U.S. SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file Number: 001-34921

AEGERION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-2960116**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification Number)**

One Main Street, Suite 800, Cambridge, Massachusetts 02142
(Address of Principal Executive Offices, including Zip Code)

617-500-7867
(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Common Stock, $0.001 Par Value	**The NASDAQ Global Select Market**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2014 was approximately $915,210,330, based upon the closing price on the NASDAQ Global Market reported for such date.

As of February 17, 2015, 28,539,381 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2015 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K

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FORM 10-K

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Forward-Looking Statements

All statements included or incorporated by reference into this Annual Report on Form 10-K, or Annual Report, other than statements or characterizations of historical fact, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are often identified by words such as “anticipates,” “expects,” “intends,” “plans,” “predicts,” “believes,” “seeks,” “estimates,” “forecasts,” “may,” “will,” “should,” “would,” “could,” “potential,” “continue,” “ongoing” and similar expressions, and variations or negatives of these words. Examples of forward-looking statements contained in this Annual Report include our statements regarding: the commercial potential for our products; our estimates as to the potential number of patients with the diseases for which our products are approved; our expectations with respect to reimbursement of our products in the United States; our expectations with respect to pricing and reimbursement approvals required for lomitapide in countries of the European Union, Mexico, Canada, and other countries in which we receive, or have received, marketing approval for lomitapide; our expectations with respect to named patient sales of our products in Brazil and in other countries where such sales are permitted; the potential for and possible timing of approval of our products in countries where we have not yet obtained approval; plans for further clinical development of our products; our expectations regarding possible future filings for approval of lomitapide in Japan and for approval of metreleptin in the European Union; our plans for commercial marketing, sales, manufacturing and distribution of our products; our expectations with respect to the impact of competition on our future operations and results; our beliefs with respect to our intellectual property portfolio for our products and the extent to which it protects us; our expectations regarding the availability of data and marketing exclusivity in the United States, the European Union and other countries; our view of ongoing government investigations and stockholder litigation and the possible impact of each on our business; our forecasts regarding sales of our products, our future expenses, our cash position and the timing of any future need for additional capital to fund operations; and our plans to acquire rights to one or more product candidates.

The forward-looking statements contained in this Annual Report and in the documents incorporated into this Annual Report by reference are based on our current beliefs and assumptions with respect to future events, all of which are subject to change. Forward-looking statements are not guarantees of future performance, and are subject to risks, uncertainties and assumptions that are difficult to predict, including those discussed in “Risk Factors” in Part I, Item 1A of this Annual Report. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors may impact our operations or results. New risks may emerge from time to time. Past financial or operating performance is not necessarily a reliable indicator of future performance. Given these risks and uncertainties, we can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them does occur or, alternatively, if any of the events described as a risk were to occur, what impact such event will have on our results of operations and financial condition. Our actual results could differ materially and adversely from those expressed in any forward-looking statement in this Annual Report or in our other filings with the Securities and Exchange Commission.

Except as required by law, we undertake no obligation to revise our forward-looking statements to reflect events or circumstances that arise after the date of this Annual Report or the respective dates of documents incorporated into this Annual Report by reference that include forward-looking statements. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in these forward-looking statements.

In this Annual Report, “Aegerion Pharmaceuticals, Inc.,” “Aegerion,” the “Company,” “we,” “us” and “our” refer to Aegerion Pharmaceuticals, Inc. taken as a whole, unless otherwise noted.

Trademarks

Aegerion, JUXTAPID, LOJUXTA and MYALEPT are trademarks of Aegerion. All other trademarks referenced in this Form 10-K are the property of their respective owners.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company dedicated to the development and commercialization of innovative therapies for patients with debilitating rare diseases.

Our first product, lomitapide, received marketing approval, under the brand name JUXTAPID ® (lomitapide) capsules ("JUXTAPID"), from the U.S. Food and Drug Administration ("FDA") in late December 2012, as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein ("LDL") apheresis where available, to reduce low-density lipoprotein cholesterol ("LDL-C"), total cholesterol ("TC"), apolipoprotein B ("apo B") and non-high-density lipoprotein cholesterol ("non-HDL-C") in adult patients with homozygous familial hypercholesterolemia ("HoFH"). We launched JUXTAPID in the U.S. in late January 2013. In July 2013, we received marketing authorization for lomitapide in the European Union ("EU"), under the brand name LOJUXTA ® (lomitapide) hard capsules ("LOJUXTA"), as a treatment for HoFH in adults. Lomitapide is also approved for the treatment of HoFH in Mexico, Canada, and a small number of other countries. We sell lomitapide, on a named patient basis, in Brazil and in a limited number of other countries outside the U.S. where a mechanism exists based on the U.S. or the EU approval.

