

Edgar Filing: Galmed Pharmaceuticals Ltd. - Form FWP

Galmed Pharmaceuticals Ltd.
Form FWP
June 18, 2018

Filed Pursuant to Rule 433

Registration No. 333-223923

Issuer Free Writing Prospectus dated June 18, 2018

Relating to Preliminary Prospectus dated June 18, 2018

June 2018

Safe Harbor and Disclaimer Statement Galmed Pharmaceuticals Ltd. (the “Company”) has filed a shelf registration statement on Form F - 3 (including a preliminary prospectus supplement and the accompanying prospectus) with the Securities and Exchange commission (“SEC”) for the offering to which this presentation relates, which was declared by the SEC effective on April 2 , 2018 . Before you invest, you should read the preliminary prospectus supplement and the accompanying prospectus included in the registration statement and the other documents the Company has filed with the SEC for more complete information about the Company and the offering. You may get these documents for free by visiting EDGAR on the SEC website on www.sec.gov . Alternatively the Company, or any underwriter or dealer participating in this offering will arrange to send you the prospectus if you request it from Stifel , Nicolaus & Company, Incorporated, Attention: Prospectus Department, One Montgomery Street, suite 3700 , San Francisco, CA 94104 , or by telephone (415) 364 - 2720 , or by e - mail syndprospectus@stifel.com ; SunTrust Robinson Humphrey, Inc. Attention: Prospectus Department, 3333 Peachtree Road NE, 9 th Floor, Atlanta, GA 30326 , or by telephone (404) 926 - 5744 , or by e - mail strh.prospectus@suntrust.com ; or Cantor Fitzgerald & Co. Attention: Capital Markets, 499 Park Ave. 6 th Floor, New York, New York 10022 , or by e - mail prospectus@cantor.com . This presentation contains forward - looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward - looking statements, orally or in writing. Forward - looking statements can be identified by the use of forward - looking words such as “believe,” “expect,” “intend,” “plan,” “may,” “should” or “anticipate” or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward - looking statements may be included in, but are not limited to, this presentation, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward - looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward - looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward - looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward - looking statements, including, but not limited to, the factors summarized below. These factors include, but are not limited to, the following: the timing and cost of Galmed’s phase IIb ARREST study and planned Phase III trials for Aramchol™, or whether Phase III trials will be conducted at all; completion and receiving favorable results the phase IIb ARREST study and potential Phase III trials for Aramchol™; regulatory action with respect to Aramchol™ by the FDA or the EMA; the commercial launch and future sales of Aramchol™ or any future product candidates; Galmed’s ability to comply with all applicable post - market regulatory requirements for Aramchol™ in the countries in which it seeks to market the product; Galmed’s ability to achieve favorable pricing for Aramchol™; Galmed’s expectations regarding the commercial market for NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus; third - party payor reimbursement for Aramchol™; Galmed’s estimates regarding anticipated capital requirements and Galmed’s needs for additional financing; market adoption of Aramchol™ by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol™; the development and approval of the use of Aramchol™ for additional indications or in combination therapy; and Galmed’s expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading “Risk Factors” included in Galmed’s most recent Annual Report on Form 20 - F filed with the SEC on March 13 , 2018 , and in other filings that Galmed has made and may make with the SEC in the future. These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward - looking statements. Given these uncertainties, you should not rely upon forward - looking statements as predictions of future events. All forward - looking statements attributable to us or persons acting on our behalf included in, but not limited to, this presentation speak only as of the date hereof and are expressly qualified in their entirety by the foregoing. We undertake no obligations to update or revise forward - looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of

unanticipated events. In evaluating forward - looking statements, you should consider these risks and uncertainties. 2

Offering Summary Issuer Galmed Pharmaceuticals Ltd. Symbol (Exchange) GLMD (NASDAQ) Offering Style Fully Marketed Follow - On (Ordinary Shares) Offering Size \$75.0 million (100% primary) Greenshoe 15% Use of Proceeds Fund the continued clinical development of Aramchol and other general corporate purposes Expected Pricing June 19, 2018 Lock - Up 90 Days for Company, Directors and Officers Bookrunners Stifel, SunTrust Robinson Humphrey and Cantor Fitzgerald 3

