; p-value generated from ANCOVA model that includes terms for treatment, baseline value as covariate p-value * < 0.05, ** < 0.01, *** < 0.001

Treatment with Epanova was also associated with the following statistically significant effects relative to olive oil: reductions in Total Cholesterol; reductions in total VLDL-C; reductions in mean VLDL particle size; reductions in small LDL particles and increases in mean LDL particle size; and reductions in mean HDL particle size. In addition, treatment with Epanova was associated with increases in plasma EPA, DHA and docosapentaenoic acid, and reductions in plasma arachidonic acid.

The ESPRIT safety analyses demonstrated that treatment with Epanova was safe and well-tolerated. Most treatment emergent adverse events were considered by the investigator to be mild or moderate in severity and unrelated to study drug. The most common system organ class of treatment emergent adverse events was gastrointestinal disorders, with higher incidences reported in the Epanova groups versus the olive oil group. Within the Epanova treatment groups, the incidence of gastrointestinal effects increased in a dose-related manner.

Manufacturing

The production of Epanova is a multi-step process and involves a complex supply chain. We do not own or operate manufacturing facilities for the production of Epanova, nor do we have plans to develop our own manufacturing operations for the commercial manufacture of Epanova in the foreseeable future. We depend on third-party suppliers and manufacturing organizations for all of our required raw materials and drug substance and to manufacture, encapsulate, bottle and package clinical quantities of Epanova.

We have secured our primary supply of bulk fish oil, the raw material for Epanova, through Ocean Nutrition Canada Limited, or ONC, and the manufacture of the active pharmaceutical ingredient in Epanova through BioVectra Inc., or BioVectra, in each case through exclusive long-term commitments. Our March 2012 agreement with ONC for the supply of bulk fish oil for Epanova includes requirements for: (i) a one-time payment of \$1.0 million due to ONC upon completion of FDA inspection of the site; (ii) a one-time payment of \$500,000 due to ONC upon shipment into commerce of the first commercial product; and (iii) us to purchase a certain percentage of our bulk fish oil from ONC. The ONC agreement has an initial term of ten years and will renew for one additional five year period in the event either party gives notice of renewal no later than 12 months prior to the expiration of such initial term. Our March 2012 agreement with BioVectra for the

manufacture of the API for Epanova, includes requirements for: (i) construction of a 100 metric ton facility exclusively for the manufacture of the API for Epanova for an amount not to exceed \$5.0 million (of which we have paid approximately \$1.4 million as of December 31, 2012); and (ii) minimum annual purchase commitments. The BioVectra agreement has an initial term of five years from the date of commencement of commercial supply and will automatically renew for consecutive one year periods upon agreement between the parties no later than six months prior to the expiration of the then-current term. Our agreements with ONC and BioVectra are cancelable by us in the event Epanova does not receive regulatory approval or if we abandon commercialization due to market conditions.

For encapsulation of the API and coating the finished capsules, we have negotiated long-term commitments with Catalent Pharma Solutions GmbH, which we believe has both the capacity and experience to support our current and future needs. We have also entered into long-term exclusive arrangements with a secondary supplier of raw material and manufacturer of the active pharmaceutical ingredient. We believe this secondary supplier, Croda Europe Limited, has the capability of supplying raw materials as well as providing the cGMP facilities required for the production of the active ingredient in Epanova. In both cases, we currently expect the primary and secondary suppliers and manufacturers to provide sufficient capacity for product to support potential commercial launch of Epanova.

Sales and Marketing

We have exclusive worldwide commercial rights to Epanova. We do not currently have sales and marketing or distribution capabilities or in-house personnel specializing in these functions. We expect to build a sales and marketing infrastructure in the United States to support a launch in patients with severe hypertriglyceridemia. We anticipate that a targeted sales force focused initially on specialists, cardiologists and primary care physicians who comprise the top prescribers of lipid-regulating therapies will be highly effective. We believe the primary promotional message to physicians will emphasize Epanova's significant triglyceride reduction in a once-daily, 2-gram dose, driven by Epanova's unique free fatty acid formulation. Outside the United States, we intend to commercialize Epanova by entering into third-party collaboration agreements with pharmaceutical partners.

Competition

The biopharmaceuticals industry is highly competitive. There are many public and private biopharmaceutical companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to our products or address similar markets. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These competitors may develop and introduce products and processes comparable to or superior to ours.

GlaxoSmithKline plc currently markets in the United States Lovaza, a prescription omega-3 fatty acid for patients with severe hypertriglyceridemia and Abbott Laboratories currently markets Tricor and Trilipix (both fibrates) and Niaspan (niacin) for treatment of severe hypertriglyceridemia and high triglycerides. In addition, pursuant to a March 2011 agreement to settle patent litigation related to Lovaza in the United States, Pronova BioPharm Norge AS, which holds patents for Lovaza, granted Apotex Corp. and Apotex Inc. a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or potentially sooner. Generic versions of Lovaza from Apotex or other companies, if available, will also create greater market competition for our product. Amarin

Corporation currently markets Vascepa, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia.

Other companies are also developing products that, if approved, will compete directly with Epanova. These companies that are in various stages of clinical development with omega-3 prescription therapies for the treatment of high triglycerides include Trygg Pharma (Phase III), Acasti Pharma, a subsidiary of Neptune Technologies and Bioresources Inc. (Phase II), Resolvix Pharmaceuticals (Phase I) and Catabasis Pharmaceuticals (Phase I).

Epanova may also compete with omega-3 dietary supplements that are available without a prescription.

Intellectual Property

We seek to protect our product candidate and our technologies through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Patents

Our commercial success will depend in part on obtaining and maintaining patent protection of Epanova and the methods used to develop and manufacture Epanova, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing Epanova and our technology depends on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of the pending patent applications filed by us or Chrysalis or with respect to any patent applications filed by us or Chrysalis in the future, nor can we be sure that any of the existing patents licensed to us or any patents that may be granted to us or Chrysalis in the future will be commercially useful in protecting Epanova or any related technology. For more comprehensive disclosure of the risks related to our intellectual property, please see “Risk Factors—Risks Relating to Our Intellectual Property Rights.”

The patent portfolio for Epanova includes four issued U.S. patents (U.S. Patent No. 5,792,795, U.S. Patent No. 5,948,818, U.S. Patent No. 7,960,370, and U.S. Patent No. 8,383,678), several pending U.S. provisional and utility applications, and corresponding international and foreign national or regional counterpart patents or applications around the world. Assuming that required maintenance fees are paid, we expect the two U.S. patents covering Epanova’s time-dependent coating to expire in 2016, excluding any additional term for patent term extensions. We anticipate applying for Hatch-Waxman patent term extension for one of these two patents, which could extend its protection until as late as 2021. We expect the two issued U.S. patents covering the composition of Epanova’s gelatin capsule to expire in 2025, assuming that required maintenance fees are paid. If patent term extension is sought on one of the two patents covering the composition of Epanova’s gelatin capsule, instead of for one of the two patents covering the time-release coating, protection under the extended patent would be expected until at least 2026. Any patents that may issue from a recently-filed U.S. patent application and its counterpart international application covering Epanova’s drug substance and methods for use in treatment would extend protection until at least 2033.

The Hatch-Waxman Amendments permit a patent term extension as compensation for patent term lost during product development and the FDA regulatory review process. The patent term extension period is generally calculated as one-half the time between the effective date of an Investigational New Drug application and the submission date of an NDA, plus the time between the

submission date of an NDA and the approval of that application. The extension period may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent among those eligible for extension by a company may be extended, and the extension must be applied for prior to expiration of the patent, and within 60 days of NDA approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the applications for any patent term extension based upon an approved NDA. Depending upon the timing, duration and specifics of FDA approval of an NDA submitted for Epanova, we believe that several of our U.S. patents may be eligible for a limited patent term extension under the Hatch-Waxman Amendments and we intend to apply for such extension for one of our patents; selection of the patent will depend on the expected length of clinical trials and other factors involved in the filing of the relevant NDA. Analogous provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

The FDA grants five years of exclusivity to the first applicant to obtain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDA cannot approve such ANDA or 505(b)(2) NDA for 30 months thereafter if the patent owner timely brings suit for infringement of the patent. In such case, NCE exclusivity can effectively expand the protection period by another one and a half years, to a total of six and a half years, before competitors with the same active ingredient can reach the market. We believe Epanova is a novel and complex mixture different from any other approved product under the FDCA, and, therefore, has the potential to be regarded as an NCE. Analogous data and market exclusivity provisions, of varying duration, may be available in Europe and other foreign jurisdictions.

Trade Secrets and Trademarks

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary manufacturing processes are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes and those of Chrysalis, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions resulting from work performed for us or relating to our business and conceived or completed by the individual during employment or assignment, as applicable, shall be our exclusive property to the extent permitted by applicable law. However, we cannot be certain that the precautions we have taken will prevent misappropriation of our technology. In addition, we seek trademark protection in the United States where available and when appropriate.

Collaboration and License Agreements

In November 2009, we entered into an exclusive license agreement with PVT Polyver Trust AG (now known as Chrysalis Pharma AG), as successor-in-interest to Tillotts Pharma AG, to develop and commercialize Epanova. Under the license agreement with Chrysalis, we retain the worldwide rights to Epanova and are subject to certain developmental and regulatory milestone payments as well as royalty

payments upon commercialization. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of patients with very high triglycerides total approximately \$9.5 million. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of patients with high triglycerides total approximately \$15.0 million. We are also required to pay Chrysalis a tiered royalty for the first 15 years of commercial sales of Epanova that ranges from approximately 7% to up to 12% based on net sales of the product. These royalties are subject to up to a 50% reduction upon certain events relating to the commercialization of competing generic products.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as Epanova. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

United States Drug Development

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Epanova must be approved by the FDA through the NDA process before it may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical study-related regulations, sometimes referred to as current good clinical practices, or cGCPs, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA for a new drug;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice requirements, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical studies are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase I generally involves a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase II trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible

adverse effects and safety risks and preliminary evaluation of efficacy. Phase III trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase III studies may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase IV studies. The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials,

companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

Following trial completion, trial data is analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials is then filed with the FDA in an NDA along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of preclinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. FDA approval of an NDA must be obtained before marketing a drug in the United States.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has 60 days after it receives an application to determine whether the NDA may be filed or if the FDA will refuse to file the application. The decision to file the NDA means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. The FDA does not always meet its PDUFA goal dates for standard NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The

FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements,

which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, known as Phase IV testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for one of our currently

owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

European Union Drug Development

In the European Union, our future products may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if marketing authorizations from the competent regulatory agencies have been obtained.

Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation is currently undergoing a revision process mainly aimed at uniforming and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency.

European Union Drug Review and Approval

In the European Economic Area, or EEA, (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The *Community MA*, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidate or a decision by a third-party payor to not cover our product candidate could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidate, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidate. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Health Care Reform Law enacted in March 2010, is expected to have a significant impact on the health care industry. The Health Care Reform Law is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Health Care Reform Law is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the Health Care Reform Law on pharmaceutical companies as many of the Health Care Reform Law reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of

which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees

As of December 31, 2012, we employed 14 full-time employees, including nine in research and development and five in general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Facilities

We occupy approximately 11,000 square feet of office space in Princeton, New Jersey under a lease that expires in 2014. We believe that our facilities are adequate for our current needs.

Legal Proceedings

We are parties to various legal matters and claims arising in the ordinary course of business. We do not expect that the final resolution of these ordinary course matters will have a material adverse impact on our financial position, results of operations or cash flows.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information about our executive officers and directors, including their ages as of March 1, 2013.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<i>Executive Officers:</i>		
Gerald L. Wisler	56	President, Chief Executive Officer and Director
Michael H. Davidson, M.D.	56	Executive Vice President and Chief Medical Officer
Christian S. Schade	52	Executive Vice President and Chief Financial Officer
Bernardus (Ben) N. Machielse	52	Executive Vice President and Chief Operating Officer
<i>Non-Employee Directors:</i>		
George Horner(1)(2)(3)	68	Chairman of the Board
Graziano Seghezzi(1)(2)(3)	44	Director
David M. Mott(1)(2)(3)	47	Director

- (1) Member of the compensation committee.
- (2) Member of the audit committee.
- (3) Member of the nominating and corporate governance committee.

The following paragraphs provide information as of the date of this prospectus about our executive officers and directors. The information presented includes information about each of our directors' specific experience, qualifications, attributes and skills that led our board of directors to the conclusion that he should serve as a director.

Gerald L. Wisler. Mr. Wisler, a co-founder of Omthera, has served as our President and Chief Executive Officer since December 2008 and as a member of our board of directors since December 2008. Mr. Wisler served as the Chief Executive Officer of Aegerion Pharmaceuticals, Inc. from February 2005 to 2008 and as a member of the Aegerion board of directors from October 2005 to 2008. From June 2003 to September 2004, Mr. Wisler served as a Vice President in Cardiovascular & Metabolic Brand Management at Novartis Pharmaceuticals Corporation, where he was responsible for its cardiovascular and metabolic franchises. From March 1983 to June 2003, Mr. Wisler held positions at Merck and Co., Inc., the last as Vice President, Managed Care, and for the five years before that as Vice President of Marketing with responsibilities for the U.S. Atherosclerosis franchise, which included Zocor, where he was responsible for the commercialization of those products. During this tenure, he played a key role in the decision by Merck to enter into a joint venture with Schering-Plough for the development and commercialization of Zetia and Vytorin. Mr. Wisler holds a B.S. in Pharmacy from the University of Toledo College of Pharmacy and an M.B.A. in Finance from the University of Toledo College of Business. We believe that Mr. Wisler's operational and historical expertise gained from serving as a co-founder and as our chief executive officer, as well as his varied experience as an executive of biopharmaceutical companies, qualify him to serve as a member of our board of directors.

Michael H. Davidson, M.D. Dr. Davidson, a co-founder of Omthera, has served as our Executive Vice President and Chief Medical Officer since December 2008. Since 2007, Dr. Davidson has been a Clinical Professor at the University of Chicago, where he also has served as Director of Preventive Cardiology. Dr. Davidson earned his medical degree from The Ohio State University College of Medicine with residency in internal medicine and fellowship in cardiology at Rush University Medical Center. Dr. Davidson is board-certified in internal medicine, cardiology, and clinical lipidology and is a Fellow of the American College of Cardiology and the American College of Chest Physicians. He also served as President of the National Lipid Association from 2010 to 2011. From 1987 to 2008, Dr. Davidson was the Founder, President and Chief Executive Officer of the Chicago Center for Clinical Research, currently part of Radiant Research, Inc. An active researcher, Dr. Davidson's clinical research background encompasses both pharmaceutical and nutritional clinical trials. His extensive

research on statins, novel lipid-lowering drugs, and omega-3 fatty acids has established him as a key opinion leader in this area. A prolific author and lecturer on lipid disorders, nutrition, and atherosclerosis, Dr. Davidson has coordinated more than 1,000 clinical trials in areas of preventive cardiology, published more than 250 articles for leading medical journals and written three books on lipidology.

