SYNAGEVA BIOPHARMA CORP
Form 425
May 11, 2015

Global Town Hall David Hallal Chief Executive Officer, Alexion May 11, 2015 Filed by Alexion Pharmaceuticals, Inc. Pursuant to Rule 425 Under the Securities Act of 1933 and deemed filed pursuant to Rule 14a - 12 of the Securities Exchange Act of 1934 Subject Company: Synageva BioPharma Corp. Commission File No.: 0 - 23155 T he following presentation was given to employees of Alexion Pharmaceuticals Inc. and made available to them on the company's internal website.

2 • Exclusive focus on life - transforming therapies for patients with devastating, life - threatening disorders • Continued steady growth of Soliris ® (eculizumab) in both PNH and aHUS across geographies worldwide • Preparing for 2015 launch of next product, Strensiq for the treatment of patients with hypophosphatasia • Robust pipeline with potential for up to 7 new indications or product approvals through 2018 • Global leadership in complement science to serve patients through the next two decades • A strong foundation for future growth with an additional 17 pre - clinical development programs spanning diverse modalities and therapeutic areas • A balance sheet aligned with our strong growth objectives 2

3 Fast Facts: Who We Are • Global, fully integrated biopharmaceutical company • Serving patients with devastating and rare diseases • Established in 1992 • First product approval in 2007 (Soliris® for PNH) • More than 2,500 employees worldwide • Platform to serve patients in 50 countries • U.S. public company (NASDAQ: ALXN)

4 Sydney, Australia Asia - Pacific Regional HQ Country Operations Mumbai , India Global Business Services Shanghai, China Country Operations Tokyo, Japan Japan Regional HQ Country Operations Toronto, Canada Country Operations Cambridge, MA Translational Medicine Group Cheshire, CT Global Headquarters North America Regional HQ Smithfield, RI Manufacturing Operations Washington DC Global Government Affairs Stockholm, Sweden Nordic Country Operations Barcelona, Spain Country Operations Milan, Italy Country Operations Munich, Germany Country Operations Paris, France European Service Center Country Operations Brussels, Belgium Government Affairs, EMEA Country Operations London, UK Country Operations Dublin, Ireland Global Supply Chain and Distribution Buenos Aires, Argentina Country Operations São Paulo, Brazil Country Operations Mexico City, Mexico Country Operations Bogotá, Colombia Country Operations Miami, FL Latin America Regional HQ Dubai, UAE Middle East Operations Country Operations Moscow, Russia Country Operations Lausanne, Switzerland EMEA Operations Center Country Operations Istanbul, Turkey Country Operations Our Global Footprint ~ 2,500 dedicated employees serving patients in 50 countries Osaka, Japan Country Operations

5 * $2,1465M excludes ~$88M in prior years' sales in France ; ‡ Midpoint of guidance range Growth in PNH and aHUS markets drives increasing operating and financial leverage * $4.84 excludes $0.37/sh in non - GAAP EPS related to ~$88M in prior years' sales in France ; ‡ Midpoint of guidance range † EPS has been restated for historical stock splits 541 783 1,134 1,551 2,575 0 500 1,000 1,500 2,000 2,500 3,000 2010 2011 2012 2013 2014 2015E MIILLIONS ($) Revenue 2,146 * 2,550 - 2,600 ‡ Non - GAAP EPS 0.89 1.38 2.13 3.08 0.00 1.00 2.00 3.00 4.00 5.00 6.00 2010 2011 2012 2013 2014 2015E EARNINGS PER SHARE ($) 5.60 - 5.80 ‡ 4.84*

6 Soliris (eculizumab) Anti - C5 Antibody PRECLINICAL EARLY CLINICAL DEVELOPMENT ADVANCED CLINICAL DEVELOPMENT REGISTRATION FILINGS Refractory Myasthenia Gravis (MG) Antibody - Mediated Rejection (AMR) Delayed Graft Function (DGF) ALXN1210 METABOLIC DISORDERS INFLAMMATORY DISORDERS GI - GVHD ALXN1007 Anti - C5a Antibody Strensiq Hypophosphatasia (HPP) MoCD Type A cPMP Replacement Therapy (ALXN1101) APS mRNA Therapeutics Other Preclinical PRECLINICAL MoCD: Molybdenum Cofactor Deficiency Type A APS: Antiphospholipid Syndrome GI - GVHD: Gastrointestinal Graft versus Host Disease ALXN5500 6 Next Generation Portfolio KIDNEY TRANPLANT, NEUROLOGY Relapsing Neuromyelitis Optica (NMO) Add NF1

