

SYNAGEVA BIOPHARMA CORP

Form 425

May 06, 2015

Alexion: Global Leader in Rare Diseases Filed by Alexion Pharmaceuticals, , Inc. Pursuant to Rule 425 Under the Securities Act of 1933 and deemed filed pursuant to Rule 14d - 2 of the Securities Exchange Act of 1934 Subject Company: Synageva BioPharma Corp. Commission File No.: 0 - 23155

2 This communication includes statements that may be forward - looking statements. The words “believe,” “expect,” “anticipate,” “project” and similar expressions, among others, generally identify forward - looking statements. Alexion and Synageva caution that these forward - looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward - looking statements. Such risks and uncertainties include, but are not limited to, the likelihood that the transaction is consummated on a timely basis or at all, including whether the conditions required to complete the transaction will be met, realization of the expected benefits of the transaction, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action and changes to laws and regulations applicable to our industry, status of our ongoing clinical trials, commencement dates for new clinical trials, clinical trial results, decisions and the timing of decisions of regulatory authorities regarding marketing approval or material limitations on the marketing of our approved products or any future approved products, delays or interruptions in manufacturing or commercial operations including due to actions of regulatory authorities or otherwise, the possibility that results of clinical trials in approved and investigational indications are not predictive of safety and efficacy in broader patient populations, the adequacy of our pharmacovigilance and drug safety reporting processes, the risk that acquisitions will not result in the anticipated clinical milestones or long - term commercial results, the risk that initial results of commercialization in approved indications are not predictive of future performance, risks involving the ability to license necessary intellectual property on reasonable terms or at all, the risk that third party payors, public or private, will not reimburse for the use of Soliris, Strensiq (asfotase alfa) or Kanuma (sebelipase alfa), or any future products at acceptable rates or at all, risks regarding estimates of the ultimate size of various patient populations, risks relating to foreign currency fluctuations, exposures to additional tax liabilities, and a variety of other risks. Additional information about the economic, competitive, governmental, technological and other factors that may affect the companies’ operations is set forth, in the case of Alexion, in Item 1.A, “Risk Factors,” in Alexion’s Quarterly Report on Form 10 - Q for the quarter ended March 31, 2015, which has been filed with the Securities and Exchange Commission (the “SEC”) and, in the case of Synageva, in Item 1.A, “Risk Factors,” in Synageva’s Quarterly Report on Form 10 - Q for the quarter ended March 31, 2015, which has been filed with the SEC. Neither Alexion nor Synageva undertakes any obligation to release publicly any revisions to forward - looking statements as a result of subsequent events or developments, except as required by law. Additional Information and Where to Find It The exchange offer referenced in this communication has not yet commenced, and no proxies are yet being solicited. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares, nor is it a substitute for any materials that Alexion and its offering subsidiary, Galaxy Merger Sub Inc. (“Offeror”), will file with the SEC. Forward - Looking Statements