Christian S. Schade. Mr. Schade has served as our Executive Vice President and Chief Financial Officer since September 2011. From March 2010 to September 2011, Mr. Schade served as Executive Vice President and Chief Financial Officer at NRG Energy Inc., a NYSE listed, S&P 500 wholesale power-generation company based in Princeton, NJ. While there, he was responsible for corporate financial functions, including Treasury, Accounting, Tax, Risk, Credit Management and Insurance. Prior to joining NRG Energy Inc., from October 2000 to December 2009, he was Senior Vice President Administration and Chief Financial Officer at Medarex Inc., a Princeton-based biopharmaceutical company that was acquired by Bristol-Myers Squibb Co. in September 2009. He also helped Medarex to grow to become a leading pharmaceutical development company, raising capital through a series of public capital market and asset monetization transactions. While there, he also oversaw the manufacturing for multiple development/clinical programs and was responsible for the business development team. Before joining Medarex in 2000, Mr. Schade served as Managing Director at Merrill Lynch in London, where he was head of the European Corporate Funding Group and was responsible for certain capital markets activities of Merrill Lynch's European corporate clients. He also held various corporate finance and capital markets positions in New York and London for both Merrill Lynch and JP Morgan Chase & Co. Mr. Schade currently serves as a director of Integra LifeSciences (NASDAQ: IART), a publicly-traded medical technology company, and is Chair of the Board of Trustees of Princeton Academy School. Mr. Schade holds an A.B. degree from Princeton University and an M.B.A. from the Wharton School at the University of Pennsylvania.

Bernardus (Ben) N. Machielse. Mr. Machielse has served as our Executive Vice President and Chief Operating Officer since June 2010. During his professional career, Mr. Machielse has been involved with the development and approval of seven biologic drugs. Prior to joining Omthera, he spent 11 years with MedImmune, Inc., or MedImmune, the last five as Executive Vice President Operations. In that role, he led the worldwide manufacturing of therapeutic antibodies, small molecules and vaccine products—including the development and launch of the first H1N1 vaccine product available in the United States. He also oversaw quality assurance/quality control, GxP compliance, validation, supply chain, health and safety and other functional areas. Prior to his tenure with MedImmune, Mr. Machielse held the position of Vice President of Quality Assurance and Quality Control for Xoma Corporation, and before that, served in various positions in manufacturing, process and analytical development for Centocor BV. Mr. Machielse holds a Master of Science in biochemistry and a Bachelor of Science in Medical Biology from the University of Utrecht, in Utrecht, The Netherlands. He is a former member of the Board of Directors of Xencor, Inc. and a current member of the Board of Directors for Tetragenetics, Inc.

George Horner. Mr. Horner has served as a member of our board of directors since April 2010. Mr. Horner serves as chairman of the board of directors of Creabilis SA and a member of the board of directors of DBV Technologies—siège social. From 2009 to 2010, Mr. Horner served as Executive In Residence at Sofinnova Ventures. From 2006 to 2008, Mr. Horner served as the President and Chief Executive Officer of Prestwick Pharmaceuticals, Inc., until it was sold to Biovail Corp. From 2006 to 2009, he served as a member of the board of directors of Endo Pharmaceuticals Holdings Inc., and from 2009 to 2012, he served as a member of the board of directors of Durata Therapeutics, Inc. From 1996 until 2005, Mr. Horner served as President, Chief Executive Officer and as a member of the board of directors of Vicuron Pharmaceuticals, Inc. until its acquisition by Pfizer Inc. in September 2005. Mr. Horner holds an A.B. from Belmont Abbey College. We believe that Mr. Horner's 40-year career in the biotechnology sector, including extensive experience as an executive in a number of private and public companies, including Vicuron Pharmaceuticals, Inc., and his service on the boards of

directors of other biopharmaceutical companies, give him the qualifications and skills to serve as a director and provide the board with valuable insight into a broad range of issues related to our business activities at this stage in our development.

Graziano Seghezzi. Mr. Seghezzi has served as a member of our board of directors since November 2009. Mr. Seghezzi has been a partner at Sofinnova Partners since joining the firm in 2006. Prior to joining Sofinnova Partners, Mr. Seghezzi was principal at Index Ventures in Geneva, Switzerland, where he invested in biotechnology and biopharmaceutical companies. Before this, he worked for Sofinnova Partners, identifying new investment opportunities in Italian pharmaceutical and medical device companies out of Milan, Italy. Mr. Seghezzi serves as a member of the board of directors of Creabilis Therapeutics (Italy), Crescendo Biologics (United Kingdom) and GlycoVaxyn (Switzerland). Mr. Seghezzi holds a degree in genetics and microbiology from the University of Pavia (Italy) and an M.B.A. from the RSM, Erasmus University (Netherlands). We believe that Mr. Seghezzi's experience as a venture capital investor in biopharmaceutical companies and his training in both business and biology qualify him to serve as a member of our board of directors.

David M. Mott. Mr. Mott has served as a member of our board of directors since April 2011. Mr. Mott has been a general partner at New Enterprise Associates since 2008 where he leads the healthcare investing practice. Prior to joining New Enterprise Associates, Mr. Mott served as Chief Executive Officer of MedImmune since 2000 and as Executive Vice President of AstraZeneca Plc, following its acquisition of MedImmune in 2007. He joined MedImmune in April 1992 as Vice President and held various other positions between 1992 and 2000. Prior to joining MedImmune, Mr. Mott was a Vice President in the Health Care Investment Banking Group at Smith Barney, Harris Upham & Co. Inc. Mr. Mott is currently chairman of the board of directors of 3-V Biosciences, Mersana Therapeutics, Inc., TESARO Inc. and Zyngenia, is a member of the board of directors of Ardelyx, Inc., Epizyme, Inc. and Prosensa, and is a former director of MedImmune and Shire plc. He holds a Bachelor of Arts degree from Dartmouth College. We believe that Mr. Mott's experience as an executive of several biopharmaceutical companies and his service on the boards of directors of other biopharmaceutical companies qualify him to serve as a member of our board of directors.

Composition of our Board of Directors

Our board of directors currently consists of four members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation and our voting agreement, which agreement is described under "Certain Relationships and Related Party Transactions" in this prospectus. These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, and professional and personal experiences and expertise relevant to our growth strategy.

Our board of directors has determined that all members of the board of directors, except Mr. Wisler, are independent directors, including for purposes of the rules of NASDAQ Global Market and relevant federal securities laws and regulations. There are no family relationships among any of our directors or executive officers.

Immediately prior to the closing of this offering, our board of directors will be divided into three staggered classes of directors of the same or nearly the same number and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The

terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2014 for Class I directors, 2015 for Class II directors and 2016 for Class III directors.

- Our Class I director will be George Horner;
- Our Class II directors will be David M. Mott and Graziano Seghezzi; and
- Our Class III director will be Gerald L. Wisler.

Our amended and restated certificate of incorporation and amended and restated by-laws provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a charter adopted by our board of directors. Upon the closing of this offering, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the NASDAQ Global Market and the SEC rules and regulations.

Audit committee. Messrs. Horner, Mott and Seghezzi currently serve on the audit committee, which is chaired by Mr. Horner. Our board of directors has determined that Mr. Horner is “independent” for audit committee purposes as that term is defined in the rules of the SEC and the applicable NASDAQ Global Market rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Mr. Horner as an “audit committee financial expert,” as defined under the applicable rules of the SEC. Our board has determined that while Messrs. Mott and Seghezzi satisfy the independence requirements under applicable NASDAQ Global Market rules, they do not satisfy the independence requirements of the SEC applicable to members of audit committees. The transition rules of the SEC provide that two members of the audit committee may be exempt from these more stringent independence requirement for 90 days after the effectiveness of this registration statement, and one member may be exempt for one year after the effectiveness of this registration statement. Our board of directors intends to cause our audit committee to comply with the transition rules within the applicable time periods. The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

- recommending based upon the audit committee’s review and discussions with management and the independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases and scripts.

Compensation committee. Messrs. Horner, Mott and Seghezzi currently serve on the compensation committee, which is chaired by Mr. Mott. Our board of directors has determined that each member of the compensation committee is “independent” as defined in the applicable NASDAQ Global Market rules. The compensation committee’s responsibilities include:

- annually reviewing and making recommendations to the board of directors with respect to corporate goals and objectives relevant to the compensation of our chief executive officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and making recommendations to the board of directors with respect to the compensation of our chief executive officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation; and
- reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K.

Nominating and corporate governance committee. Messrs. Horner, Mott and Seghezzi currently serve on the nominating and corporate governance committee, which is chaired by Mr. Seghezzi. Our board of directors has determined that each member of the nominating and corporate governance committee is “independent” as defined in the applicable NASDAQ Global Market rules. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- reviewing and discussing with the board of directors corporate succession plans for the chief executive officer and other key officers;

- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines;
- developing a mechanism by which violations of the code of business conduct and ethics can be reported in a confidential manner; and
- overseeing the evaluation of the board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, our code of business conduct and ethics will be available on our website at www.omthera.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website.

Board Leadership Structure and Board's Role in Risk Oversight

The positions of chairman of the board and chief executive officer are presently separated and have historically been separated at Omthera. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated by-laws and corporate governance guidelines do not require that our chairman and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our operations, strategic direction and intellectual property as more fully discussed under "Risk Factors" in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on Omthera, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board

meeting. This enables to the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Limitation of Liability and Indemnification Arrangements

As permitted by the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated by-laws that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated by-laws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the Delaware General Corporation Law; and
- advance expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also expect to enter into indemnification agreements with each of our executive officers and directors in connection with this offering. These agreements will provide that we will indemnify each of our directors to the fullest extent permitted by the Delaware General Corporation Law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

We also maintain general liability insurance to provide insurance coverage to our directors and officers for losses arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling the registrant pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

These provisions may discourage stockholders from bringing a lawsuit against our directors in the future for any breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors, officers and certain employees pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that might result in a claim for such indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2012 to our chief executive officer and our three other highest-paid executive officers as of December 31, 2012. We refer to these officers as our named executive officers.

Name and Principal Position(1)	Year	Salary (\$)	Option Awards(2) (\$)	Non-Equity Incentive Plan Compensation(3) (\$)	All Other Compensation(4) (\$)	Total (\$)
Gerald L. Wisler <i>President and Chief Executive Officer</i>	2012	\$350,000	—	(5)	\$10,000	(5)
Michael H. Davidson, M.D. <i>Executive Vice President and Chief Medical Officer</i>	2012	\$300,000	—	\$126,000	\$10,000	\$436,000
Christian S. Schade <i>Executive Vice President and Chief Financial Officer</i>	2012	\$300,000	—	(5)	\$10,000	(5)
Bernardus (Ben) N. Machielse <i>Executive Vice President and Chief Operating Officer</i>	2012	\$300,000	\$303,308	\$126,000	\$10,000	\$739,308

- (1) We have included compensation information for our three highest-paid executive officers (in addition to our chief executive officer) rather than two other highest paid executive officers as required for emerging growth companies because the total compensation for 2012 has not yet been finally determined for all of our executive officers.
- (2) Amounts reflect the grant date fair value of option awards granted in 2012 in accordance with ASC Topic 718. For information regarding assumptions underlying the valuation of equity awards, see note 10 to our financial statements and the discussion under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Application of Critical Accounting Policies—Stock-Based Compensation” included elsewhere in this prospectus. These amounts do not correspond to the actual value that will be recognized by the named executive officers. 25% percent of Mr. Machielse’s option vests on December 1, 2013, with the remainder of the vesting in 36 equal monthly installments at the end of each month thereafter.
- (3) Amounts represent cash bonuses earned in 2012, and paid during 2013, based on achievement of performance goals and other factors deemed relevant by our board of directors. Our 2012 company objectives related primarily to clinical development and partnering achievements. However, the payment of bonuses to our named executive officers is subject to the sole discretion of the board of directors.
- (4) Amounts represent the company match in accordance with the 401(k) Plan.
- (5) Our board of directors has not yet made final determinations with respect to the 2012 bonus amounts for Mr. Wisler and Mr. Schade. As a result, the total compensation for 2012 has not yet been finally determined for these executive officers. We anticipate that such determinations will be made and bonuses will be paid by April 30, 2013.

Narrative to Summary Compensation Table

Employment Arrangements with Our Named Executive Officers

Gerald L. Wisler. On November 13, 2009, we entered into an employment agreement with Gerald Wisler for the position of President and Chief Executive Officer. The employment agreement has no specified term, but can be terminated by either party upon six months prior written notice, except in the event we terminate Mr. Wisler’s employment for cause, in which case no notice is required. Mr. Wisler currently receives a base salary of \$350,000, which is reviewed annually and may

be adjusted at the discretion of the board of directors. Mr. Wisler is also eligible for an annual merit bonus with a target bonus opportunity of 40% of his base salary, payable at the discretion of the board of directors, if he achieves certain mutually agreed upon performance milestones set each fiscal year. Mr. Wisler is eligible to participate in our employee benefit plans, to the extent he is eligible for those plans, on the same terms as other similarly situated executive officers of Omthera.

Michael H. Davidson, M.D. On October 3, 2011, we entered into an employment agreement with Michael Davidson, M.D. for the position of Executive Vice President and Chief Medical Officer. The employment agreement has no specified term, but can be terminated by either party upon two weeks prior written notice, except in the event we terminate Dr. Davidson's employment for cause, in which case no notice is required. Dr. Davidson currently receives a base salary of \$300,000, which is reviewed annually and may be adjusted at the discretion of the board of directors. Dr. Davidson is also eligible for an annual merit bonus with a target bonus opportunity of 35% of his base salary, payable at the discretion of the board of directors, if he achieves certain mutually agreed upon performance milestones set each fiscal year. Dr. Davidson is eligible to participate in our employee benefit plans, to the extent he is eligible for those plans, on the same terms as other similarly situated executive officers of Omthera.