Soliris in PNH and aHUS Life - Transforming Impact for Patients 7

8 What is PNH? PNH is an acquired and ultra - rare genetic complement inhibitor deficiency disorder affecting blood cells • Defined by presence of hemolysis (destruction of RBCs by uncontrolled complement activation) • Patients suffer progressive disease burden, vital organ failure and/or thrombosis • Approximately 35% of patients die within 5 years of diagnosis without Soliris 1,2 • Soliris is the only approved treatment for PNH *Includes renal disease stabilization or improvement, disease progression observed with placebo over time (1) Hillmen P, Lewis SM, Bessler M, et al. N Engl J Med. 1995; 333: 1253 - 1258; (2) Kelly R, Hill A, Arnold L, et al. Blood. 2011 ; 117: 6786 - 6792; (3) Hillmen P, Muus, P, Roth A, et al. Br J Haematol. Jul 2013; 162(1): 62 - 73. Soliris 3 - year survival estimate of 98% sustained for over 5 years 3 100 86 73 78 95 50 92 0 20 40 60 80 100 Objective Response [Hemolysis] Reduction in LDH Anemia Transfusion Fatigue/QoL Renal Disease Pulmonary Hypertension Thrombosis IMPROVEMENT (%) Observed Impact of Soliris ® on Consequences of Hemolysis *

9 9 9 » Deploying field - based medical teams in US, Europe and Japan; hiring our in - country metabolic commercial teams » Leveraging PNH and aHUS learnings to best serve patients with HPP » Initial market research suggests that low disease awareness typically results in missed diagnoses Region Regulatory Submission Status Estimated Approval Timing US Accepted Priority Review Granted 2H 2015 EU Validated 2H 2015 Japan Submitted Mid 2015 ROW Ongoing 2016+

10 Globally, the majority of patients with PNH have yet to commence appropriate therapy Significant opportunity to increase penetration across geographies including the U.S., Europe and Japan as well as more recently launched territories Disease awareness and diagnostic initiatives continue to result in improved patient care 10 Paroxysmal Nocturnal Hemoglobinuria (PNH) The majority of patients have yet to receive an accurate diagnosis * Launch of Soliris in Japan 8 years into launch, we continue to identify a consistent number of new PNH patients annually Annual Newly Identified PNH Patients in Core Markets

11 What is aHUS? aHUS is a genetic, ultra - rare complement inhibitor deficiency disorder affecting children & adults • Leads to clotting in small blood vessels throughout the body (systemic TMA) • Causes progressive & sudden damage to vital organs, resulting in stroke, heart attack and renal failure • >50% of patients die, have kidney failure requiring dialysis or permanent renal damage within 1 year of diagnosis without Soliris 1,2 • Soliris is the only approved treatment for aHUS Eculizumab produces a substantial gain in quality - adjusted life of a magnitude rarely seen for any new drug treatment – NICE ECD 3 (1) Caprioli J, Noris M, Brioschi S, et al. Blood. 2006; 108: 1267 - 1279; (2) Noris M and Remuzzi G. Nat Rev Neph. 2014; 10: 174 - 180. (3) National Institute for Health and Clinical Excellence (NICE) Evaluation Consultation Document (ECD) 100 87 88 100 59 80 0 20 40 60 80 100 Objective Response Platelet Count Normalization TMA Event-Free PE/PI Reduced Significantly Improved Kidney Function Eliminated Dialysis IMPROVEMENT (%) Objective Response Platelet Count Normalization TMA Event - Free Status PE/PI Reduced Significantly Improved Kidney Function Eliminated Dialysis Observed Impact of Soliris ® on TMA and Patient Morbidities

