UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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	FORM 8-K	
Pursuant to Sec	CURRENT REPORT tion 13 or 15(d) of the Securities Exch	nange Act of 1934
	December 31, 2024	
Date	of Report (Date of earliest event repo	orted)
	PHARMACEUTICA name of registrant as specified in its	
Delaware (State of incorporation)	001-38738 (Commission File Number)	37-1858472 (I.R.S. Employer Identification Number)
(Addı	21925 W. Field Parkway, Suite 235 Deer Park, Illinois 60010-7208 ress of principal executive offices) (Zij	o code)
(Regist	(847) 787-7361 rant's telephone number, including an	rea code)
Check the appropriate box below if the Form 8-K filir following provisions:	ng is intended to simultaneously satisf	y the filing obligation of the registrant under any of the
☐ Written communications pursuant to Rule 425 under	the Securities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14a-12 under the	Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rul	e 14d-2(b) under the Exchange Act (17	CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rul	e 13e-4(c) under the Exchange Act (17	CFR 240 13e-4(c))
•	s registered pursuant to Section 12(b)	
Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ETON	NASDAQ Global Market
		Rule 405 of the Securities Act of 1933 (§230.405 of this
Emerging growth company □		
If an emerging growth company, indicate by check mark or revised financial accounting standards provided pursua		he extended transition period for complying with any new . \Box

Item 2.01: Completion of Acquisition or Disposition of Assets

On December 31, 2024, Eton Pharmaceuticals, Inc. ("Eton" or the "Company") acquired Galzin® (zinc acetate) from Teva Pharmaceuticals USA, Inc. ("Teva"). Galzin® is the only FDA-approved zinc treatment for the maintenance of patients with Wilson Disease who have been initially treated with a chelating agent. It is estimated that less than 5,000 patients in the United States are currently being treated for Wilson Disease.

Eton expects to assume the commercialization of the product in the United States in the first quarter of 2025 with its metabolic sales force supporting healthcare professionals who treat Wilson Disease. As part of the transaction, Eton has also acquired European rights to the product, where it is commercialized under the tradename Wilzin® by a third party. Under an existing agreement, Eton will continue to supply the product to the third party and the third party is responsible for all commercialization activities.

Under the terms of the purchase agreement, the Company purchased Galzin® for \$7.0 million at closing and paid an additional \$0.2 million for product inventory. The Company will also pay Teva a royalty of 10% of U.S. net sales through the tenth anniversary of the Company's first commercial sale of the product in the U.S.

A copy of the asset purchase agreement dated December 31, 2024 and the press release announcing the transaction dated January 3, 2025 are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K.

Item 9.01: Financial Statements and Exhibits

Exhibit No.	Description
Exhibit 10.1	Asset Purchase Agreement dated December 31, 2024 between Teva Pharmaceuticals USA, Inc. and the Registrant (portions of the Exhibit have been redacted).
Exhibit 99.1 104	Press Release dated January 3, 2025. Cover Page Interactive Data File (embedded within the Inline XBRL document)
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 3, 2025

By: /s/ James R. Gruber

James R. Gruber Chief Financial Officer and Secretary (Principal Financial Officer)

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Certain information has been redacted from this exhibit because it is both not material and is the type that the Registrant treats as private or confidential

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this "<u>Agreement</u>") is effective as of the latest date set forth on the signature page hereto (the "<u>Effective Date</u>"), by and between Teva Pharmaceuticals USA, Inc., a Delaware corporation, with offices at 400 Interpace Parkway, Parsippany, NJ 07054, acting directly or through its Affiliates (as defined hereinafter) ("<u>Teva</u>"), on the one hand, and Eton Pharmaceuticals, Inc., a Delaware corporation, with offices at 21925 Field Pkwy, Suite 235, Deer Park, IL 60010 ("<u>Buyer</u>"), on the other hand.

WHEREAS, Teva owns the US Product NDA (as defined below) and, subject to the terms of the [information redacted] (as defined herein), the Ex-US Product Marketing Authorizations (as defined below) for the Products (as defined below) that are part of the Purchased Assets (as defined below); and

WHEREAS, Buyer wishes to purchase the Purchased Assets from Teva, all upon the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual covenants and conditions hereinafter expressed, Buyer and Teva, intending to be legally bound, hereby agree as follows:

- 1. <u>Definitions</u>. For purposes of this Agreement, the following terms have the following meanings:
- (a) "Affiliate" means any Person that controls, is controlled by, or is under common control with the applicable Person. For purposes of this definition, "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote for the election of directors, or otherwise having the power to control or direct the affairs of such Person; and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest or the power to direct the management and policies of such noncorporate entities.
 - (b) "Assumed Liabilities" has the meaning ascribed to the term in Section 3 of this Agreement.
 - (c) [information redacted]
 - (d) [information redacted]
- (e) "Bill of Sale" means a bill of sale and assignment and assumption agreement to be executed and delivered by each Party on the Effective Date, substantially in the form of Exhibit A-1.

- (f) "Business Day" means any day on which commercial banks are not authorized or required to close in New York, New York.
- (g) "Buyer Indemnified Parties" has the meaning ascribed to the term in Section 9(b) of this Agreement.
- (h) "Closing Press Release" means a press release to be made by Buyer on or following the Effective Date, substantially in the form of

(i) "<u>Code</u>" means the Internal Revenue Code of 1986, as amended.