Christian S. Schade. On August 2, 2011, we entered into an employment agreement with Christian Schade for the position of Executive Vice President and Chief Financial Officer. The employment agreement has no specified term, but can be terminated by either party upon two weeks prior written notice, except in the event we terminate Mr. Schade's employment for cause, in which case no notice is required. Mr. Schade currently receives a base salary of \$300,000, which is reviewed annually and may be adjusted at the discretion of the board of directors. Mr. Schade is also eligible for an annual merit bonus with a target bonus opportunity of 30% of his base salary, payable at the discretion of the board of directors, if he achieves certain mutually agreed upon performance milestones set each fiscal year. Mr. Schade is eligible to participate in our employee benefit plans, to the extent he is eligible for those plans, on the same terms as other similarly situated executive officers of Omthera.

Bernardus (Ben) N. Machielse. On June 10, 2011, we entered into an employment agreement with Ben Machielse for the position of Executive Vice President and Chief Operating Officer. The employment agreement has no specified term, but can be terminated by either party upon two weeks prior written notice except in the event we terminate Mr. Machielse's employment for cause, in which case no notice is required. Mr. Machielse currently receives a base salary of \$300,000, which is reviewed annually and may be adjusted at the discretion of the board of directors. Mr. Machielse is also eligible for an annual merit bonus with a target bonus opportunity of 30% of his base salary, payable at the discretion of the board of directors, if he achieves certain mutually agreed upon performance milestones set each fiscal year. Mr. Machielse is eligible to participate in our employee benefit plans, to the extent he is eligible for those plans, on the same terms as other similarly situated executive officers of Omthera.

Payments Provided Upon Death or Disability

Under the terms of each employment agreement, if the named executive officer's employment is terminated by reason of the named executive officer's death or disability, such named executive officer is entitled to (i) base salary and benefits continuation for six months following death or disability and (ii) payment of any bonus previously granted but not paid, subject to the named executive officer's execution and non-revocation of a general release of claims.

Payments Provided Upon Termination for Good Reason or Without Cause

Under the terms of the employment agreements we have entered into with our named executive officers, if the named executive officer terminates his employment for good reason or if we terminate his employment without cause, in either case prior to a change in control, he is entitled to receive:

- in the case of Mr. Wisler, base salary and benefits continuation for 12 months following termination as severance compensation, and payment of any bonus granted but not paid;
- in the case of Dr. Davidson, base salary continuation and continuation of health benefits for 12 months following termination as well as payment of such percentage of health premiums as would have been paid during the term of Dr. Davidson's employment for 12 months following termination as severance compensation and payment of any bonus earned as of the end of the most recent fiscal year but not paid; and
- in the case of Mr. Schade and Mr. Machielse, base salary continuation and continuation of health benefits for nine months following termination as well as payment of such percentage of health premiums as would have been paid during the term of the respective employee's employment for nine months following termination as severance compensation and payment of any bonus earned as of the end of the most recent fiscal year end but not paid.

The payment of any such severance compensation is subject to the named executive officer's execution and non-revocation of a general release of claims.

In addition, under certain option agreements that we have entered into with our named executive officers, we have agreed that if the named executive officer is terminated by us other than for cause (as defined in the respective named executive officer's employment agreement) or if the named executive officer resigns for good reason (as defined in the respective named executive officer's employment agreement), then twenty-five percent of the then-unvested option will immediately vest.

Payments Provided Upon a Change in Control

Subject to a named executive officer's execution and non-revocation of a general release of claims, in the event that a named executive officer terminates his employment for good reason or if we terminate his employment without cause, in either case concurrently with or following a change in control, he will be entitled to receive:

- in the case of Mr. Wisler and Dr. Davidson, (i) continuation of base salary and benefits for the longer of two years from the consummation of the change in control or 12 months from the date of termination and (ii) continuation of health care benefits until the later of his death or the death of his spouse and payment of any bonus that was previously granted but not paid;
- in the case of Mr. Schade, base salary and benefits continuation for 12 months following termination and payment of any bonus that was previously granted but not paid;
- in the case of Mr. Machielse, continuation of base salary and benefits for nine months following termination, and payment of any bonus that was previously granted but not paid.

Employee Confidentiality, Non-Competition, Non-Solicitation and Assignment Agreements

Each of our named executive officers has entered into a standard form agreement with respect to confidential information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the

course of employment. Such agreement also provides that during the period of the named executive officer's employment and for 12 months thereafter, the named executive officer will not compete with us or solicit our employees, consultants, customers or suppliers.

Outstanding Equity Awards at Fiscal Year-End

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2012.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested(1) (\$)
Gerald L. Wisler	—	—	—	—	268,752(2)	\$2,150,016
Michael H. Davidson, M.D. . .	—	—	—	—	268,752(3)	\$2,150,016
Christian S. Schade	98,841	217,451(4)	\$ 2.08	9/7/2021	—	—
Bernardus (Ben) N. Machielse	69,188	152,216(4)	\$ 2.08	9/7/2021	—	—
	—	28,667(5)	\$15.36	10/31/2022	—	—

- (1) There was no public market for our common stock at December 31, 2012. We have estimated the market value of the unvested stock awards based on the initial public offering price of \$8.00 per share.
- (2) Under the terms of Mr. Wisler's November 13, 2009 restricted stock agreement, the remaining unvested shares will vest in equal monthly installments through November 13, 2013. Vesting of all restricted shares subject to the agreement accelerates in connection with an acquisition event. The number of shares listed includes an aggregate of 824,195 shares previously transferred to family trusts and family members.
- (3) Under the terms of Dr. Davidson's November 13, 2009 restricted stock agreement, the remaining unvested shares will vest in equal monthly installments through November 13, 2013. Vesting of all restricted shares subject to the agreement accelerates in connection with an acquisition event. The number of shares listed includes an aggregate of 520,756 shares previously transferred to a trust for the benefit of Dr. Davidson.
- (4) Represent options to purchase shares of our common stock granted on September 7, 2011. The shares underlying these options vest as follows: 25% vest on September 7, 2012, with the remainder of the shares vesting in equal monthly installments over the following three years through September 7, 2015.
- (5) Represent options to purchase shares of our common stock granted on October 31, 2012. The shares underlying these options vest as follows: 25% vest on October 31, 2013, with the remainder of the shares vesting in equal monthly installments over the following three years through October 31, 2016.

Director Compensation

The following table sets forth a summary of the compensation we paid to our non-employee directors during 2012.

<u>Name</u>	<u>Fees Earned or Paid in Cash</u>	<u>Total</u>
George Horner	\$35,000	\$35,000
Graziano Seghezzi	—	—
David M. Mott	—	—

We have historically provided our non-employee directors with an annual cash retainer of \$35,000 and a one-time grant of stock options upon initial election to our board of directors. We expect to adopt a formal director compensation policy after our initial public offering.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk-taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on our company.

Stock Option Plans

2010 Stock Option Plan

Our 2010 Stock Option Plan was approved by our board of directors on April 4, 2010, was subsequently approved by our stockholders on April 11, 2010 and was most recently amended in August 2011. We refer to our 2010 Stock Option Plan, as amended, as the 2010 Plan. We have reserved an aggregate of 1,188,274 shares of our common stock for the issuance of options under the 2010 Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Effective upon the closing of this offering, our board of directors has determined not to grant any further awards under our 2010 Plan. The shares we issue under the 2010 Plan are authorized but unissued shares or shares we reacquire. The shares of common stock underlying any options that are forfeited, canceled, repurchased, expire or are otherwise terminated (other than by exercise) under the 2010 Plan are currently added back to the shares of common stock available for issuance under the 2010 Plan. Upon the closing of this offering, such shares will be added to the shares of common stock available for issuance under the 2013 Plan (as defined below).

The 2010 Plan permits us to make grants of incentive stock options and non-qualified stock options to officers, employees, directors, consultants and other key persons (including prospective employees but conditioned upon their employment). Our 2010 Plan is administered by our board of directors. Our board of directors has the authority to select the individuals to whom awards will be granted, to make any combination of awards to participants, to accelerate the exercisability or vesting of any award and to determine the specific terms and conditions of each award.

The 2010 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or Code, and (2) options that do not so qualify. The option exercise price of each option will be determined by our board of directors but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by the board of directors

and may not exceed ten years from the date of grant. All stock option awards that are granted to employees are covered by a stock option agreement.

The 2010 Plan provides that upon the occurrence of a “sale event,” as defined in the 2010 Plan, all outstanding stock options will terminate at the effective time of such sale event, unless the parties to the sale event agree that such awards will be assumed, continued or substituted by the successor entity. If options under the 2010 Plan terminate, optionees will be provided an opportunity to exercise their options prior to the consummation of the sale event. In the case of a sale event in which our stockholders will receive cash consideration, our board of directors has the right to provide for cash payment to holders of vested options in an amount equal to the difference between the per share cash consideration and the exercise price of such options.

Our board of directors may amend, suspend or terminate the 2010 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The board of directors may also amend, modify or terminate any outstanding award, provided that no amendment to an award may materially impair any of the rights of a participant under any awards previously granted without his or her written consent.

No awards may be granted under the 2010 Plan after the date that is 10 years from the date the 2010 Plan was approved by the stockholders. Our board of directors has determined not to make any further awards under the 2010 Plan following the closing of this offering.

2013 Stock Option and Incentive Plan

Our 2013 Stock Option and Incentive Plan was adopted by our board of directors and approved by our stockholders in March 2013 and will become effective immediately prior to this offering. We refer to the 2013 Stock Option and Incentive Plan as the 2013 Plan. The 2013 Plan will replace the 2010 Plan. The 2013 Plan allows our compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We have initially reserved 1,218,375 shares of our common stock for the issuance of awards under the 2013 Plan. The 2013 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2014, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2013 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2013 Plan and the 2010 Plan are added back to the shares of common stock available for issuance under the 2013 Plan.

Stock options and stock appreciation rights with respect to no more than 1,433,383 shares of stock may be granted to any one individual in any one calendar year and the maximum “performance-based award” payable to any one individual under the 2013 Plan is 1,433,383 shares of stock or \$2.0 million in the case of cash-based awards. No more than 1,218,375 shares may be issued as incentive stock options in any one calendar year period, subject to increase on an annual basis.

The 2013 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2013 Plan. Persons eligible

to participate in the 2013 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2013 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of fair market value of the common stock on the date of grant.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2013 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant performance share awards to participants which entitle the recipient to receive share awards of common stock upon the achievement of certain performance goals and such other conditions as our compensation committee shall determine. Our compensation committee may grant dividend equivalent rights to participants which entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2013 Plan to participants, subject to the achievement of certain performance goals.

Our compensation committee may grant awards of restricted stock, restricted stock units, performance shares or cash-based awards under the 2013 Plan that are intended to qualify as “performance-based compensation” under Section 162(m) of the Code. Those awards would only vest or become payable upon the attainment of performance goals that are established by our compensation committee and related to one or more performance criteria. The performance criteria that would be used with respect to any such awards include: earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, development, clinical or regulatory milestones, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, stockholder returns, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of common stock, sales or market shares and number of customers, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. From and after the time that we become subject to Section 162(m) of the Code, the maximum award that is intended to qualify as “performance-based compensation” under Section 162(m) of the Code that may be made to any one

employee during any one calendar year period is 1,433,383 shares of common stock with respect to a stock-based award and \$2.0 million with respect to a cash-based award.

The 2013 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2013 Plan, in the event that awards are not assumed or continued or substituted by the successor entity, the 2013 Plan and all outstanding awards shall terminate as of the effective time of the sale event. However, our compensation committee may cause certain awards to become vested and/or exercisable immediately prior to the sale event. In addition, in connection with a sale event, we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights.

Our board of directors may amend or discontinue the 2013 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2013 Plan require the approval of our stockholders.

No awards may be granted under the 2013 Plan after the date that is 10 years from the date of stockholder approval of the 2013 Plan. No awards under the 2013 Plan have been made prior to the date hereof.

Senior Executive Cash Incentive Bonus Plan

In March 2013, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to corporate, financial and operational measures or objectives, or Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); sales or revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; funds from operations or similar measure; development, clinical or regulatory milestones; acquisitions or strategic transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of customers; number of new customers or customer references; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and the company, an executive officer must be employed by the company on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan

also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

401(k) Plan and Other Benefits

We have a defined contribution retirement plan, which we refer to as the 401(k) Plan, in which all employees are eligible to participate. Our 401(k) Plan is intended to qualify under Section 401(k) of the Code so that contributions by employees and by us to the 401(k) Plan and income earned on plan contributions are not taxable to employees until withdrawn or distributed from the 401(k) Plan, and so that contributions, including employee salary deferral contributions, will be deductible by us when made. We currently provide matching contributions under the 401(k) Plan of \$1.00 for each dollar contributed up to the first three percent of compensation and \$0.50 for each dollar contributed for the next two percent of compensation, up to an aggregate maximum match of \$10,000 per person. We also contribute to medical, disability and other standard insurance for our employees.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than the compensation agreements and other arrangements described under “Executive and Director Compensation” in this prospectus and the transactions described below, since January 1, 2010, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, \$120,000 and in which any director, executive officer, holder of five percent or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, had, or will have, a direct or indirect material interest.

In connection with this offering, we have adopted a written policy that requires all future transactions between us and any director, executive officer, holder of five percent or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons (as defined in Item 404 of Regulation S-K) or their affiliates, in which the amount involved is equal to or greater than \$120,000, be approved in advance by our audit committee. Any request for such a transaction must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, the extent of the related party’s interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

All of the transactions described below were entered into prior to the adoption of this written policy, but each was approved or ratified by a majority of our board of directors. We believe that we have executed all of the transactions set forth below on terms no less favorable to us than we could have obtained from unaffiliated third parties.

Private Placements of Securities

Convertible Note Issuances

On December 1, 2010, we sold a convertible promissory note to Sofinnova Partners for an aggregate purchase price of \$2.5 million. On February 7, 2011, we sold an additional convertible promissory note to Sofinnova Partners for an aggregate purchase price of \$7.5 million. Graziano Seghezzi, a partner of Sofinnova Partners, of which Sofinnova Capital VI FCPR is an affiliated fund, is a member of our board of directors. The convertible promissory notes accrued interest at a rate of 8% per annum and had a maturity date of December 31, 2011. On February 28, 2011, in connection with the Series B Preferred Stock financing described below, the convertible promissory notes, along with accrued but unpaid interest thereon, were automatically converted into an aggregate of 2,058,539 shares of our Series B Preferred Stock.

Series B Financing

On February 28, 2011, we entered into a securities purchase agreement pursuant to which we agreed to issue up to an aggregate of 8,019,139 shares of our Series B Preferred Stock at a price of approximately \$4.90 per share. These shares were to be issued in two tranches. The securities purchase agreement was subsequently amended in December 2011 to provide that 2,240,321 additional shares of Series B Preferred Stock could be issued in an existing tranche and in two additional tranches. The first additional tranche of Series B Preferred Stock was issued on April 3, 2012 and the second on July 24, 2012.