12 12 Atypical Hemolytic Uremic Syndrome (aHUS) Market Opportunity is Larger than PNH In the U.S. 14 quarters post approval, there are more patients with aHUS actively receiving Soliris Matched for time since their respective approvals, more patients in the U.S. are currently receiving Soliris for aHUS than there had been for PNH Launch trend in Europe is the same 3 years post launch Incidence of aHUS appears greater than the incidence of PNH U.S. and E.U. labels strengthened U.S. Patients on Soliris U.S. Patients Actively Treated on Soliris 14 Quarters from FDA Approval PNH aHUS

Beyond PNH & aHUS Growing Our Portfolio with New Soliris Indications and Other Highly Innovative Products 13

14 Genetic and often life - threatening ultra - rare metabolic disease Caused by mutations in the gene for tissue non - specific alkaline phosphatase (TNSALP) Accumulation of metabolic substrates results in the following: • Prevention of effective bone formation, leading to bone destruction and deformation • Profound muscle weakness • Seizures • Impaired renal function • Respiratory failure Approximately 70% of infants and young children die within 3 years 1 Strong clinical data support the transformative role of Strensiq * Image: Whyte et al NEJM, 2012 Baseline Week 24 * Asfotase alfa is not approved for the treatment of patients with hypophosphatasia (1) White M, Rockman - Greenberg C, Hofmann C, et al. Improved Survival with Strensiq Treatment in Pediatric Patients with Hypophosphatasia at High Risk of Death; Presented at ASBMR, Houston, TX, September 2014.

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16 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; At least $150M in cost synergies starting 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 D iseases *Alexion’s 2015 revenue guidance as of 4/23/2015

17 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 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

18 Synageva’s Pipeline will 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

19 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 - 12 79; 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 aPopulation 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 M edian a ge at death: 3.7 months Kaplan - Meier Estimate: Survival in Infants with LAL - D with Growth Failure

20 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

21 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

22 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

23 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

24 Following Approval, Kanuma w ill 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 * $2,1465M excludes ~$88M in prior years' sales in France ; ‡ Midpoint of FY15 guidance range PNH aHUS HPP LAL - D Lenny wants following approval 541 783 1,134 1,551 2,575 2010 2011 2012 2013 2014 2015E 2016E 2017E 2018E 2019E 2020E MIILLIONS ($) Revenue 2,146 * 2,550 - 2,600 ‡

25 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

26 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

Our Combined Ambitions for Tomorrow • Global leader in developing, manufacturing and commercializing the most innovative portfolio of complement inhibitors • Multiple therapeutic areas independent of complement • Most innovative R&D in biotech industry • World - class capability in manufacturing the highest quality therapies • G lobal leader in serving patients suffering from devastating diseases • The preferred partner amongst innovators • Leading independent biotech company by market cap

Alexion and Synageva – a Shared Culture • Setting the highest patient - centric ambitions • Never settling for conventional plans and timelines • Self - critical discipline • Insatiable thirst for doing better • Turning “No” into “Yes”

Questions

Forward - Looking Statements This communication includes statements that may be forward - looking statements. The words “believe,” “expect,” “anticipate,” “pr oject” 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 lim ited 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 o f t he expected benefits of the transaction, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, advers e l itigation 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, cl ini cal 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 fut ure approved products, delays or interruptions in manufacturing or commercial operations including due to actions of regulatory authorities or otherwise, the possibility that res ults of clinical trials in approved and investigational indications are not predictive of safety and efficacy in broader patient populations, the adequacy of our pharmacovigilance a nd 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 commerc ialization 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 t hat 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 ri sks. 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 require d 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 commun ication 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 Ale xio n and its offering subsidiary, Galaxy Merger Sub Inc. (“Offeror”), will file with the SEC. Offeror plans to file a tender offer statement on Schedule TO, together with other related exchange offer documents, includin g 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 co mpleted, 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 thr oug h 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. SYNAGEVASTOCKHOLDERS 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 TRANSACTIO N. 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 approva l o f 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 fr om 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 f il ed with the SEC on April 28, 2015. Other information regarding potential participants in any such proxy solicitation will be conta ined in any proxy statement filed in connection with the transaction .