Galmed Snapshot Galmed is advancing its lead compound, Aramchol™ towards registration with a focus on NASH, a market opportunity estimated to reach \$ 35 - 40 B/ yr by 2025 * Experienced pharma leadership team We believe that data s upports c ontinued d evelopment of Aramchol™ 600 mg to Phase 3 • Pre - Phase 3 meeting with the FDA Q 4 2018 Expected Short Term Catalyst: Effects in animals translated to NAFLD patients in Phase 2a study and in a one - year global Phase 2b study in 247 biopsy - proven NASH patients 4 *Deutsche Bank “NASH - the next big global epidemic in 10 years?” July 14 , 2014

Aramchol™ – NASH Disease Modification Potential Fast Track Designation for development of Aramchol™ for NASH granted by FDA First - in - class, orally active, liver targeted SCD - 1 modulator Effects in animal models translated into human clinical data High safety margin and B/R ratio ~400 subjects exposed across 7 clinical trials Potent mechanism with multiple intervention points along the pathogenic pathway 5

Leadership Chaim Hurvitz CEO of CH Health; Previously, member of Teva's senior management team and Board of directors. Carol L. Brosgart, M.D. Consultant to biotechnology companies in the areas of liver disease; Former director of Tobira Therapeutics. William S. Marth President & CEO of Albany Molecular Research Inc. (AMRI) ; former President & CEO of Teva in the Americas. David Sidransky, M.D. Professor of Oncology Pathology at John Hopkins University. Ran Oren, M.D. Head of the Institute of Gastroenterology and Liver Disease at Hadassah Ein Kerem Hospital. Tali Yaron - Eldar Formerly Israeli Tax Commissioner; Chief Legal Advisor of the Finance Ministry of the State of Israel. Shmuel Nir President & CEO of Tushia Consulting Engineers Ltd.; Chairman of the Board of Directors of Matan Digital Printers Ltd. Allen Baharaff President, CEO and Co - Founder of Galmed BOARD OF DIRECTORS Guy Nehemya , Adv., MBA, VP Operations Yael Hollander, Adv .,MBA, VP, Legal Affairs & Strategy Yohai Stenzler, CPA, MBA, CFO + 10 years of experience, Senior Clinical Program Leader at Teva Pharmaceuticals Dr. Tali Gorfine, M.D., CMO + 16 years of experience in drug development, Teva Pharmaceuticals Dr. Liat Hayardeny , Ph.D., MBA, CSO Allen Baharaff , President and CEO Co - founder of Galmed + 6 years of financial management experience at Ernst & Young LLP +6 years of experience at Gross, Kleinhendler , Hodak , Halevy, Greenberg & Co. +4 years of experience as the Company's Director of Operations. Management + 34 years of CMC experience, former Chief Scientific Officer at Chemagis (Perrigo API) Dr. Yossi Caspi, Ph.D., Senior Director Drug Development 6

Aramchol™ from Scientific Rationale to Clinical Results SCD 1 Modulator - One Mechanism, Multiple Activities, Translated to Reduction in Liver Fat and Fibrosis

Oxidative Stress & Liver Injury Steatosis Glucose Serum FA FA FA Oxidation MUFA ER OxFA Mitochondria
GSH/GSSG DG TG Lipid droplets CD 36 DNL PX ROS Effect of ARAMCHOL PC (22 : 6) VLDL SCD - 1 IN
MCD DIET MODEL 8

Aramchol™ - Antisteatogenic Effect - Translation from Animal Models to Human (phase 2 a and 2 b) Aramchol TM 5mg/kg in mice and 300mg in humans demonstrated statistically significant reduction of liver fat 1. Iruarrizaga-Lejarreta , Marta, et al. "Role of Aramchol in steatohepatitis and fibrosis in mice"; Hepatology Communications 1.9 (2017) 2. Safadi et al. "The fatty acid – bile acid conjugate Aramchol reduces liver fat content in patients with nonalcoholic fatty liver disease." Clinical Gastroenterology and Hepatology 12.12 (2014)