The following table summarizes the participation in the Series B Preferred Stock financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

<u>Name</u>	<u>Shares of Series B Preferred Stock</u>	<u>Aggregate Purchase Price Paid</u>
Sofinnova Capital VI FCPR(1)	3,666,061	\$17,959,446
New Enterprise Associates(2)	6,172,892	\$30,240,011
JAWZ II LLC(3)	102,065	\$ 500,000
Gerald L. Wisler	51,033	\$ 250,002
Christian S. Schade	35,722	\$ 175,001
Bernardus (Ben) N. Machielse	35,722	\$ 175,001

- (1) Graziano Seghezzi, a partner of Sofinnova Partners SAS, the management company of Sofinnova Capital VI FCPR, is a member of our board of directors.
- (2) Consists of shares of Series B Preferred Stock purchased by New Enterprise Associates 13, L.P. (6,165,748 shares) and NEA Ventures 2011, Limited Partnership (7,144 shares). David M. Mott, a member of our board of directors, is a Director of NEA 13 GP, LTD, the sole general partner of NEA Partners 13, L.P., the sole general partner of New Enterprise Associates 13, L.P.
- (3) James Wisler, Gerald L. Wisler's brother, is manager of JAWZ II LLC, the assets of which are held for the benefit of James Wisler's children.

February 2013 Note and Warrant Issuance

On February 15, 2013, we issued \$17.6 million aggregate principal amount of 8% secured convertible promissory notes due February 15, 2014 to existing and new investors. Among the existing investors, we issued a \$5.0 million convertible promissory note to Sofinnova Partners, a \$5.0 million secured convertible promissory note to New Enterprises Associates and a \$2.5 million secured convertible promissory note to JAWZ II LLC. David M. Mott, a partner of New Enterprises Associates, of which New Enterprise Associates 13, L.P is an affiliated fund, is a member of our board of directors. Graziano Seghezzi, a partner of Sofinnova Partners, of which Sofinnova Capital VI FCPR is an affiliated fund, is a member of our board of directors. James Wisler, the manager of JAWZ II LLC, is the brother of Gerald L. Wisler, our President and Chief Executive Officer. In the event of a default under the convertible promissory notes, the interest rate will be increased from 8% to 15%.

In connection with the convertible promissory notes, we issued warrants to each investor, including a \$1.25 million warrant to Sofinnova Partners, a \$1.25 million warrant to New Enterprises Associates and a \$650,000 warrant to New Enterprises Associates, to purchase shares of our capital stock up to 25% of the principal amount of the notes divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. The warrants automatically net exercise for shares of our common stock upon the closing of our initial public offering. The warrants expire on February 15, 2023. See "Liquidity and Capital Resources—February 2013 Note and Warrant Issuance" for additional details regarding this transaction.

Agreements with Stockholders

In connection with the Series B Preferred Stock financing, we entered into the Amended and Restated Investors' Rights Agreement, dated as of February 28, 2011, with certain of our stockholders,

including our principal stockholders and their affiliates, the Amended and Restated Voting Agreement, dated as of February 28, 2011, with certain of our stockholders, including our principal stockholders and their affiliates, and the Right of First Refusal and Co-Sale Agreement, dated as of February 28, 2011, with certain of our stockholders, including our principal stockholders and their affiliates. All of the provisions of these agreements will terminate immediately upon completion of the offering, other than the provisions relating to registration rights, which will continue in effect following completion of the offering and entitle the holders of such rights to have us register their shares of our common stock for sale in the United States. See “Description of Capital Stock—Registration Rights.”

Executive Officer and Director Compensation

See “Executive and Director Compensation” for information regarding compensation of directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding our agreements with our named executive officers for the fiscal year ended 2012, see “Executive and Director Compensation—Narrative to Summary Compensation Table—Employment Arrangements with Our Named Executive Officers.”

Indemnification Agreements

We have entered into or plan to enter into indemnification agreements with each of our directors and officers, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. The indemnification agreements and our restated certificate of incorporation and restated by-laws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law. See “Management—Limitation of Liability and Indemnification Arrangements.”

Participation in this Offering

Certain of our existing stockholders, Sofinnova Partners, New Enterprise Associates and JAWZ II LLC, will purchase an aggregate of 2,087,500 shares of our common stock in this offering at the initial public offering price. The shares purchased by these investors will be subject to lock-up restrictions described in “Shares Eligible for Future Sale.”

PRINCIPAL STOCKHOLDERS

The following table presents information concerning the beneficial ownership of the shares of our common stock as of March 1, 2013 by:

- each person we know to be the beneficial owner of 5% or more of our outstanding shares of our capital stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, a person is deemed to be a beneficial owner of our common stock if that person has a right to acquire ownership within 60 days by the exercise of vested options or the conversion of our convertible preferred stock. A person is also deemed to be a beneficial holder of our common stock if that person has or shares voting power, which includes the power to vote or direct the voting of our common stock, or investment power, which includes the power to dispose of or to direct the disposition of such capital stock. Except in cases where community property laws apply or as indicated in the footnotes to this table, we believe that each stockholder identified in the table possesses sole voting and investment power over all shares of common stock shown as beneficially owned by the stockholder.

Percentage of beneficial ownership prior to this offering in the table below is based on 13,635,948 shares of common stock deemed to be outstanding as of March 1, 2013, assuming the conversion of all outstanding shares of convertible preferred stock into common stock, but does not give effect to (i) the conversion, as described below, of \$17.6 million aggregate principal amount outstanding as of March 1, 2013 and all accrued but unpaid interest on the convertible promissory notes due upon the closing of this offering into an aggregate of 2,228,925 shares of our common stock or (ii) the automatic net exercise of outstanding warrants for an aggregate of 549,995 shares of our common stock, in each case based on the initial public offering price of \$8.00 per share and the closing of this offering on April 16, 2013. Percentage of beneficial ownership after the offering in the table below is based on 24,414,868 shares of common stock to be outstanding after this offering and gives effect to (i) the conversion of all outstanding shares of convertible preferred stock into common stock, (ii) the conversion, as described below, of \$17.6 million aggregate principal amount outstanding as of March 1, 2013 and all accrued but unpaid interest on the convertible promissory notes due upon the closing of this offering into an aggregate of 2,228,925 shares of our common stock, based on the initial public offering price of \$8.00 per share and that the closing occurs on April 16, 2013 and (iii) the automatic net exercise of outstanding warrants for an aggregate of 549,995 shares of our common stock, based on the initial public offering price of \$8.00 per share.

The table below assumes that the underwriters do not exercise their over-allotment option. If the over-allotment option is exercised in full, we will sell an aggregate of 1,200,000 additional shares of common stock. Shares of common stock subject to options that are currently exercisable or exercisable within 60 days of March 1, 2013 are considered outstanding and beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless indicated below, the address of each individual listed below is c/o Omthera Pharmaceuticals, Inc., 707 State Road, Princeton, NJ 08540.

Certain of our existing principal stockholders, Sofinnova Partners and New Enterprise Associates, will purchase an aggregate of 1,250,000 shares of our common stock in this offering at the initial public offering price. The following table reflects such purchases by these existing stockholders.

<u>Number and Address of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned Prior to this Offering</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Prior to this Offering</u>	<u>After this Offering</u>
5% Stockholders			
Sofinnova Capital VI FCPR(1)	5,745,044	42.1%	29.3%
New Enterprise Associates(2)	4,424,060	32.4%	23.9%
Named Executive Officers and Directors			
George Horner(3)	157,469	1.1%	*
Graziano Seghezzi(1)	—	—	—
David M. Mott(2)	—	—	—
Gerald L. Wisler(4)	1,362,451	10.0%	5.7%
Michael H. Davidson, M.D.(5)	1,485,343	10.9%	6.1%
Christian S. Schade(6)	150,799	1.1%	*
Bernardus (Ben) N. Machielse(7)	113,240	*	*
All executive officers and directors as a group (7 persons)(8) . .	3,269,343	23.9%	13.5%

* Indicates beneficial ownership of less than one percent.

- (1) Consists of 3,117,609 shares common stock issuable upon conversion of Series A Preferred Stock and 2,627,435 shares common stock issuable upon conversion of Series B Preferred Stock. The percentage of shares beneficially owned after the offering also includes (i) 633,219 shares of common stock issuable to Sofinnova Capital VI FCPR upon the conversion at the closing of this offering of the \$5.0 million aggregate principal amount of convertible promissory notes held by Sofinnova Capital VI FCPR, plus all accrued but unpaid interest, as described above, (ii) 156,250 shares of common stock issuable to Sofinnova Capital VI FCPR upon the exercise of outstanding warrants, in each case based on the initial public offering price of \$8.00 per share and the closing of this offering on April 16, 2013 and (iii) 625,000 shares of common stock that will be purchased in this offering. Mr. Seghezzi is a partner of Sofinnova Partners SAS, the management company of Sofinnova Capital VI FCPR. Mr. Seghezzi disclaims beneficial ownership with respect to any such shares, except to the extent of his pecuniary interest therein, if any. The address of Sofinnova Capital VI FCPR is 17 rue de Serene, Paris 75008, France.
- (2) Consists of 4,418,940 shares common stock issuable upon conversion of the shares of Series B Preferred Stock held by New Enterprise Associates 13, L.P., or NEA 13, and 5,120 shares common stock issuable upon conversion of the shares of Series B Preferred Stock held by NEA Ventures 2011, Limited Partnership, or NEA 2011 LP. The percentage of shares beneficially owned after the offering also includes (i) 633,219 shares of common stock issuable to NEA 13 upon the conversion at the closing of this offering of the \$5.0 million aggregate principal amount of convertible promissory notes held by NEA 13, plus all accrued but unpaid interest, as described above, (ii) 156,250 shares of common stock issuable to NEA 13 upon the exercise of outstanding warrants, in each case based on the initial public offering price of \$8.00 per share, and the closing of this offering on April 16, 2013 and (iii) 625,000 shares of common stock that will be purchased in this offering. The shares directly held by NEA 13 are indirectly held by NEA Partners 13, L.P., or NEA Partners 13, the sole general partner of NEA 13, NEA 13 GP, LTD, or NEA 13 LTD, the sole general partner of NEA Partners 13 and each of the individual Directors of NEA 13 LTD. The individual Directors, or collectively, the Directors, of NEA 13 LTD are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Patrick J. Kerins, Krishna Kolluri, David M. Mott (a member of our board of directors), Scott D.

Sandell, Ravi Viswanathan and Harry R. Weller. The shares directly held by NEA 2011 LP are indirectly held by Karen P. Welsh, the general partner of NEA 2011 LP. NEA 13, NEA Partners 13, NEA 13 LTD and the Directors share voting and dispositive power with regard to the shares directly held by NEA 13. Karen P. Welsh, the general partner of NEA 2011 LP, holds voting and dispositive power over the shares held by NEA 2011 LP. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The principal business address of New Enterprise Associates, Inc. is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.

- (3) Consists of options to purchase 157,469 shares exercisable within 60 days of March 1, 2013.
- (4) Includes 36,574 shares of common stock issuable upon conversion of shares of Series B Preferred Stock held by Mr. Wisler and 716,690 shares of common stock held in trusts for the benefit of certain of his family members. The percentage of shares beneficially owned after the offering also includes (i) 12,664 shares of common stock issuable to Mr. Wisler upon the conversion at the closing of this offering of the \$100,000 aggregate principal amount of convertible promissory notes held by Mr. Wisler, plus all accrued but unpaid interest, as described above, (ii) 3,125 shares of common stock issuable to Mr. Wisler upon the exercise of outstanding warrants, in each case based on the initial public offering price of \$8.00 per share and the closing of this offering on April 16, 2013 and (iii) 18,750 shares of common stock that will be purchased in this offering.
- (5) Includes 520,756 shares of common stock held by the Michael H. Davidson 2012 GRAT u/a/d October 2, 2012 and 51,960 shares of common stock issuable upon conversion of shares of Series A Preferred Stock held by Dr. Davidson.
- (6) Consists of 25,601 shares of common stock issuable upon conversion of shares of Series B Preferred Stock and options to purchase 125,198 shares exercisable within 60 days of March 1, 2013.
- (7) Consists of 25,601 shares of common stock issuable upon conversion of shares of Series B Preferred Stock and options to purchase 87,639 shares exercisable within 60 days of March 1, 2013.
- (8) Includes options to purchase 370,306 shares exercisable within 60 days of March 1, 2013.

DESCRIPTION OF CAPITAL STOCK

Upon the completion of this offering, our authorized capital stock will consist of 120,000,000 shares of common stock. As of March 1, 2013, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon completion of this offering, but excluding the effect of the conversion of the convertible promissory notes and the automatic net exercise of outstanding warrants into shares of our common stock upon completion of this offering, we would have had 13,635,948 shares of common stock outstanding held of record by 19 stockholders.

Immediately following the completion of this offering, we will have 24,414,868 shares of common stock outstanding (and 25,614,868 shares of common stock outstanding if the underwriters exercise their option to purchase additional shares in full) and no shares of convertible preferred stock outstanding.

In February 2013, we borrowed \$17.6 million through the issuance of convertible promissory notes and warrants for the purchase of our common stock. The convertible promissory notes will automatically convert into 2,228,925 shares of common stock and the warrants will automatically net exercise into 549,995 shares of common stock, in each case upon the closing of this offering, based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013.

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated by-laws are summaries of material terms and provisions and are qualified by reference to our amended and restated certificate of incorporation and amended and restated by-laws, copies of which have been filed with the SEC as exhibits to the registration statement of which this prospectus is a part. The descriptions of our common stock and preferred stock reflect amendments to our amended and restated certificate of incorporation and amended and restated by-laws that will become effective immediately prior to the completion of this offering.

Common Stock

Upon the completion of this offering, we will be authorized to issue one class of common stock. Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Except as described under “Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws” below, a majority vote of the holders of common stock is generally required to take action under our amended and restated certificate of incorporation and amended and restated by-laws.

Preferred Stock

Upon the closing of this offering, our board of directors will be authorized, without action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common

stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock. See also “Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws—Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws—Undesignated preferred stock” below.

Our board of directors will make any determination to issue such shares based on its judgment as to our company’s best interests and the best interests of our stockholders. Upon the completion of this offering, we will have no shares of preferred stock outstanding and we have no current plans to issue any shares of preferred stock.