3 Offeror plans to file a tender offer statement on Schedule TO, together with other related exchange offer documents, including a letter of transmittal, in connection with the offer; Synageva plans to file a Solicitation/Recommendation Statement on Schedule 14D - 9 in connection with the offer; and Alexion plans to file a registration statement on Form S - 4 that will serve as a prospectus for Alexion shares to be issued as consideration in the offer and merger. If the offer is successfully completed, the remaining shares of Synageva will be purchased by Alexion in a second - step merger and, in accordance with applicable law, no vote by the Synageva stockholders will be required. Under certain circumstances described in the definitive transaction documents, the parties may determine to instead to terminate the offer and effect the transaction through a merger only, in which case the relevant documents to be filed with the SEC will include a separate registration statement on Form S - 4 filed by Alexion that will serve as a prospectus for Alexion shares to be issued as consideration in the merger and as a proxy statement for the solicitation of votes of Synageva stockholders to approve the merger. **IN EITHER CASE, THESE DOCUMENTS WILL CONTAIN IMPORTANT INFORMATION ABOUT ALEXION, SYNAGEVA AND THE TRANSACTIONS. SYNAGEVA STOCKHOLDERS ARE URGED TO READ THESE DOCUMENTS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BEFORE MAKING ANY DECISION REGARDING EXCHANGING THEIR SHARES OR, IF NECESSARY, VOTING ON THE TRANSACTION.** These documents will be made available to Synageva stockholders at no expense to them and will also be available for free at the SEC's website at www.sec.gov. Additional copies may be obtained for free by contacting Alexion's investor relations department at 203 - 699 - 7722 or Synageva's investor relations department at 781 - 357 - 9947. In addition to the SEC filings made in connection with the transaction, each of Alexion and Synageva files annual, quarterly and current reports and other information with the SEC. You may read and copy any reports or other such filed information at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1 - 800 - SEC - 0330 for further information on the public reference room. Alexion's and Synageva's filings with the SEC are also available to the public from commercial document - retrieval services and at the website maintained by the SEC at <http://www.sec.gov>. If the exchange offer is terminated and the parties seek to effect the transaction by merger only, in which case, the approval of Synageva stockholders must be obtained, Alexion, Synageva and their respective directors and executive officers may be deemed to be participants in any such solicitation of proxies from Synageva's stockholders in connection with the proposed transaction. Information regarding Alexion's directors and executive officers is available in its proxy statement for its 2015 annual meeting of stockholders, which was filed with the SEC on April 8, 2015; information regarding Synageva's directors and executive officers is available in its proxy statement for its 2015 annual meeting of stockholders, which was filed with the SEC on April 28, 2015. Other information regarding potential participants in any such proxy solicitation will be contained in any proxy statement filed in connection with the transaction. Forward - Looking Statements

4 Our Exclusive Focus : Treating Patients with Devastating and Rare Diseases Alexion is focused on developing life - transforming treatments for patients with devastating and rare diseases 4 Severe Life - Threatening No Effective Treatments Transformative Clinical Benefit Devastating

5 Alexion: Global Leader in Rare Diseases • Kanuma (sebelipase alfa) for LAL Deficiency aligns with our exclusive focus on bringing transformative therapies to patients suffering from under - diagnosed , devastating and rare diseases, such as PNH, aHUS and HPP Exclusive Focus on Life - Transforming Therapies • Establishes the premier metabolic rare disease franchise, with the anticipated launches of Strensiq and Kanuma in 2015 • Launch two transformative therapies with a single metabolic sales force Premier Metabolic Franchise • Creates the most robust rare disease pipeline, including eight highly innovative product candidates in the clinic for 11 indications, with at least four additional innovative programs to enter the clinic in 2016 Robust Rare Disease Pipeline • Accelerates and diversifies revenue from a growing \$2.55B - \$ 2.60B* revenue base; Achieves annual cost synergies starting this year and growing to at least \$150M in 2017; Accretive to non - GAAP EPS in 2018 Growth & Diversification Acquisition of Synageva Strengthens Alexion's Global Leadership in Developing & Commercializing Transformative Therapies for Patients with Devastating and Rare Diseases *Alexion's 2015 revenue guidance as of 4/23/2015

6 Transaction Details • Total consideration of approximately \$230 per share, based on the 9 day volume - weighted average closing price of Alexion stock through May 5, 2015 \$ 115.00 in cash and 0.6581 shares of Alexion common stock for each Synageva share Total stock issuance of 26.2 million shares; stock component tax - free to Synageva shareholders • Total transaction value of approximately \$8.4 billion, net of cash Consideration • Accelerates and diversifies revenue growth • Achieves annual cost synergies starting this year and growing to at least \$150M in 2017 • Accretive to non - GAAP EPS in 2018 Financial Benefits Financing • Felix Baker, Ph.D., Chairman of Synageva, to join Alexion's Board of Directors, upon closing of the transaction • Closing expected in mid - 2015 Other • Combination of cash on hand and committed financing from Bank of America Merrill Lynch and J.P. Morgan