Aramchol™ – Antifibrogenic Translation from HSC's (Collagen producing cells) to Animal Models to Human Studies 10
0 0.4 0.8 1.2 1.6 2 48h Relative Gene Expression SCD 1 in Hepatic Stellate Cells Vehicle Aramchol 10µM 0 2 4 6 8
10 12 48h Relative Gene Expression PPAR Vehicle Aramchol 10µM *** 0 0.5 1 1.5 2 48h Relative Gene Expression
Collagen 1 a Vehicle Aramchol 10µM 0 0.5 1 1.5 2 48h Relative Gene Expression SMA Vehicle Aramchol 10µM ***
1. Iruarrizaga-Lejarreta , Marta, et al. "Role of Aramchol in steatohepatitis and fibrosis in mice"; Hepatology
Communications 1.9 (2017) 2. R. Golan - Gerstl 1 , N. Koroukhov 1 , R.Khweiss 1 , L. Litinetsky 2 , L.Hayardeny 2
and S.Shimon Reif. "The in vitro anti fibrotic effect of Aramchol in primary hepatic stellate cells" (2018); The
international liver congress (EASL), Paris, France 3. Friedman S et al, "Treating NASH with Aramchol - The scientific
rationale" Galmed Mini - Workshop EASL 2018 *** p ≤ 0.001

TAA + A ramchol™ 5 mg/kg TAA No Treatment Fibrosis Score (Masson & Goldner staining) Treatment Prevention
61.5 % 40% R. Golan - Gerstl 1 , M. Valitsky 1 , R. Oren 1 , E. Brazovski 2 , L. Hayardeny 1 , S. Shimon Reif . "The
anti - fibrotic effect of Aramchol on liver fibrosis in TAA animal model" (2017); The international liver congress
(EASL), Amsterdam, the Netherlands. Aramchol™ – Antifibrogenic Translation from HSC's (Collagen producing cells)
to Animal Models to Human Studies Effect in the TAA model is considered the best predictor of efficacy in humans

In a one year, global Phase 2 b ARREST study, Galmed's Aramchol 600 mg achieved NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application.

Aramchol™ Across Modalities 13 -5 -4 -3 -2 -1 0 1 2 Placebo (N=41) Aramchol 400 (N=90) Aramchol 600 (N=83)
 Change from Baseline in Mean Liver Fat Liver fat - Mean Change from Baseline 24.4 % 36.7 % 47.0 % 0% 10% 20%
 30% 40% 50% Placebo (N=41) Aramchol 400 (N=90) Aramchol 600 (N=83) MRI Responders - Reduction ≥ 5 %
 absolute change 5.0% 7.5 % 16.7 % 0% 5% 10% 15% 20% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600
 (N=78) Proportion of patients NASH Resolution without Worsening of Fibrosis 17.5 % 21.3 % 29.5 % 0% 5% 10%
 15% 20% 25% 30% 35% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600 (N=78) Proportion of patients
 Fibrosis Improvement Without Worsening of NASH -25.0 -20.0 -15.0 -10.0 -5.0 0.0 5.0 10.0 15.0 20.0 Change from
 Baseline ALT – mean change from Baseline Week 52 Week 40 Week 24 Liver Enzymes Biopsy MRS -15.0 -10.0 -5.0
 0.0 5.0 10.0 15.0 Change from Baseline AST – mean change from Baseline Week 52 Week 40 Week 24

Phase 2b Study: ARREST ARamachol™ for RESolution of Steatohepatitis A Phase 2 b, double blind randomized, controlled clinical trial, to evaluate the efficacy and safety of two Aramchol™ doses versus placebo in patients with Non - Alcoholic Steatohepatitis (NCT 02279524) Design: Multicenter, global, randomized, double - blind, placebo - controlled, dose ranging study ~ 1/3 USA, 1/3 Latin America, 1/3 Europe and Israel Participants : Biopsy - diagnosed NASH patients with overweight/ obesity and pre - diabetic/ type II diabetic 60% having stage 2 and 3 fibrosis and 70% having NAS≥5 at baseline Doses: • 400 mg; 60 mg; Placebo • 2:2:1 Treatment Plan: 12 months treatment (once daily tablet) and 3 months of follow - up Number of Subjects: 277 patients Primary Endpoint: Change from baseline to end of study in liver triglycerides ratio as measured by MRS (Aramchol 600mg vs placebo) - centrally read Key Secondary Endpoints: Biopsy – centrally read; fibrosis improvement; > 2 point NAS improvement; NASH resolution ALT 14

Subjects Disposition 247 - No. of Subjects Randomized and included in ITT Placebo N= 48 Aramchol 400 N= 101 Aramchol 600 N= 98 41 (85.4%) Normal Termination 7 – Early Termination: • 3 - Withdrawal of Consent • 2 - Adverse Event • 0 - Lost to FU • 0 - Other Reason • 2 - Disallowed Medications 90 (89.1 %) Normal Termination 11 – Early Termination: • 6 - Withdrawal of Consent • 3 - Adverse Event • 1 - Lost to FU • 1 - Other Reason • 0 - Disallowed Medications 88 (89.8 %) Normal Termination 10 – Early Termination: • 3 - Withdrawal of Consent • 4 - Adverse Event • 1 - Lost to FU • 2 - Other Reason • 0 - Disallowed Medications 15