Warrants

In February 2013, we issued warrants to purchase the number of shares of our capital stock equal to \$4.4 million divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. Upon closing of this offering, the warrants will be automatically net exercised for 549,995 shares of common stock based on the initial public offering price per share of \$8.00, the price set forth on the cover of this prospectus and the closing of this offering on April 16, 2013. The warrants expire on February 15, 2023.

In connection with our March 2013 loan facility, we agreed to issue to Hercules Technology Growth Capital, Inc., effective April 1, 2013, a warrant to purchase a number of shares of our common stock initially equal to 78,125 shares of common stock (which will increase to 97,656 shares if we draw down on the term loan facility) at an exercise price of \$6.40 per share, based on the initial public offering price per share of \$8.00. If we do not complete an initial public offering on or before September 30, 2013, the warrant will be exercisable for shares of our Series B Preferred Stock or shares of a subsequent class of preferred stock, subject to certain conditions. The warrant will expire upon the earlier of April 1, 2020 or five years after the completion of our initial public offering.

Registration Rights

We are party to an agreement with the holders of our convertible preferred stock providing for rights to register under the Securities Act the shares of our common stock issuable upon the conversion of convertible preferred stock held by them. Under this agreement, holders of shares having registration rights can request that their shares be covered by a registration statement that we are otherwise filing.

Piggyback Registration Rights. If we decide to register any of our securities under the Securities Act, either for our own account or for the account of a security holder or holders, the holders of registration rights are entitled to prompt notice of the registration and are entitled to include their shares of our common stock in the registration.

Demand Registration Rights. In addition, the holders of 20% or more in interest of the common stock issued or issuable upon conversion of the convertible preferred stock held by the parties that have such registration rights may demand us to use our best efforts to effect the expeditious registration of their shares of our common stock on up to two occasions.

S-3 Registration. If we qualify for registration on Form S-3, certain holders of registration rights may also request a registration on Form S-3 and we are required to effect the expeditious registration of their shares of our common stock as soon as practicable. We may defer the filing of a registration statement on Form S-3 for up to 60 days if our board of directors determines in its good faith judgment that such registration would be materially detrimental to us and our stockholders. We may delay a registration on Form S-3 in this manner no more than once in any twelve-month period.

Expenses of Registration. We are required to pay all registration expenses except any underwriting discounts and applicable selling commissions.

Antitakeover Effects of Delaware Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws

Certain provisions of the Delaware General Corporation Law and of our amended and restated certificate of incorporation and amended and restated by-laws that will become effective upon the completion of this offering could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the time of determination of interested stockholder status, 15% or more of the corporation’s outstanding voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the time the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers and employee stock plans, in some instances; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated By-laws

Our amended and restated certificate of incorporation and amended and restated by-laws to be in effect upon completion of this offering will include a number of provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies. In accordance with our amended and restated certificate of incorporation, which will be effective upon the completion of this offering, our board is

divided into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

No written consent of stockholders. Our amended and restated certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our by-laws or removal of directors by our stockholder without holding a meeting of stockholders.

Meetings of stockholders. Our amended and restated by-laws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our by-laws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements. Our amended and restated by-laws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in our amended and restated by-laws.

Amendment to certificate of incorporation and by-laws. As required by the Delaware General Corporation Law, any amendment of our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability and the amendment of our amended and restated certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated by-laws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the by-laws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if the board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock. Our amended and restated certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and

unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol “OMTH.”

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of March 1, 2013, upon completion of this offering, 24,414,868 shares of common stock will be outstanding, assuming no exercise of the underwriter's over-allotment option and no exercise of options and including the effect of the conversion of the convertible promissory notes and the net exercise of outstanding warrants into shares of our common stock upon the closing of this offering. All of the shares sold in this offering will be freely tradable, except for any shares of our common stock purchased by certain of our existing stockholders, which will be subject to lock-up agreements. The remaining 18,521,118 shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale in compliance with Rule 144 or Rule 701 under the Securities Act. "Restricted securities" as defined under Rule 144 of the Securities Act were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

In general, under Rule 144 under the Securities Act, a person who is one of our affiliates and has beneficially owned shares of our common stock for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- one percent of the number of shares of common stock then outstanding, which will equal approximately 24,415 shares immediately after the completion of this offering; or
- the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. For a person who has not been deemed to have been one of our affiliates at any time during the 90 days preceding a sale, sales of our securities held longer than six months, but less than one year, will be subject only to the current public information requirement.

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, and will be subject only to the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144. 18,521,118 shares of our common stock will qualify for resale under Rule 144 within 180 days of the date of this prospectus, subject to the lock-up agreements as

described under “Lock-up Agreements” below and under “Underwriting” in this prospectus, and to the extent such shares have been released from any repurchase option that we may hold.

Rule 701

Rule 701 under the Securities Act, or Rule 701, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

In connection with this offering, we and each of our directors and officers, all existing stockholders and all holders of securities convertible into, or exercisable or exchangeable for, our common stock have agreed that, subject to certain exceptions, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (as such period may be extended under certain circumstances), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of directly or indirectly, any shares of common stock or any securities convertible into, or exercisable or exchangeable for, common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction is to be settled by delivery of our common stock or such other securities, in cash or otherwise. These restrictions are subject to certain exceptions, as described in more detail under “Underwriting” in this prospectus.

Warrants

In February 2013, we issued warrants to purchase the number of shares of our capital stock equal to \$4.4 million divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. Upon closing of this offering, the warrants will be automatically net exercised for 549,995 shares of common stock based on the initial public offering price per share of \$8.00 and the closing of this offering on April 16, 2013. The shares purchased pursuant to these warrants will be restricted shares and may be sold in the public market only if they are registered under the Securities Act or qualify for an exemption from such registration.

In connection with our March 2013 loan facility, we agreed to issue to Hercules Technology Growth Capital, Inc., effective April 1, 2013, a warrant to purchase a number of shares of our common stock initially equal to 78,125 shares of common stock (which will increase to 97,656 shares if we draw down on the term loan facility) at an exercise price of \$6.40 per share, based on the initial public offering price per share of \$8.00. If we do not complete an initial public offering on or before September 30, 2013, the warrant will be exercisable for shares of our Series B Preferred Stock or shares of a subsequent class of preferred stock, subject to certain conditions. The warrant will expire upon the earlier of April 1, 2020 or five years after the completion of our initial public offering. Any shares purchased pursuant to this warrant will be restricted shares and may be sold in the public market only if they are registered under the Securities Act or qualify for an exemption from such registration.

Registration Rights

We are party to a registration rights agreement which provides that holders of our convertible preferred stock and our founding stockholders have the right to demand that we file a registration statement or request that their shares of our common stock be covered by a registration statement that we are otherwise filing. See “Description of Capital Stock—Registration Rights” in this prospectus. Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration, subject to the expiration of the lock-up period described above and under “Underwriting” in this prospectus, and to the extent such shares have been released from any repurchase option that we may hold.

Stock Option Plans

As soon as practicable after the completion of this offering, we intend to file a Form S-8 registration statement under the Securities Act to register shares of our common stock subject to options outstanding or reserved for issuance under our stock plans. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements. For a more complete discussion of our stock plans, see “Executive and Director Compensation—Stock Option Plans.”

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a general discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term “non-U.S. holder” means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election in effect to be treated as a U.S. person under applicable U.S. Treasury Regulations.

An individual may be treated as a resident instead of a nonresident of the United States in any calendar year for U.S. federal income tax purposes if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with the current calendar year. For purposes of this calculation, all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year are counted. Subject to the provisions of certain tax treaties between the United States and other nations, non-citizens of the United States treated as U.S. residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances nor does it address any aspects of state, local or non-U.S. taxes, or U.S. federal taxes other than income and estate taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;

- passive foreign investment companies;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- certain U.S. expatriates;
- persons subject to the alternative minimum tax; or
- persons that acquire our common stock as compensation for services.

In addition, this discussion does not address the tax treatment of partnerships or other entities that are transparent for U.S. federal income tax purposes or persons who hold their common stock through partnerships or other entities that are transparent for U.S. federal income tax purposes. A partner in a partnership or other transparent entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other transparent entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock.

Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "Gain on Disposition of Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not constitute a dividend because we do not anticipate having current or accumulated earnings and profits, we intend not to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations. If we or another withholding agent apply over-withholding, a non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To obtain this exemption, a non-U.S. holder must generally provide us with a properly executed original and unexpired IRS Form W-8ECI properly certifying such exemption. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on gain recognized on a disposition of our common stock (other than a redemption that is treated as a distribution for U.S. federal income tax purposes and taxed as described above) unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition; or
- we are or were a "U.S. real property holding corporation" during a certain look-back period, unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than five percent of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we have not been and are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate (currently 28%) with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain

other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Account Tax Compliance Act

The Foreign Account Tax Compliance Act, or FATCA, will generally impose a 30% withholding tax on any "withholdable payment" to a "foreign financial institution," unless such institution enters into an agreement with the U.S. government to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which would include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with United States owners) or another applicable exception applies. The FATCA will also impose a 30% withholding tax on any "withholdable payment" to a foreign entity that is not a financial institution, unless such entity provides the withholding agent with a certification identifying the substantial U.S. owners of the entity (which generally includes any U.S. person who directly or indirectly owns more than 10% of the entity) or another applicable exception applies. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes.

"Withholdable payments" will include U.S.-source payments otherwise subject to nonresident withholding tax, and also include the entire gross proceeds from the sale of any equity or debt instruments of U.S. issuers. The withholding tax will apply regardless of whether the payment would otherwise be exempt from U.S. nonresident withholding tax (e.g., under the portfolio interest exemption or as capital gain). The IRS is authorized to provide rules for coordinating the FATCA withholding regime with the existing nonresident withholding tax rules.

Under proposed regulations, this withholding will apply to U.S.-source payments otherwise subject to nonresident withholding tax made on or after January 1, 2014 and to the payment of gross proceeds from the sale of any equity or debt instruments of U.S. issuers made on or after January 1, 2017.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
Merrill Lynch, Pierce, Fenner & Smith Incorporated	2,800,000
Barclays Capital Inc.	2,400,000
Leerink Swann LLC	1,120,000
Stifel, Nicolaus & Company, Incorporated	1,120,000
Piper Jaffray & Co.	560,000
Total	8,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Certain of our existing stockholders will purchase an aggregate of 2,087,500 shares of our common stock in this offering at the initial public offering price. We have directed the underwriters to sell them such shares in this offering.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover of this prospectus and to dealers at that price less a concession not in excess of \$.33 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$ 8.00	\$ 64,000,000	\$ 73,600,000
Underwriting discount	\$.56	\$ 4,480,000	\$ 5,152,000
Proceeds, before expenses, to us	\$ 7.44	\$ 59,520,000	\$ 68,448,000

The expenses of the offering, not including the underwriting discount, are estimated at \$2,000,000 and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses, in an amount of up to \$20,000, as set forth in the underwriting agreement.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,200,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

Reserved Shares

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, business associates and related persons. If these persons purchase reserved shares, it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and Barclays Capital Inc. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

NASDAQ Global Market Listing

The shares have been approved for listing on the NASDAQ Global Market under the symbol "OMTH."

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,

- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the NASDAQ Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or Relevant Implementation Date, no offer of shares may be made to the public in that Relevant Member State other than:

- A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or
- C. in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that (A) it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive and (B) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than “qualified investors” as defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression “an offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in France

This document has not been prepared in the context of a public offering of financial securities in France within the meaning of article L.411 1 of the French Code monétaire et financier and Title I of Book II of the Règlement Général of the Autorité des marchés financiers (the French financial markets authority, or “AMF”). Consequently, the shares may not be, directly or indirectly, offered or sold to the public in France (“offre au public de titres financiers”), and neither this document nor any offering or marketing materials relating to the shares must be made available or distributed in any way that would constitute, directly or indirectly, an offer to the public in France.

The shares may only be offered or sold in France to qualified investors (“investisseurs qualifiés”) other than individuals and/or to providers of investment services relating to portfolio management for the account of third parties (“personnes fournissant le service d’investissement de gestion de portefeuille pour le compte de tiers”), all as defined in and in accordance with articles L.411.1, L.411 2, D.411 1, D.744 1, D.754 1 and D.764 1 of the French Code monétaire et financier.

Prospective investors are informed that:

- (i) this document has not been and will not be submitted for clearance to the AMF;

(ii) in compliance with articles L.411 2, D.411 1, D.744 1, D.754 1 and D.764 1 of the French Code monétaire et financier, any investors subscribing for the shares should be acting for their own account; and

(iii) the direct and indirect distribution or sale to the public of the shares acquired by them may only be made in compliance with articles L.411 1, L.411 2, L.412 1 and L.621 8 through L.621-8-3 of the French Code monétaire et financier.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts and for the underwriters by Latham & Watkins LLP.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2011 and 2012, and for each of the two years in the period ended December 31, 2012 and the period from November 19, 2008 (Inception) to December 31, 2012, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to the financial statements). We have included our financial statements in this prospectus and elsewhere in this registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The reports and other information we file with the SEC can be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington D.C. 20549. Copies of these materials can be obtained at prescribed rates from the Public Reference Section of the SEC at the principal offices of the SEC, 100 F Street, NE, Washington D.C. 20549. You may obtain information regarding the operation of the public reference room by calling 1(800) SEC-0330. The SEC also maintains a web site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC.

Upon completion of this offering, we will become subject to the reporting and information requirements of the Exchange Act and, as a result, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference room and the web site of the SEC referred to above.

MARKET AND INDUSTRY DATA AND FORECASTS

Market data and certain industry data and forecasts included in this prospectus were obtained from internal company surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. We have relied upon industry publications as our primary sources for third-party industry data and forecasts. Industry surveys, publications and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. We have not independently verified any of the data from third-party sources, nor have we ascertained the underlying economic assumptions relied upon therein. Similarly, internal surveys, industry forecasts and market research, which we believe to be reliable based upon our management's knowledge of the industry, have not been independently verified. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements as to our market position are based on recently available data. While we are not aware of any misstatements regarding our industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under "Risk Factors" in this prospectus. While we believe our internal business research is reliable and market definitions are appropriate, neither such research nor definitions have been verified by any independent source. This prospectus may only be used for the purpose for which it has been published.