7 Synageva BioPharma: Ideal Strategic and Operational Fit • Patient - centric culture • Focus on discovering, developing and delivering medicines for patients with rare and devastating diseases Exclusive Focus on Rare Diseases

- Kanuma under review for the treatment of patients with LAL Deficiency • U.S. BLA accepted under priority review, with Breakthrough Therapy Designation for infants, and MAA validated and granted accelerated assessment in Europe
- Planned launches in the U.S. and Europe in 2015 Late Stage Metabolic Product Innovative Early Stage Pipeline
- SBC - 103, an enzyme replacement therapy (ERT), in Phase 1/2 for patients with mucopolysaccharidosis IIIB (MPS IIIB) with data expected in 2H15
- SBC - 105, an ERT in preclinical development for disorders of calcification
- 12 additional preclinical programs

8 Synageva's Pipeline to Strengthen and Broaden Alexion's Clinical and Preclinical Portfolio Source: Synageva Investor Presentation, April 2015 • Pipeline of rare disease assets • Highly innovative late - stage product, Kanuma (sebelipase alfa) • Expression platform to develop novel and next generation biologics

9 • Caused by mutations affecting the LIPA gene resulting in a deficiency of lysosomal acid lipase (LAL) activity • Characterized by the accumulation of cholesteryl esters and triglycerides in lysosomes in cells throughout the body leading to severe complications including fibrosis, cirrhosis, liver failure, splenomegaly, growth failure and death • Genetic rare metabolic disease that leads to progressive and life - threatening organ damage » Infants experience profound growth failure, liver fibrosis, cirrhosis and with a median age of death 3.7 months 1 » Approx. 50 % of children and adults with LAL - D progress to fibrosis, cirrhosis, liver transplant or death in 3 years 2 • No existing therapies • Median Age of Onset: 5.8 years 3 • Prevalence: 8 to 12 per million 4,5 Understanding Devastating Diseases: What We Know Well and Do Well Estimate of Disease Progression to Fibrosis, Cirrhosis, Liver Transplant, or Death through Year 3 in Patients who Underwent Liver Biopsy* 1. Jones S, et al. Poster presented at: Lysosomal Disease Network WORLD Symposium; February, 2014 ; 2. Based on modeling using the subset of 31 patients (≥ 5 years) in Natural History Study LAL2 - NH01 who had a liver biopsy performed during their medical care plus 1 patient without a biopsy who received a liver transplant; An important source of selection bias in this analysis is that patients who were selected by their clinician for liver biopsy would be expected to have more evidence of disease progression than the overall population of patients with CESD . 3. Quinn , A. et al. WORLDSymposium February, 2014; 4 . Scott, S.A., et al . Hepatology. 2013 Sept: 58(3) 958 - 965; 5. Muntoni, S., et al. ATVB. 2007; 27: 1866 - 1868; Lysosomal Acid Lipase Deficiency (LAL - D) Population shown (n=21) are subjects who did not undergo hematopoietic stem cell transplant (HSCT) or liver transplant. Patients had growth failure within 6 months of life Median age at death: 3.7 months Kaplan - Meier Estimate: Survival in Infants with LAL - D with Growth Failure Estimate of Disease Progression to Fibrosis, Cirrhosis, Liver Transplant or Death through Year 3 in Patients who Underwent Liver Biopsy 2

10 LAL - D is an Ideal Fit for Alexion's Exclusive Focus on Treating Patients with Devastating and Rare Diseases
Sources: Hillmen P, Lewis SM, Bessler M et al. N Engl J Med. 1995; 333:1253 - 1258; Caprioli, J., et al. Blood. 2006; 108:1267 - 1279; Whyte et al. Poster presented at the 2014 PAS Meeting, May, 2014; Jones S., et al. Poster presented at: Lysosomal Disease Network WORLD Symposium; February, 2014. PNH aHUS HPP LAL - D Overall Survival of 27% at 4 Years Natural History of Patients with Infantile - Onset HPP Survival of PNH Patients Compared to Controls Significant Morbidities and Mortality in aHUS Patients within 1 Year Despite PE/PI Population shown (n=21) are subjects who did not undergo hematopoietic stem cell transplant (HSCT) or liver transplant. Patients had growth failure within 6 months of life Median age at death: 3.7 months Kaplan - Meier Estimate: Survival in Infants with LAL - D with Growth Failure