Pre - defined Analysis Sets Randomized (ITT) (N= 247) Aramchol 400 (N= 101) Placebo (N= 48) FAS - MRI = 214
Aramchol 400 (N= 90) Aramchol 600 (N= 98) Aramchol 600 (N=83) Placebo (N = 41) FAS - biopsy = 198
Aramchol 400 (N= 80) Aramchol 600 (N= 78) Placebo (N =40) ITT= 247 • Statistical analysis plan pre - defined few
analysis sets including: • Full Analysis Set for MRI (FAS - MRI): all ITT patients with baseline and at least one 2 nd
MRS • Full Analysis Set for Liver Biopsy (FAS - biopsy): all ITT patients with baseline and 2 nd biopsy • Majority of
missing biopsies are Israeli patients (N= 24) without 2 nd biopsy - regulatory limitation • Only 3 patients that
completed 52 weeks of treatment refused the 2 nd biopsy • Good tolerability - ~ 10 % early termination during
treatment phase 16

Change from Baseline in Liver Fat (MRS) -5 -4 -3 -2 -1 0 1 2 Placebo (N=41) Aramchol 400 (N=90) Aramchol 600 (N=83) Change from Baseline in Mean Liver Fat Mean change from Baseline in Liver fat Aramchol 400 vs. Pbo p=0.0450 Aramchol 600 vs. Pbo p=0.0655 24.4 % 36.7 % 47.0 % 0% 5% 10% 15% 20% 25% 30% 35% 40% 45% 50% Placebo (N=41) Aramchol 400 (N=90) Aramchol 600 (N=83) MRI Responders Analysis: Reduction \geq 5 % absolute change from baseline Post - hoc analysis Aramchol 400 vs. Pbo p= 0.0878 Aramchol 600 vs. Pbo p= 0.0279 The primary endpoint based on mean change in liver fat for the 600mg dose vs placebo was not met. Statistical significant effect noted with Aramchol™ 600mg using the acceptable cut - off > 5% absolute change 17

NASH Resolution 5.0 % 7.5 % 16.7 % 0% 2% 4% 6% 8% 10% 12% 14% 16% 18% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600 (N=78) Proportion of patients Aramchol 400 vs. Pbo p= 0.4955 Aramchol 600 vs. Pbo p= 0.0514 Significantly more patients treated with Aramchol™ 600mg showed NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application NASH Resolution without Worsening of Fibrosis 7.5% 12.5 % 19.2 % 0% 2% 4% 6% 8% 10% 12% 14% 16% 18% 20% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600 (N=78) Proportion of patients NASH Resolution Aramchol 400 vs. Pbo p=0.2237 Aramchol 600 vs. Pbo p=0.0462 18

Fibrosis Improvement 17.5 % 21.3 % 29.5 % 0% 5% 10% 15% 20% 25% 30% 35% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600 (N=78) Proportion of patients Fibrosis Improvement (≥ 1 stage) Without Worsening of NASH Aramchol 400 vs. Pbo p= 0.8425 Aramchol 600 vs. Pbo p= 0.2110 More patients with fibrosis improvement and less patients progressing to cirrhosis with Aramchol™ 600mg 7.5 % 7.5 % 1.3 % 0% 1% 2% 3% 4% 5% 6% 7% 8% Placebo (N=40) Aramchol 400 (N=80) Aramchol 600 (N=78) Proportion of patients Post - Hoc Analysis - Progression to Cirrhosis Aramchol 400 vs. Pbo p=0.5693 Aramchol 600 vs. Pbo p=0.1008 19

Change from Baseline to week 52 in ALT (U/L) -25.0 -20.0 -15.0 -10.0 -5.0 0.0 5.0 10.0 15.0 20.0 Change from Baseline Placebo Aramchol 400 Aramchol 600 Change from Baseline in ALT (U/L) Week 52 Week 40 Week 24 Week 52 Analyses Aramchol 400 vs. Pbo : p= 0.0002 Aramchol 600 vs. Pbo : p<. 0001 A statistically significant reduction in ALT with Aramchol™ 400mg and 600mg 20