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Omthera Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Omthera Pharmaceuticals, Inc. (a development stage company) as of December 31, 2011 and 2012, and the related statements of operations, comprehensive loss, convertible preferred stock and changes in stockholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2012 and the period from November 19, 2008 (Inception) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Omthera Pharmaceuticals, Inc. at December 31, 2011 and 2012 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2012 and the period from November 19, 2008 (Inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and will require additional funding in the future. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects of the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 8, 2013,
except for Note 16, as to which the date is
April 1, 2013

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)

Balance Sheets

	December 31,		Pro forma December 31, 2012
	2011	2012	(Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	\$ 10,869,129	\$ 2,505,076	\$ 20,105,076
Short-term investments	6,641,649	—	—
Prepaid expenses and other current assets	1,013,647	161,303	161,303
Total current assets	18,524,425	2,666,379	20,266,379
Other assets	—	319,890	319,890
Property and equipment, net	31,664	21,976	21,976
Total assets	\$ 18,556,089	\$ 3,008,245	\$ 20,608,245
Liabilities, convertible preferred stock, and stockholders' (deficit) equity			
Current liabilities:			
Accounts payable	\$ 3,019,297	\$ 1,768,861	\$ 1,768,861
Accrued expenses and other liabilities	1,158,259	3,713,508	3,713,508
Total current liabilities	4,177,556	5,482,369	5,482,369
Commitments and contingencies (<i>Note 15</i>)			
Series A 8%, cumulative convertible preferred stock, \$0.001 par value; 4,694,375 shares authorized, issued and outstanding at December 31, 2012 and December 31, 2011. Liquidation value of \$7,900,003 at December 31, 2012.	6,388,092	6,388,092	—
Series B 8%, cumulative convertible preferred stock, \$0.001 par value; 10,131,879 shares authorized; 8,090,583 issued and outstanding at December 31, 2011. At December 31, 2012, 10,131,879 shares were issued and outstanding. Liquidation value of \$55,617,722 at December 31, 2012.	39,404,351	49,389,307	—
Stockholders' (deficit) equity			
Common stock, \$0.001 par value; 22,000,000 shares authorized at December 31, 2012 (unaudited and pro forma) and December 31, 2011; 3,010,101 shares issued and outstanding at December 31, 2012 and December 31, 2011; 16,414,868 issued and outstanding at December 31, 2012 (unaudited and pro forma)	3,010	3,010	16,415
Additional paid-in capital	642,200	6,365,460	79,960,906
Accumulated other comprehensive loss	(6,633)	—	—
Deficit accumulated during development stage	(32,052,487)	(64,619,993)	(64,851,445)
Total stockholders' (deficit) equity	(31,413,910)	(58,251,523)	15,125,876
Total liabilities, convertible preferred stock, and stockholders' (deficit) equity . .	\$ 18,556,089	\$ 3,008,245	\$ 20,608,245

The accompanying notes are an integral part of these financial statements.

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)
Statements of Operations

	<u>Year Ended December 31,</u>		<u>Period From</u>
	<u>2011</u>	<u>2012</u>	<u>November 19,</u>
			<u>2008</u>
			<u>(Inception) to</u>
			<u>December 31,</u>
			<u>2012</u>
Operating expenses			
Research and development	\$ 21,209,568	\$ 22,673,422	\$ 48,133,996
General and administrative	3,722,288	4,915,877	10,874,570
Total operating expenses	<u>24,931,856</u>	<u>27,589,299</u>	<u>59,008,566</u>
Loss from operations	(24,931,856)	(27,589,299)	(59,008,566)
Other income (expense)			
Interest expense, net	(67,222)	—	(709,444)
Other income	64,868	21,784	98,008
Net loss	<u>(24,934,210)</u>	<u>(27,567,515)</u>	<u>(59,620,002)</u>
Less dividends on preferred stock, not declared	(2,864,162)	(4,160,344)	(7,415,200)
Less beneficial conversion charge	—	(4,999,991)	(4,999,991)
Net loss attributable to common stockholders	<u>\$(27,798,372)</u>	<u>\$(36,727,850)</u>	<u>\$(72,035,193)</u>
Net loss per share (basic and diluted)	<u>\$ (22.73)</u>	<u>\$ (19.20)</u>	
Weighted average shares outstanding (basic and diluted) . .	<u>1,222,794</u>	<u>1,912,421</u>	
Pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited)		<u>\$ (3.08)</u>	
Weighted-average number of common shares used in pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited)		<u>11,939,170</u>	

The accompanying notes are an integral part of these financial statements

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)
Statements of Comprehensive Loss

	Year Ended December 31,		Period from November 19, 2008 (Inception) to December 31, 2012
	2011	2012	2012
Net loss	\$(24,934,210)	\$(27,567,515)	\$(59,620,002)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments	(6,633)	6,633	—
Comprehensive loss	\$(24,940,843)	\$(27,560,882)	\$(59,620,002)

The accompanying notes are an integral part of these financial statements

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)

Statements of Convertible Preferred Stock and Changes in Stockholders' (Deficit) Equity

Period from November 19, 2008 (Inception) to December 31, 2012

	Convertible Preferred Stock		Common Stock		Accumulated Comprehensive Income	Deficit Accumulated During Development Stage	Additional Paid-In Capital	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at November 19, 2008 (inception)	—	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of restricted common stock at \$0.001 per share	—	—	3,010,101	3,010	—	—	1,190	4,200
Net loss	—	—	—	—	—	(24,285)	—	(24,285)
Balance at December 31, 2008	—	—	3,010,101	3,010	—	(24,285)	1,190	(20,085)
Stock-based compensation	—	—	—	—	—	—	37,800	37,800
Issuance of Series A Preferred Stock, net of issuance cost	1,564,791	2,071,425	—	—	—	—	—	—
Net loss	—	—	—	—	—	(697,117)	—	(697,117)
Balance at December 31, 2009	1,564,791	2,071,425	3,010,101	3,010	—	(721,402)	38,990	(679,402)
Issuance of Series A Preferred Stock, net of issuance cost	3,129,584	4,316,667	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	239,598	239,598
Net loss	—	—	—	—	—	(6,396,875)	—	(6,396,875)
Balance at December 31, 2010	4,694,375	6,388,092	3,010,101	3,010	—	(7,118,277)	278,588	(6,836,679)
Issuance of Series B Preferred Stock, net of issuance cost	8,090,583	39,404,351	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	363,612	363,612
Net unrealized loss on short-term investments	—	—	—	—	(6,633)	—	—	(6,633)
Net loss	—	—	—	—	—	(24,934,210)	—	(24,934,210)
Balance at December 31, 2011	12,784,958	45,792,443	3,010,101	3,010	(6,633)	(32,052,487)	642,200	(31,413,910)
Issuance of Series B Preferred Stock, net of issuance cost	2,041,296	9,984,956	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	723,269	723,269
Beneficial conversion charge	—	—	—	—	—	(4,999,991)	4,999,991	—
Net unrealized gain on short-term investments	—	—	—	—	6,633	—	—	6,633
Net loss	—	—	—	—	—	(27,567,515)	—	(27,567,515)
Balance at December 31, 2012	14,826,254	\$55,777,399	3,010,101	\$3,010	\$ —	\$(64,619,993)	\$6,365,460	\$ (58,251,323)

The accompanying notes are an integral part of these financial statements.

Omthera Pharmaceuticals, Inc.
(A Development-Stage Company)
Statements of Cash Flows

	<u>Year Ended December 31</u>		<u>Period From</u>
	<u>2011</u>	<u>2012</u>	<u>November 19, 2008</u>
			<u>(Inception) to</u>
			<u>December 31,</u>
			<u>2012</u>
Operating activities			
Net loss	\$(24,934,210)	\$(27,567,515)	\$(59,620,002)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	12,704	15,673	35,127
Amortization of premiums and discounts on short-term investments	109,104	47,372	156,476
Gain on sales of short-term investments	(779)	—	(779)
Warrant interest expense	67,222	—	692,222
Stock based compensation	363,612	723,269	1,364,279
Changes in assets and liabilities:			
Grant receivable	61,636	—	—
Other assets	—	(319,890)	(319,890)
Prepaid and other current assets	(783,551)	852,344	(161,303)
Accounts payable and accrued expenses	2,773,266	1,304,813	5,481,319
Net cash used in operating activities	<u>(22,330,996)</u>	<u>(24,943,934)</u>	<u>(52,372,551)</u>
Investing activities			
Purchase of property and equipment	(32,357)	(5,985)	(57,103)
Purchases of short-term investments	(19,073,644)	(399,090)	(19,472,734)
Maturities and sales of short-term investments	12,316,311	7,000,000	19,316,311
Net cash (used in) provided by investing activities	<u>(6,789,690)</u>	<u>6,594,925</u>	<u>(213,526)</u>
Financing activities			
Note payable to related parties	—	—	2,500,000
Proceeds from the issuance of convertible preferred stock, net of issuance costs	36,213,905	9,984,956	52,586,953
Proceeds from sale of common stock	—	—	4,200
Net cash provided by financing activities	<u>36,213,905</u>	<u>9,984,956</u>	<u>55,091,153</u>
Net increase (decrease) in cash	7,093,219	(8,364,053)	2,505,076
Cash at beginning of period	3,775,910	10,869,129	—
Cash at end of period	<u>\$ 10,869,129</u>	<u>\$ 2,505,076</u>	<u>\$ 2,505,076</u>
Supplemental disclosure of cash flow information			
Non-cash financing activities:			
Conversion of note payable and related warrants to convertible Series B Preferred Stock	<u>\$ 3,209,444</u>	<u>\$ —</u>	<u>\$ 3,209,444</u>

The accompanying notes are an integral part of these financial statements.

Notes to the Financial Statements

1. Organization and Description of Business

Omthera Pharmaceuticals, Inc. (the “Company”) was incorporated on November 19, 2008, in Delaware. The Company is dedicated to the clinical development of new therapies for dyslipidemia. The sole product candidate is Epanova, an Omega 3 fatty acid containing a novel formulation of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The Company’s activities since inception have consisted principally of raising capital, and performing research and development. Accordingly, the Company is considered to be in the development stage. The Company is financed by venture capital investors and is headquartered in Princeton, New Jersey.

On November 13, 2009, the Company entered into a License Agreement with Chrysalis Pharma AG (“Chrysalis”). Under the agreement, the Company obtained a worldwide exclusive license for the development, use, manufacture, and commercialization of Epanova.

Going Concern

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings. Management expects operating losses and negative cash flows to continue at more significant levels in the future. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidate and achieving a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional cash. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources. Based on the Company’s operating plan, existing working capital at December 31, 2012 was not sufficient to meet the cash requirements to fund planned operations through December 31, 2013 without additional sources of cash. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company’s assets and the satisfaction of liabilities in the normal course of business.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States (U.S.) generally accepted accounting principles (U.S. GAAP) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented.

Use of Estimates

The preparation of the Company’s financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors, with input from management. The

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

board of directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. The methodologies included an option pricing method and a probability-weighted expected return methodology that determined an estimated value under an IPO scenario and a sale scenario based upon an assessment of the probability of occurrence of each scenario. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of preclinical studies and clinical trials and the time to completing an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Unaudited Pro Forma Presentation

The unaudited pro forma balance sheet information as of December 31, 2012 assumes (i) the conversion of all outstanding shares of convertible preferred stock into 10,625,847 shares of common stock occurring immediately prior to the closing of the Company's proposed initial public offering, and (ii) the issuance and conversion of the Company's February 2013 \$17.6 million aggregate principal amount of 8% convertible notes and related warrants. Pro forma cash and cash equivalents, total current assets and total assets includes approximately \$17.6 million as a result of the conversion of the Company's convertible promissory notes into common stock.

Unaudited pro forma net loss per share is computed using the weighted-average number of common shares outstanding after giving effect to the pro forma effect of the conversion of all convertible preferred stock during the year ended December 31, 2012 into shares of the Company's common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later and assumes dividends have been declared. The effect, if any, of the Company's issuance of 8% convertible promissory notes and related warrants is not reflected since the number of shares issuable upon conversion is not yet determinable.

Cash, Cash Equivalents, and Short-term Investments

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Marketable securities with original maturities greater than three months and less than one year are considered to be short-term investments and consist of corporate debt obligations. Short-term investments are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders' deficit. Realized gains, realized losses, the amortization of

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

premiums and discounts, interest earned and dividends earned are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on management's intent to fund current operations with these securities or to make them available for current operations. A decline in the market value of a security below its cost value that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and short-term investments. The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federal insurance limits. Exposure to credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings. Short-term investments are invested in accordance with the Company's investment policy. The investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance-sheet risk of accounting loss.

Segment and Geographic Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing drugs that target very high triglycerides.

Fair Value of Financial Instruments

According to ASC 825, *Financial Instruments*, disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Cash, cash equivalents and short-term investments are carried at fair value (see Note 3). Financial instruments, including accounts payable and accrued liabilities, are carried at cost, which approximates fair value given their short-term nature.

Deferred Offering Costs

Costs directly attributable to the Company's offering of its equity securities are deferred and capitalized as Other Assets. These costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public sale of its common stock. The Company incurred no IPO costs prior to 2012. Future costs will be deferred until the completion of IPO, at which time they will be reclassified to additional paid-in capital as a reduction of the IPO proceeds. If the Company terminates its plan for an IPO or delay such plan for more than 90 days, any costs deferred will be expensed immediately.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Property and Equipment

Property and equipment, which consist of furniture and fixtures and computer equipment, are stated at cost, less accumulated depreciation. Depreciation is calculated over the estimated useful lives of the respective assets, which is two years for computer equipment and five years for furniture and fixtures.

Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to earnings in the period in which the costs are incurred. Major replacements, improvements, and additions are capitalized in accordance with Company policy.

Impairment of Long-Lived Assets

In accordance with ASC 360, *Property, Plant, and Equipment*, the Company's policy is to review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Through December 31, 2012, no impairment of long-lived assets has occurred.

Research and Development Costs

Research and development costs are charged to expense as incurred and are typically made up of salaries and benefits, clinical trial activities, drug development and manufacturing, and third-party service fees, including clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials 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 by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued expenses.

Foreign Currency

Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Transaction gains and losses are recorded to other income (expense), net in the Statements of Operations.

Income Taxes

The Company accounts for income taxes using the asset and liability method as required by ASC 740, *Income Taxes*. Under this method deferred income tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and the related tax basis and also for operating losses and tax credit carryforwards, using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded if it is "more-likely-than-not" that a portion or all of a deferred tax asset will not be realized.

Stock-Based Compensation

At December 31, 2012 and 2011, the Company had one stock-based employee compensation plan, which is described more fully in Note 12.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

The Company grants stock options for a fixed number of shares to employees and non-employees with an exercise price equal to the fair value of the share at the grant date.