11 Kanuma: An Investigational Treatment for Patients Suffering From LAL - D • ALT Normalization » 31% of sebelipase alfa patients vs. 7% of placebo patients (p=0.027) • AST Normalization » 42% of sebelipase alfa patients vs. 3% of placebo patients (p<0.001) • Relative Reduction in LDL - C » Mean reduction of 28 % in sebelipase alfa patients vs. 6 % in placebo patients (p<0.001) • Relative Reduction in Hepatic Fat Fraction » Mean reduction of 32% in sebelipase alfa patients vs. 4% in placebo patients (p<0.001) • Reduction in Liver Volume » Mean reduction of 10.3% in sebelipase alfa patients vs. 2.7% in placebo patients (p=0.007) • Most common AEs were headache, pyrexia, oropharyngeal pain and nasopharyngitis • Most common SAEs related to sebelipase alfa were infusion reaction (2.8%, 1 patient) Phase 3 ARISE Study in Children & Adults with LAL - D (N = 66) • Six infants met the primary endpoint of survival at 12 months of age » Median age of death for infants diagnosed and untreated with LAL Deficiency is 3.7 months [1.4 – 46.3 months] • Patients also experienced improved weight gain, reductions in hepatosplenomegaly and improvement in gastrointestinal symptoms • SAEs were mainly related to central line infections for hospitalization for treatment with antibiotics Ongoing Phase 2/3 Trial in Infants with LAL - D (N = 10) • U.S . BLA accepted under priority review, with Breakthrough Therapy Designation in infants • MAA validated and granted accelerated assessment • Preparing for launches in U.S . and Europe in 2015 Regulatory & Launch Timelines Sources: Quinn, A. G., et al. Poster presented at the AASLD Annual Meeting, November, 2014; Jones, S.A., et al. Poster presented at the NASPGHAN Annual Meeting, October, 2014.

12 Kanuma, an Investigational Treatment for LAL - D, is Aligned with Alexion's Portfolio of Life - Transforming Therapies Sources: Hill A et al. Presented at the Annual ASH Meeting December, 2012; Johnson et al. Presented at ERA - EDTA Congress , May, 2014; Licht C et al. ASH 2012. Poster 985; Whyte MP, et al. ASBMR , 2014; Poster presented at: Lysosomal Disease Network WORLD Symposium; February, 2014; Jones, S.A., et al. Poster presented at the NASPGHAN Annual Meeting, October, 2014. PNH aHUS HPP LAL - D Kaplan - Meier Plot of Survival, N = 9 Improved Survival with Sebelipase Alfa Treatment from Birth to 12 Months of Age: Primary Efficacy Set *Survival after 10 - years is slightly inferior to controls with causes of death related to bone marrow failure and not hemolysis or thrombosis . Patients with PNH on Soliris Compared with Healthy Age - and Gender - Matched Controls Time to Death for Patients with aHUS Treated with Soliris (Kaplan - Meier Estimation) C 08 - 002 , C 08 - 003 , C 10 - 003 , C 10 - 004 , N= 100 ; Intent to Treat Population Improved Survival with Asfotase Alfa Treatment in Pediatric Patients with HPP at High Risk of Death N = 48 Historical Controls, N = 37 Treated Patients

13 Alexion's Proven Track Record in Identifying Patients with Underdiagnosed, Devastating and Rare Diseases PNH
Annual Newly Identified PNH Patients in Core Markets Alexion's PNH diagnostic initiatives have enabled the company to identify a similar number of new PNH patients annually since the Soliris launch in the US, Europe and Japan * Launch of Soliris in Japan