Change from Baseline to week 52 in AST (U/L) A statistically significant reduction in AST with Aramchol™ 400 mg and 600 mg -15.0 -10.0 -5.0 0.0 5.0 10.0 15.0 Change from Baseline Placebo Aramchol 400 Aramchol 600 Change from Baseline in AST (U/L) Week 52 Week 40 Week 24 Week 52 Analyses Aramchol 400 vs. Pbo : p= 0.0011 Aramchol 600 vs. Pbo : p<. 0001 21

Aramchol's safety and tolerability • Good tolerability • Early terminations due to AEs occurred in 4.2 %, 3.0 % and 4.1 % in placebo, Aramchol 400 mg and 600 mg arms respectively • SAEs reported in 12.5 %, 8.9 % and 9.2 % of patients in placebo, Aramchol 400 mg and 600 mg arms respectively • No clustering of events were reported in either Aramchol arms • No atypical events for the studied population • Severe AEs reported in 10.4 %, 6.9 % and 6.1 % of patients in placebo, 400 mg and 600 mg arms respectively Aramchol™ continues to show a favorable safety and tolerability profile 22

Conclusions • ARREST was a placebo - controlled, one year global phase 2 b study in 247 biopsy - proven NASH patients with risk factors • Study results are compelling for Aramchol™ 600 mg demonstrating: • A significant effect on NASH resolution without worsening of fibrosis, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application • An increase in the number of patients that show fibrosis improvement by at > 1 stage without worsening of NASH, one of two endpoints that may currently constitute a primary endpoint for a Phase 3 trial to support an FDA marketing application • High proportion of patients benefit from treatment with Aramchol 600 mg • Good safety profile and tolerability Data Supports Continued Development of Aramchol™ 600 mg to Phase 3 23

ARREST (5) MGL - 3196 (4) CENTAUR (3) GOLDEN (2) FLINT (1) 125 289 274 283 ; ITT 219 Number of patients 52 weeks 36 weeks 52 weeks 52 weeks 72 weeks Duration 16.7 % vs. 5 % 8 % vs. 6 % 19 % vs. 9 % (7) 2 NASH resolution without fibrosis worsening (6) 19.2 % vs. 7.5 % 27 % vs. 6 % 22 % vs. 13 % NASH resolution (6) 29.5 % vs. 17.5 % 20 % vs. 10 % Fibrosis improvement without NASH worsening (6) 29 % vs. 23 % 35 % vs. 19 % Fibrosis improvement (6) (1) Source: A multicentre , randomised , placebo - controlled trial, Neuschwander - Tetri et al Lancet, November 7 , 2014 . (2) Source : Elafibranor , an Agonist of the Peroxisome Proliferator - Activated Receptor - Induces Resolution of Nonalcoholic Steatohepatitis Without Fibrosis Worsening, Ratziu et al, Gastroenterology 2016 . (3) Source : A Randomized , Placebo - Controlled Trial of Cenicriviroc for Treatment of Nonalcoholic Steatohepatitis with Fibrosis, Friedman et al., Hepatology. 2018 May; 67 (5): 1754 – 1767 . (4) Source: Madrigal press release, May 31 , 2018 . (5) Aramchol 600 mg (6) Results in table show treated drug vs placebo. (7) Patients with $NAS \geq 4$; Elafibranor 120 mg. Aramchol's place among the leading NASH potential compounds 24 Disclaimer : the studies presented herein may not be comparable to each other, and if such candidates were placed in one or more head - to - he ad studies, the results could differ from the data presented above, and such differences could be material.

We presented here a set of data that speaks to the potential effect of Aramchol™ on multiple pathologies in NASH as measured by different modalities, MRS, biopsy and liver enzymes. The totality of the data together with the good safety profile and tolerability gives us confidence in advancing Aramchol™ to a pivotal study.

Corporate Overview Financials* Intellectual Property • 10 Patent Families • Areas of Focus: NASH, Combinations, Chemistry of Aramchol™, New Indications • Patent family (WO 2002/2083147) for use of Aramchol™ for the treatment of fatty liver granted worldwide. • 2 patent families (2017) for the use of Aramchol™ for treating fibrosis. • Market Cap ~\$247M • 52W Low-High: \$3.61-\$27.06 • 3M Average Volume: ~368K • Outstanding Shares: ~15.9M • Cash: ~\$22.0M • Long Term Liabilities: \$0** * As of June 14, 2018 ** Unaudited *** Consisting of cash, cash equivalents and marketable securities 26 ** ***

Thank You ! NASDAQ: GLMD