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*. The Company selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility was calculated based on the weighted-average of historical information of similar public entities. The Company will continue to use a weighted-average approach using other similar public entities' volatility information until historical volatility of the Company is relevant to measure expected volatility for future option grants. The average expected life was determined according to the Securities and Exchange Commission (SEC) shortcut approach as described in Staff Accounting Bulletin (SAB) No. 110, which is the midpoint between the vesting date and the end of the contractual term.

Beneficial Conversion

When the Company issues a debt or a equity security that is convertible into common stock at a discount from the fair value of the common stock at the date the debt or equity security counterparty is legally committed to purchase such a security ("Commitment Date"), a beneficial conversion feature is measured and recorded on the Commitment Date for the difference between the fair value of the Company's common stock and the effective conversion price of the convertible debt or equity security. If the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the convertible debt or equity security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the convertible debt or equity security. The amount allocated to the beneficial conversion feature is presented as a discount or reduction to the related debt security or as an immediate charge to earnings available to common shareholders for convertible preferred stock instruments that are convertible by the shareholders at any time.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method. Dilutive common stock equivalents are comprised of convertible preferred stock and options outstanding under the Company's stock option plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common equivalent shares):

	Year Ended December 31,	
	2011	2012
Convertible preferred stock outstanding	9,162,874	10,625,847
Common stock options	1,144,024	1,179,906
Total	10,306,898	11,805,753

The following table summarizes the Company's historical computation of basic and diluted net loss per share:

Historical Net Loss per Share

	Year Ended December 31,	
	2011	2012
Numerator		
Net loss	\$(24,934,210)	\$(27,567,515)
Less dividends on preferred stock, not declared	(2,864,162)	(4,160,344)
Less beneficial conversion charge	—	(4,999,991)
Net loss attributable to common stockholders	\$(27,798,372)	\$(36,727,850)
Denominator		
Common shares outstanding	3,010,101	3,010,101
Less weighted average unvested common shares	1,787,325	(1,097,719)
Weighted average shares used to compute net loss per share	1,222,776	1,912,421
Net loss per share, basic and diluted	\$ (22.73)	\$ (19.20)

Although the common shares are legally outstanding, these shares are subject to vesting provisions and therefore the unvested shares are excluded from the basic earnings per share calculation.

Recent Accounting Standards

During May 2011, an accounting standard update regarding fair value measurement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. This standard update also changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The standard is effective for interim and annual periods beginning after December 15, 2011. The adoption of this standard update did not have a significant impact on the Company's financial position.

Notes to the Financial Statements (Continued)

3. Fair Value Measurements

ASC 820—*Fair Value Measurements and Disclosures* describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1** Quoted prices in active markets for identical assets and liabilities. The Company's Level 1 assets and liabilities consist of money market investments.
- Level 2** Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities. The Company's Level 2 assets and liabilities consist of corporate debt securities
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the warrant liability.

Fair Value on a Recurring Basis

	Fair Value as of December 31, 2011		
	Level 1	Level 2	Level 3
Assets			
Cash equivalents	\$9,921,157	\$ —	\$—
Corporate debt securities	—	6,641,649	—
Total assets	\$9,921,157	\$6,641,649	\$—
	Fair Value as of December 31, 2012		
	Level 1	Level 2	Level 3
Assets			
Cash equivalents	\$1,630,532	\$—	\$—
Corporate debt securities	—	—	—
Total assets	\$1,630,532	\$—	\$—

There were no transfers between Levels 1, 2, or 3 during 2012 or 2011 other than as disclosed in the table below.

The table below sets forth a summary of changes in the fair value of the Company's Level 3 assets for the year ended December 31, 2011.

	Warrant Liability
Level 3 Liabilities	
As of December 31, 2010	\$ 625,000
Exercise of warrant liability	(625,000)
As of December 31, 2011	\$ —

Notes to the Financial Statements (Continued)

4. Short-term Investments

The Company's short-term investments at cost or amortized cost value and fair market value by contractual maturity were:

	Cost or Amortized Cost Value	Fair Market Value
December 31, 2011		
Due in one year or less	\$6,648,282	\$6,641,649
Total	\$6,648,282	\$6,641,649

The types of securities included in the Company's available for sale investments were:

	Cost or Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Market Value
December 31, 2011				
Corporate debt securities	\$6,648,282	\$105	\$(6,738)	\$6,641,649
Total	\$6,648,282	\$105	\$(6,738)	\$6,641,649

No securities have been in a continuous unrealized loss position for more than 12 months at December 31, 2011.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2011	2012
Prepaid clinical trial expenses	\$ 801,273	\$ 90,000
Prepaid insurance	87,557	35,770
Interest receivable	50,806	—
Security deposit	46,580	35,533
Prepaid rent	25,367	—
Other	2,064	—
Total prepaid expenses and other current assets	\$1,013,647	\$161,303

6. Property and Equipment

	December 31,	
	2011	2012
Property and equipment:		
Computer equipment	\$ 33,569	\$ 39,554
Furniture and fixtures	17,548	17,548
Total property and equipment	51,117	57,102
Less accumulated depreciation	(19,453)	(35,126)
Property and equipment, net	\$ 31,664	\$ 21,976

The Company utilizes the straight-line method for depreciation, using two to five-year depreciable asset lives. Depreciation expense was not material for all periods presented.

Notes to the Financial Statements (Continued)

7. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2011	2012
Salaries	\$ 100,893	\$ —
Employee bonuses	851,095	870,427
Milestone payable	—	2,000,000
Clinical studies	64,952	115,153
Professional and legal fees	74,317	365,365
CMO Costs	—	354,000
Other	67,002	8,562
Total accrued expenses and other liabilities	<u>\$1,158,259</u>	<u>\$3,713,508</u>

8. Bridge Note Payable to Related Parties

On December 1, 2010, the Company signed a one year, 8% interest rate, Bridge Note to raise \$2.5 million due and payable on December 31, 2011 or on the closing of the Series B financing. Interest is paid annually and the note is convertible into Class “B” preferred shares. In connection with the issuance of the Note, the Company issued a warrant equal to 25% of the principal amount of the note. The warrant had a term of 5 years or upon closing of next round of qualified or non-qualified financing. The warrant had an exercise price of \$0.001 per share. The Company recorded a non-cash charge of \$625,000 for the accretion on bridge note which is recorded in interest expense on the Statement of Operations during the year ended December 31, 2010.

On February 28, 2011 the Company closed a Series B financing and issued 6,921,939 shares of Series B Preferred Stock with total proceeds of \$33.9 million. As part of the Series B close, the Bridge Note payable of \$2.5 million and related accrued interest of \$84,444 was converted into 520,418 shares of Series B Preferred Stock and the related warrants of \$625,000 were exercised for 127,581 shares of Series B Preferred Stock.

9. Capital Structure—Common Stock

As of December 31 2012 and December 31, 2011, the Company was authorized to issue 22,000,000 shares at a par value of \$0.001 per share.

As of December 31, 2012 and December 31, 2011, the Company issued an aggregate of 3,010,101 shares of common stock to its founders at a par value of \$0.001 per share, of which 2,320,039 and 1,567,633 shares of common stock were vested and outstanding as of December 31, 2012 and 2011, respectively, and 1,406,758 and 1,442,473 shares remain unvested as of December 31, 2012 and 2011, respectively. The unvested shares of common stock, representing the Founders’ Shares described in Note 11, will continue to vest following the IPO in connection with the founders’ continued service to the Company pursuant to the founders’ stock restriction agreements.

The voting, dividend, and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers, and preferences of the holders of the Preferred Stock. Each holder of common stock is entitled to vote on all matters and is entitled to one vote for each share held.

Notes to the Financial Statements (Continued)

10. Capital Structure—Convertible Preferred Stock

On February 28, 2011, the Company entered into a Series B Preferred Stock Purchase Agreement with various investors (“Series B Agreement”) which provides for the issuance of up to 10,131,879 shares of Series B preferred stock subject to various terms and conditions. On February 28, 2011, the Company issued 6,921,939 shares of Series B Preferred Stock at a par value of \$.001 and an issuance price of \$4.90 for total consideration of \$33.9 million. As part of the Series B close, the Bridge Note payable of \$2.5 million and related accrued interest of \$84,444 was converted into 520,418 shares of Series B Preferred Stock and related warrants of \$625,000 were exercised for 127,581 shares of Series B Preferred Stock and the Company issued Series B Preferred Stock, which resulted in gross cash proceeds of \$31.3 million received for the February 28, 2011 offering. The terms of the Series B agreement included additional tranches of preferred stock to be issued within ninety days of the original issuance and upon the achievement of a certain milestone by the Company or at any other time within ninety days of the original issuance (“additional closing”), as well as additional closings at the option of the holders (“optional closings”). On May 31, 2011, the Company had a closing of 51,033 shares for cash proceeds of \$250,003.

On December 22, 2011, the Series B Preferred Stock Purchase Agreement was amended to remove the additional closing clause, to include three additional tranches of preferred shares to be issued upon certain milestones to be met by the Company and to amend the terms of the optional closing clauses. Further, on December 22, 2011, the Company issued 990,030 shares for gross cash proceeds of \$4.9 million.

On April 4, 2012, the Company completed the sale and third closing of 1,020,648 shares of Series B Preferred Stock at an issuance of \$4.90, with gross proceeds received totaling \$5.0 million.

On July 24, 2012, the Company completed an additional sale of 1,020,648 shares of Series B Preferred Stock at an issuance of \$4.90, with gross proceeds received totaling \$5.0 million. As such, as of December 31, 2012, 10,131,879 shares of Series B Preferred Shares were outstanding.

Total issuance costs related to the Series B Preferred Shares issued during 2011 and 2012 were \$230,126 and \$15,026, respectively.

On November 13, 2009, the Company authorized the sale and issuance of up to 4,694,375 shares of Series A Preferred Stock. The Company completed the initial closing on that date and sold 1,564,791 shares at an issuance price of \$1.38, with cash proceeds received totaling \$2.1 million, which is net of issuance costs of \$86,908.

During 2010, the Company completed the sale and second closing of 3,129,584 shares of Series A Preferred Stock at an issuance of \$1.38, with gross proceeds received totaling \$4.3 million. As such, as of December 31, 2011 and 2010, the Company had 4,694,375 shares of Series A Preferred Shares outstanding.

JAWZ II LLC invested in Series A and Series B Preferred Shares at the issuance prices of \$1.38 and \$4.90, respectively. James Wisler, the brother of Gerald Wisler (CEO), is manager of JAWZ II LLC.

Notes to the Financial Statements (Continued)

10. Capital Structure—Convertible Preferred Stock (Continued)

Significant rights, restrictions, and preferences of the Series A and Series B preferred shares are as follows:

Dividend Provisions

The holders of each outstanding share of Series A and B preferred stock are entitled to receive annual, cumulative dividends of 8% of the applicable Original Issuance Price of \$1.38 and \$4.90 per share, respectively (subject to appropriate adjustments in the event of any stock dividend, stock split, combination or other similar recapitalizations with respect to such shares) (the Accrued Dividends). Accruing Dividends shall accrue from day-to-day, whether or not declared, and shall be cumulative, provided except for in the event of a liquidation, such accruing dividends shall be payable, when and as declared by the Board of Directors, in preference to any distribution to the holders of the common stock. After payment of such dividends, any additional dividends or distributions shall be distributed among all holders of common stock and preferred stock in proportion to the number of shares of common stock that would be held by each such holder if all shares of preferred stock were converted to common stock. Through December 31, 2012, the Company has not declared any dividends. In the event of liquidation, the cumulative to date amount of dividends that could be payable at December 31, 2012 was approximately \$7.4 million.

Liquidation Preferences

In the event of a liquidation, dissolution, or winding-up of the affairs of the Company, including a change in control, the holders of each Series A and B share shall be entitled to receive the applicable Original Issuance Price per share, adjusted for any combinations or subdivisions with respect to such shares and, in addition, an amount equal to all declared but unpaid dividends prior and in preference to any distribution to the holders of the common stock. All remaining proceeds will be shared pro rata by the holders of the preferred and common stock on an as-converted basis until, with respect to each Series A and B of preferred stock, such holders shall have received an amount per share equal to \$1.38 and \$4.90, respectively, multiplied by the Original Issuance Price per share of preferred stock. Thereafter, if proceeds remain, the holders of the common stock shall receive the remaining proceeds pro rata based on the number of shares of common stock held by each. In any liquidating transaction, if proceeds received by this corporation or its shareholders are other than cash; its value will be deemed its fair market value.

Voting Rights

As long as any shares of Series A and B preferred shares are outstanding, the holders of such shares shall be entitled to each elect one director. The holders of Series A and B preferred and common stock, voting together as a single class, on an as-converted basis, shall be entitled to elect any remaining directors. On all other matters, each holder of Series A and B preferred shares shall have the right to vote for each share of common stock into which such preferred stock could then be converted.

Conversion Rights

Each share of Series A and B preferred stock is convertible, at the option of the shareholder at any time, into shares of common stock, subject to adjustments for certain dilutive events and calculated by dividing the Conversion Price into the per share Conversion Value. The initial per share conversion

Notes to the Financial Statements (Continued)

10. Capital Structure—Convertible Preferred Stock (Continued)

price of the Series A and B preferred stock shall be \$1.38 and \$4.90, respectively. Each share shall automatically convert upon (1) the closing of an underwritten public offering of the Company's common stock which meets certain conditions or (2) the vote or written consent of a majority of the preferred shareholders.

Beneficial Conversion

In connection with the issuance of the Series B Preferred stock on July 24, 2012, the Company recorded a beneficial conversion charge representing the difference between the conversion price and the fair value of the Company's common stock as of the Commitment Date. The intrinsic value was in excess of the proceeds at the commitment date; therefore, the beneficial conversion charge was limited to the proceeds of approximately \$5.0 million.

11. Stock Compensation

Founders' Shares

In connection with the issuance of the Company's Series A convertible preferred stock in November 2009, the Company's founders agreed to modify their common shares outstanding and include, among other things, vesting provisions that require continued service to the Company in order to vest in those shares. As such, the modified shares were presumed to be compensatory upon such modification. The resulting compensation cost is being recognized over the requisite service period. The total compensation cost resulting from the modification is approximately \$907,000 and is being recognized over the four year vesting term. Unrecognized compensation cost is \$189,000 as of December 31, 2012.