14 Alexion's PNH and aHUS Diagnostic Expertise will be Leveraged for Our HPP and LAL - D Patient Identification Initiatives PNH aHUS HPP LAL - D Driving Diagnosis Across Multiple Rare Diseases Soliris for PNH Soliris for aHUS Hematology & Nephrology Franchise Strensiq for HPP Kanuma for LAL - D Metabolic Franchise

15 Alexion to Maximize Synageva's Value, Leveraging Our Expertise Across Our 50 - Country Platform • Leverage our 50 - country platform and expand Alexion's metabolic franchise to launch Kanuma • Utilize Alexion's global regulatory expertise to secure approvals in all key markets • Secure worldwide reimbursement and create access for patients Global Platform • Build on Synageva's momentum of disease awareness and patient identification globally • Apply Alexion's leadership in disease education and diagnostic initiatives to ensure that patients are rapidly and accurately diagnosed Disease Education & Diagnostic Initiatives • Support through Alexion's OneSource dedicated nurse case managers • Patient disease education and symptom monitoring support • Assistance with access to therapy, including uninsured and underinsured patients Patient & Caregiver Support

16 Following Approval, Kanuma will Further Accelerate and Diversify Our Strong, Consistently Growing Revenues Across Our 50 - Country Platform Revenues in 2016 – 2020 are illustrative and should not be taken as guidance * \$2,146M excludes ~\$88M in prior years' sales in France ; ‡ Midpoint of FY15 guidance range PNH aHUS HPP LAL - D Lenny wants following approval 541 783 1,134 1,551 2,575 2010 2011 2012 2013 2014 2015E 2016E 2017E 2018E 2019E 2020E MILLIONS (\$) Revenue 2,146 * 2,550 - 2,600 ‡

17 METABOLIC FRANCHISE Anticipated Launches in 2015 PRECLINICAL CLINICAL DEVELOPMENT
REGISTRATION FILINGS Alexion Program Synageva Program cPMP MoCD Type A Strensiq HPP Asfotase Alfa
NF - 1 SBC - 105 GACI/Other Undisclosed Preclinical #6 SBC - 103 MPSIIIB mRNA Therapies #1 Kanuma LAL -
D Undisclosed Preclinical #1 Undisclosed Preclinical #2 mRNA Therapies #2 Undisclosed Preclinical #3 mRNA
Therapies #3 Undisclosed Preclinical #5 mRNA Therapies #5 Undisclosed Preclinical #4 mRNA Therapies #4 mRNA
Therapies #6

18 Creating the Most Robust Rare Disease Pipeline in Biotech PRECLINICAL EARLY CLINICAL DEVELOPMENT ADVANCED CLINICAL DEVELOPMENT REGISTRATION FILINGS MARKETED Soliris Next Gen Inflammatory Metabolic Undisclosed Synageva Complement Inhibition Soliris DGF ALXN1007 APS Complement Inhibitor (4) ALXN5500 SBC - 105 GACI/ Other Other Preclinical (10) Soliris AMR ALXN1210 Other Preclinical (5) Soliris Relapsing NMO Soliris aHUS ALXN1007 GI - GVHD mRNA Therapies (7) Kanuma LAL Deficiency Soliris Refractory MG Soliris PNH cPMP MoCD Type A Strensiq HPP Asfotase Alfa NF - 1 SBC - 103 MPSIIIB SBC - 106 SBC - 342

19 • Strengthens Alexion's global leadership in developing and commercializing therapies for patients with devastating and rare diseases • Expands Alexion's metabolic franchise with the addition of Kanuma for patients with LAL - D • Launches of Kanuma and Strensiq expected in 2015 • Creates the most robust rare disease pipeline in biotech; adds SBC - 103 to Alexion's clinical development programs • Combined pipeline to have eight highly innovative product candidates in the clinic for 11 indications, with at least four additional highly innovative programs to enter the clinic in 2016 • Accelerates and diversifies Alexion's growing revenues • Accretive to non - GAAP EPS in 2018 19 Alexion: Global Leader in Rare Diseases