We acquired our second product, metreleptin, in January 2015, pursuant to an asset purchase agreement (the "Asset Purchase Agreement") dated November 5, 2014 with Amylin Pharmaceuticals, LLC ("Amylin") and AstraZeneca Pharmaceuticals LP, an affiliate of Amylin (together referred to as "AstraZeneca"). Metreleptin, a recombinant analog of human leptin, is currently marketed in the U.S. under the brand name MYALEPT ® (metreleptin) for injection ("MYALEPT"). MYALEPT received marketing approval from the FDA in February 2014 as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy ("GL"). Under the terms of the Asset Purchase Agreement, we paid AstraZeneca $325.0 million to acquire the global rights to develop, manufacture and commercialize metreleptin, subject to an existing distributor license with Shionogi & Co., Ltd. ("Shionogi") covering Japan, South Korea and Taiwan. The distribution agreement with Shionogi was assigned to us as part of the transaction. We also assumed certain other assets and liabilities of AstraZeneca related to the metreleptin program.

We expect that our near-term efforts will be focused on:

- maintaining market acceptance of JUXTAPID as a treatment for adult HoFH patients in the U.S., particularly in light of the anticipated introduction of competitive products, and continuing to support named patient sales of lomitapide as a treatment for HoFH in Brazil and in other key countries where such sales are permitted;
- building and maintaining market acceptance for MYALEPT in the U.S. for the treatment of complications of leptin deficiency in GL patients, and initiating named patient sales of metreleptin in GL in Brazil and other key countries where such sales are permitted as a result of the U.S. approval;
- gaining pricing and reimbursement approvals for lomitapide in key EU markets, Mexico, and Canada;
- gaining regulatory and pricing and reimbursement approvals to market our products in key countries in which the products are not currently approved, including filing a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA") seeking marketing approval of metreleptin in the EU as a treatment for complications of leptin deficiency in GL patients, and, if approved, commencing commercialization efforts in those markets where it makes commercial sense to do so;
- minimizing the number of patients who are eligible to receive but decide not to commence treatment with our products or who discontinue treatment, including with lomitapide, due to tolerability issues and with metreleptin, due to its route of administration, as an injection, through activities such as patient support programs, to the extent permitted in a particular country;

- clinical development activities to support a potential marketing authorization application for lomitapide in HoFH in Japan, and in support of our planned clinical study of lomitapide in pediatric HoFH patients;
- evaluating the potential for future clinical development of metreleptin in additional indications; and
- assessment, and possible acquisition, of potential new product opportunities targeted at rare diseases where we believe we can leverage our infrastructure and expertise.

Prior to 2015, we generated revenues solely from sales of lomitapide. In the near-term, we expect that the majority of our revenues will continue to be derived from sales of our products in the U.S. We also expect to generate revenues from sales of lomitapide in those countries outside the U.S. in which we have or receive marketing approval, and are able to obtain pricing and reimbursement approval at acceptable levels, and from sales of both our products in a limited number of other countries where they are, or may in the future be, available on a named patient sale basis as a result of existing approvals. We expect that named patient sales of lomitapide in Brazil in the near term will continue to be our second largest source of revenues for lomitapide, on a country-by-country basis. We expect to begin generating revenues from named patient sales of metreleptin in Brazil based on U.S. approval in the second half of 2015. We expect net product sales from named patient sales to fluctuate quarter-over-quarter significantly more than sales in the U.S. In some countries, including Brazil, orders for named patient sales are for multiple months of therapy which can lead to an unevenness in orders. In addition, net product sales from named patient sales may fluctuate quarter-over-quarter as a result of government actions, economic pressures and political unrest. For example, with respect to named patient sales of lomitapide in Brazil in 2014, we experienced longer than expected turn-around times between price quotation and order at the federal level, and delays in receipt of orders from the state government of São Paolo as a result of an ongoing São Paolo investigation focused on determining whether there has been any violation of Brazilian anti-corruption laws in connection with prescriptions written for lomitapide in São Paolo. A similar investigation has also been initiated by the federal government in Brazil.

We have submitted documentation seeking pricing and reimbursement approvals for lomitapide from governmental authorities in key markets of the EU, and are seeking such approvals from governmental authorities, social funds and private payers in Mexico and Canada. We anticipate reimbursement decisions in some of those countries in 2015. In March 2014, the reimbursement authority in Germany, the G-BA (Gemeinsamer Bundesausschuss) deemed our dossier for LOJUXTA to be incomplete as a result of certain technical deficiencies. As a result of the technical deficiencies, LOJUXTA was automatically put into the category of “no additional benefit” under the G-BA process, without a review of the clinical merits, which limits the reimbursement level significantly. After the G-BA assessment, we withdrew LOJUXTA from the German market in July 2014. We intend to re-file our dossier for LOJUXTA in June 2015, which we expect would result in an assessment by the G-BA in late 2015.

During the year ended December 31, 2014, we generated approximately $158.4 million of revenues from net product sales of lomitapide, of which $143.4 million was derived from prescriptions for lomitapide written in the U.S., and $15.0 million was derived from prescriptions for lomitapide written outside the U.S., primarily in Brazil. We did not generate revenues from sales of metreleptin in the year ended December 31, 2014, as we had not yet completed acquisition of the product from AstraZeneca. As of December 31, 2014, we had approximately $375.9 million in cash, cash equivalents and marketable securities on hand, of which $325.0 million was used to acquire MYALEPT in January 2015.

HoFH

HoFH is a serious, rare genetic disease that impairs the function of the receptor responsible for removing LDL-C (“bad” cholesterol) from the blood. An impairment of low density lipoprotein receptor (“LDL-R”) function results in significant elevation of blood cholesterol levels.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.