A summary of the Company's non-vested restricted stock as of December 31, 2012 and changes during the year ended December 31, 2012 is as follows:

	<u>No. of Shares</u>
Non-Vested Restricted Stock	
Non-vested as of December 31, 2010	2,194,879
Granted	—
Vested	(752,406)
Cancelled	—
Non-vested as of December 31, 2011	1,442,473
Granted	—
Vested	(752,406)
Cancelled	—
Non-vested as of December 31, 2012	690,067

2010 Equity Incentive Plan

In January 2010, the Company adopted the 2010 Equity Incentive Plan (the "2010 Plan"), which provides for the issuance of non-qualified and incentive common stock options to the Company's employees, members of the Company's board of directors and consultants. In general, the options expire ten years from the date of grant and vest over a four-year period, with 25% exercisable at the

Notes to the Financial Statements (Continued)

11. Stock Compensation (Continued)

end of one year from the date of the grant and the balance vesting ratably thereafter. The total number of shares reserved for issuance under the 2010 Plan is 1,188,275 shares as of December 31, 2012.

At December 31, 2011 and December 31, 2012, the Company had 44,250 and 8,369 shares available, respectively, for future grant under the 2010 Plan.

The following table summarizes the Company's stock option activity:

	<u>Common Stock Options</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term (In Years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at December 31, 2010	329,729	\$ 0.42		
Granted	814,296	2.08		
Exercised	—	—		
Canceled/forfeited/expired	—	—		
Outstanding at December 31, 2011	1,144,025	1.60	9.38	
Granted	154,807	11.57		
Exercised	—	—		
Canceled/forfeited/expired	(118,926)	(2.08)		
Outstanding at December 31, 2012	<u>1,179,906</u>	2.86	8.50	\$14,751,529
Vested and expected to vest at December 31, 2012	<u>1,179,906</u>	2.86	8.50	\$14,751,529
Exercisable at December 31, 2012	<u>451,610</u>	1.30	8.13	\$ 6,353,969

The weighted average estimated grant date fair value per share of employee stock options granted during the years ended December 31, 2011 and 2012 was \$1.69 and \$7.97, respectively.

No options were exercised during the years ended December 31, 2011 and 2012. The Company did not recognize any income tax benefits from stock option exercises as the Company continues to record a valuation allowance on its deferred tax assets.

Intrinsic value in the above table was calculated as the difference between the Company's estimated stock price as of December 31, 2012 and the exercise price, multiplied by the number of options.

As of December 31, 2012, total unrecognized compensation cost related to unvested employee stock options was \$1,993,815, which is expected to be recognized over a weighted average period of 2.17 years. The Company expects to recognize \$631,901 in 2013, \$619,969 in 2014 and \$741,845 in 2015 and beyond.

The following table summarizes the weighted average assumptions the Company used in its Black-Scholes calculations:

	<u>Year Ended December 31,</u>	
	<u>2011</u>	<u>2012</u>
Employee stock options:		
Risk-free interest rate	1.97%	0.61%
Expected dividend yield	0.0	0.0
Expected volatility	80.0	80.0
Expected term (years)	6.25	6.25

Notes to the Financial Statements (Continued)

11. Stock Compensation (Continued)

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on comparable companies in the biotechnology and specialty pharmaceutical industries.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historic exercise behavior, Management determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period.

Forfeitures. The Company reduces stock-based compensation expense for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The following table summarizes the allocation of the Company's stock compensation expense:

	Year Ended December 31,	
	2011	2012
Research and development	\$186,006	\$400,100
General and administrative	177,606	323,169
Total	\$363,612	\$723,269

12. Income Taxes

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,	
	2011	2012
Federal income tax (benefit) at statutory rate	34%	34%
State income tax benefit, net of federal benefit	5.00	5.9
Other	0.12	(.3)
Increase to valuation allowance	(39.12)	(39.6)
Effective income tax rate	0.00%	0.00%

Notes to the Financial Statements (Continued)

12. Income Taxes (Continued)

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2011	2012
Deferred tax assets		
Deferred costs	\$ 2,355,649	\$ 3,725,564
Net operating loss carryforward	9,964,904	18,054,241
Stock-based compensation	59,844	238,432
Accrued expenses and other	—	1,246,530
Total deferred tax assets	12,380,397	23,264,767
Valuation allowance	(12,380,397)	(23,264,767)
Net deferred tax assets	\$ —	\$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2011 and 2012.

As of December 31, 2012, the Company has approximately \$45.1 million of federal and state net operating loss carryforwards to offset future taxable income, if any. Such net operating loss carryforwards expire at varying times through the year 2032, if not utilized.

The Internal Revenue Code of 1986, as amended (the "Code") provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the Code) that could limit the Company's ability to utilize these carryforwards. At this time, the Company has not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation, due to the costs and complexities associated with such a study. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financing transactions. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

The Company does not have any significant unrecognized tax benefits.

As of December 31, 2012, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2009 through December 31, 2012 are still subject to examination by major tax jurisdictions.

The Company recorded an increase to the valuation allowance of \$10.9 million during the year ended December 31, 2012.

Notes to the Financial Statements (Continued)

13. Licenses and Supply Agreement

On November 13, 2009, the Company entered into an exclusive worldwide license agreement with Chrysalis. The license provides the Company with patents and know-how to develop and commercialize Epanova for all human indications within a specified field of use with the opportunity to expand the license grant to include additional indications on approval by Chrysalis. Under this agreement, the Company is required to make certain developmental and regulatory milestone payments as well as royalty payments upon commercialization. The potential developmental and regulatory milestones payments to be paid by the Company to Chrysalis that are associated with Epanova and the treatment of patients with very high triglycerides are approximately \$9.5 million. The developmental and regulatory milestones associated with Epanova and the treatment of patients with high triglycerides are approximately \$15.0 million. The developmental and worldwide regulatory milestone payments associated with Epanova and the treatment of atrial fibrillation, heart failure or cardiovascular indications for patients with type II diabetes total approximately \$10.0 million. As of December 31, 2012, approximately \$400,000 was paid by the Company as a result of the successful completion of a development milestone. In addition, the Company accrued \$2.0 million as of December 31, 2012, related to the successful completion of its Phase III clinical trial.

For the first 15 years of commercial sales of Epanova the Company will be required to pay Chrysalis a tiered royalty on net sales of the product for the first 15 years of commercial sales of Epanova that ranges from approximately 7% to up to 12% based on net sales of the product. These royalties are subject to up to a 50% reduction upon certain events relating to the commercialization of competing generic products. This license, unless earlier terminated by mutual consent, shall remain in effect on a country by country basis until expiry of the royalty period.

The Company's rights, with respect to this agreement, to develop and commercialize Epanova may terminate if the Company fails to meet certain development or commercialization requirements.

In March 2012, the Company entered into an agreement with Ocean Nutrition Canada Limited, or ONC, for the supply of bulk fish oil for Epanova. The agreement includes requirements for: (i) a one-time payment of \$1.0 million due to ONC upon completion of FDA inspection of the site; (ii) a one-time payment of \$500,000 due to ONC upon shipment into commerce of the first commercial product; and (iii) the Company to purchase a certain percentage of the Company's bulk fish oil from ONC. The agreement is cancelable by the Company in the event the product does not receive regulatory approval or if the Company abandons commercialization due to market conditions.

In March 2012, the Company entered into an agreement with BioVectra Inc. for the manufacture of the active pharmaceutical ingredient, or API, for Epanova. The agreement includes requirements for: (i) construction of a 100 metric ton facility exclusively for the manufacture of the API for Epanova for an amount not to exceed \$5.0 million (of which the Company has paid approximately \$1.4 million as of December 31, 2012); and (ii) minimum annual purchase commitments. The agreement is cancelable by the Company in the event the product does not receive regulatory approval or if the Company abandons commercialization due to market conditions.

14. Commitments and Contingencies

Operating Leases

The Company leases office space in Princeton, New Jersey under a non-cancelable three-year lease agreement, which is renewable at the option of the Company for up to two additional three-year periods. The Company also leases office space in Bethesda, Maryland under a non-cancelable one year

Notes to the Financial Statements (Continued)

14. Commitments and Contingencies (Continued)

lease. Future minimum rental commitments, by fiscal year and in the aggregate, for the Company's operating leases are provided below:

	<u>December 31, 2012</u>
2013	\$208,238
2014	<u>190,884</u>
Total minimum lease payments	<u>\$399,122</u>

Rental expense for the years ended December 31, 2012 and 2011 was \$181,315 and \$116,300, respectively.

15. Employee Benefit Plan

In 2011, the Company created a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code for its employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the IRS annual limits. The Company matches contributions up to 4% of the eligible employee's compensation or the maximum amount permitted by law. Total expense for contributions made to employees was \$27,900 for the year ended December 31, 2011 and \$106,700 for the year ended December 31, 2012.

16. Subsequent Events

The following events occurred subsequent to December 31, 2012.

Product Supply Agreement

In February 2013, the Company entered into a long-term exclusive agreement for the supply of bulk fish oil and the manufacture of Active Pharmaceutical Ingredient ("API") for Epanova. The agreement is cancellable by the Company in the event Epanova does not receive regulatory approval or if the Company decides not to commercialize Epanova within 12 months post regulatory approval. The Company is obliged to pay certain development fees which are creditable against future purchases of product.

Convertible Promissory Notes and Warrants

In February 2013, the Company issued \$17.6 million of 8% Secured Convertible Promissory Notes (the "Notes") to existing investors and T. Rowe Price for cash. The Notes accrue interest at an annual rate of 8% and mature on February 15, 2014. In the event of Default (as defined in the agreements governing the Notes), the interest rate will be increased from 8% to 15%. The principal balance and all accrued and unpaid interest due on the Notes will be share settled upon the earliest to occur of the following:

- Immediately prior to the closing of a Qualified IPO (as defined below) the Notes shall automatically convert into shares of the Company's common stock at a per share price equal to the price to the public for common stock issued in the Qualified IPO. A "Qualified IPO" is defined as an initial public offering with gross proceeds of at least \$50.0 million to the Company or which has been approved by the Board of Directors including the directors designated by Sofinnova and NEA.

Notes to the Financial Statements (Continued)

16. Subsequent Events (Continued)

- Upon the completion of an equity financing other than a Qualified IPO and at the election of the holders of the Notes, the Notes will convert into shares of the securities issued in the equity financing at the per share price of the securities issued in such equity financing.
- Absence of a Qualified IPO, and at the election of the holders of the Notes, the Notes will convert into Series B convertible preferred stock or into a more recent class of securities issued by the Company.
- Upon voluntary or involuntary liquidation, dissolution or winding up of the Company or a Deemed Liquidation Event (as defined in the Company's certificate of incorporation), and at the election of the holders of the Notes, the Notes will become due and payable at three times the outstanding principal amount or will convert into Series B convertible preferred stock.

In connection with the Notes, the Company issued warrants to purchase shares of its capital stock up to 25% of the principal amount of the Notes divided by the purchase price of the applicable equity securities at an exercise price of \$0.01. The warrants are exercisable upon the earliest occurrence of the events described above and expire on February 15, 2023. The Company intends to account for the Notes as follows: Both the Notes and the related warrants will be treated as liabilities and accounted for at fair value. Upon issuance, interest expense will be recognized for the difference between the combined value of the Notes and warrants and the actual proceeds received. Subsequently, the warrants will be "marked-to-market" at each reporting date with a corresponding charge (credit) recognized in the Company's Statements of Operations.

On March 27, 2013, the Company entered into Amendment No. 9 to the license agreement between the Company and Chrysalis ("Amendment No. 9"). As of December 31, 2012, the Company accrued \$2.0 million related to the achievement of a development milestone based on the Company's receipt of an invoice from Chrysalis for payment to be made in the second quarter of 2013. Amendment No. 9 provides that this \$2.0 million development milestone will now be due and payable upon the initiation of an outcomes study for the reduction of high triglycerides. Because the Company has not initiated an outcomes study and is under no obligation to conduct such a study at this time, the milestone payment is no longer due to Chrysalis and the Company will reduce this liability during the first quarter of 2013.

On March 29, 2013, the Company's board of directors approved a 1-for-1.3953 reverse stock split of the Company's common stock, which the Company effected on April 1, 2013. All share and per share amounts of common stock in the accompanying financial statements have been restated for all periods to give retroactive effect to the stock split. The shares of common stock retained a par value of \$0.001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from "common stock" to "Additional paid-in capital" in an amount equal to the par value of the decreased shares resulting from the reverse stock split.

On March 29, 2013, the Company entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. ("Hercules"), pursuant to which Hercules has agreed to provide the Company with a term loan facility of up to \$12.5 million. The Company may draw down on the facility in two tranches of at least \$5.0 million each commencing on March 29, 2013 and ending September 30, 2013. Under the terms of the loan and security agreement, the term loan will bear interest at a floating yearly rate equal to the higher of either (i) 9.50%, or (ii) the sum of (A) 9.50% plus (B) the prime rate as reported in the Wall Street Journal minus 3.25%. The loan is secured by all of the Company's assets,

Notes to the Financial Statements (Continued)

16. Subsequent Events (Continued)

excluding intellectual property. If the Company borrows any amounts under the facility, it will be required to make interest only payments through the end of 2013, which may be extended to July 1, 2014 if the Company receives, on or before January 1, 2014, net cash proceeds of at least \$50.0 million from the issuance of equity securities or other net upfront payments from investors reasonably acceptable to Hercules (an "Equity Event"). Thereafter, the loan will be repaid in thirty equal monthly installments of principal and interest. All outstanding amounts, including principal and interest, will be due and payable in full on July 1, 2016, which will be extended to January 1, 2017 if the Company completes an Equity Event on or before January 1, 2014. To date, the Company has not borrowed any amounts under the loan facility.

In connection with the loan and security agreement, the Company agreed to issue to Hercules, effective April 1, 2013, a warrant to purchase shares of the Company's common stock initially equal to \$500,000 divided by 80% of the per share price of the common stock to the public in the Company's initial public offering if it completes an initial public offering on or before September 30, 2013, which will increase to \$625,000 divided by 80% of the per share price of the Company's common stock to the public in its initial public offering if it draws down on the term loan facility, at an exercise price equal to 80% of the price per share of the common stock in the initial public offering. If the Company does not complete an initial public offering on or before September 30, 2013, the warrant will be exercisable for shares of its Series B preferred stock or shares of a subsequent class of preferred stock, subject to certain conditions. The warrant will expire upon the earlier of April 1, 2020 or five years after the completion of the Company's initial public offering.

The Company intends to account for the warrant as a liability and account for it at fair value. Subsequently, the warrant will be "marked-to-market" at each reporting date with a corresponding charge (credit) recognized in the Company's Statements of Operations.

Through and including May 6, 2013 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

8,000,000 Shares



Common Stock

PROSPECTUS

BofA Merrill Lynch

Barclays

Leerink Swann

Stifel

Piper Jaffray

April 11, 2013