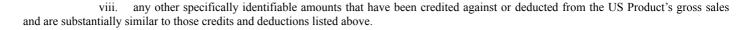
- (j) "Commercially Reasonable Efforts" means, with respect to a Party, use of commercially reasonable efforts, consistent with normal business practices used by a similarly-situated pharmaceutical company in the exercise of its reasonable business discretion relating to a prescription pharmaceutical product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its product life, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory environment, the profitability of the applicable products (including, without limitation, post-marketing study commitments, pricing and reimbursement status achieved), the relevant supply chain of the compound or product, and other relevant factors, including without limitation technical, legal, scientific, and/or medical factors.
 - (k) [information redacted]

Exhibit D.

- (1) "Confidential Information" has the meaning ascribed to the term in Section 13(d) of this Agreement.
- (m) "Current Inventory" means the inventory set forth on Schedule 7(b).
- (n) "Current Inventory Value" has the meaning ascribed to the term in Section 7(b) of this Agreement.
- (o) "<u>Deductible</u>" has the meaning ascribed to the term in <u>Section 10(b)</u> of this Agreement.
- (p) "<u>Domain Assignment Agreement</u>" means a domain assignment agreement to be executed and delivered by each Party on the Effective Date, substantially in the form of <u>Exhibit A-2</u>.
- (q) "Encumbrance" means, with respect to any asset, any imperfection of title, mortgage, charge, lien, security interest, hypothecation, easement, right of way, option, preemptive right, adverse claim, pledge or encumbrance of any nature whatsoever, or any contract to create any of the following.

- (r) "Ex-US Product Marketing Authorizations" means any marketing authorizations for sale of the [information redacted], as set forth on Schedule I.
 - (s) "Excluded Assets" has the meaning ascribed to the term in Section 2(b) of this Agreement.
- (t) "Excluded Liabilities" means any Liabilities that are not Assumed Liabilities and includes (i) Excluded Taxes, (ii) Liabilities arising out of or resulting from [information redacted], and (iii) except for Liabilities arising out of or resulting from Buyer's obligation to forward AE Reports set forth in Section 4(c), any Liability arising out of or resulting from [information redacted].
- (u) "Excluded Taxes" means any Taxes imposed on, arising in connection with or otherwise attributable to (i) Teva for any taxable period, (ii) the Purchased Assets for any Pre-Closing Tax Period, and (iii) any transfer taxes for which Teva is responsible pursuant to Section 5(e).
- (v) "FDA" means the United States Food and Drug Administration, including all divisions under its direct control, or any successor organization thereto.
- (w) "Governmental Entity" means any international, national, foreign, provincial, federal, state or local judicial, legislative, executive, administrative or regulatory body or authority.
 - (x) "Indemnified Parties" has the meaning ascribed to the term in Section 9(b) of this Agreement.
 - (y) "Indemnifying Party" has the meaning ascribed to the term in Section 11(a) of this Agreement.
- (z) "knowledge" means (i) the actual knowledge, as of the Effective Date, of any employee of Teva or Buyer, as applicable, and (ii) the knowledge such individuals would reasonably be expected to obtain in the course of diligently performing his or her duties in connection with the Products (in the case of Teva) or making a reasonable inquiry into the matters contemplated by this Agreement (in the case of Buyer); provided, however, with respect to the [information redacted], (ii) shall mean Teva's knowledge solely with respect to its supply of the [information redacted].
- (aa) "<u>Law</u>" means each federal, state, provincial, municipal, local, or foreign law, statute, ordinance, order, determination, judgment, common law, code, rule, official standard, or regulation, enacted, enforced, entered, promulgated, or issued by any Governmental Entity.
- (bb) "<u>Liabilities</u>" means any and all debts, liabilities and obligations, whether accrued or fixed, absolute or contingent, matured or unmatured, or known or unknown, including those arising under applicable Law or governmental action and those arising under any contract, arrangement, commitment or undertaking, or otherwise.

- (cc) "<u>Licensed Territory</u>" means the entire world, but excluding the [information redacted].
- (dd) "Losses" has the meaning ascribed to the term in Section 9(a) of this Agreement.
- (ee) "NDA" means a New Drug Application filed with the FDA pursuant to its rules and regulations.
- (ff) "Net Sales" shall mean, with respect to the US Product sold in the US by a Product Seller, the aggregate gross sales amount invoiced by the US Product Seller on an arms-length basis to third parties in the US, less the following deductions, all determined in accordance with generally accepted accounting principles, consistently applied:
 - i. two percent (2%) of gross sales in the US to cover cash discounts given;
 - ii. reasonable estimates for any adjustments on account of price adjustments, billing adjustments, bid defaults, shelf stock adjustments, promotional payments, or other similar allowances affecting the US Product;
 - iii. reasonable estimates for chargebacks, rebates, administrative fee arrangements, reimbursements, and similar payments to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or healthcare organizations or other customers and/or patients;
 - iv. reasonable estimates for amounts due to third parties on account of rebate payments, including Medicaid rebates, or other price reductions provided, based on sales to any governmental or regulatory authority in respect of state or federal Medicaie, Medicaid, Veterans Administration, any purchasers of the federal supply schedule or similar programs;
 - v. allowances and credits to third parties on account of rejected, damaged, returned or recalled US Product;
 - vi. any government mandated manufacturing tax, including, without limitation, the brand manufacturer's tax imposed pursuant to the Patient Protection and Affordable Care Act (Pub. L. No. 111-148) (as amended or replaced);
 - vii. the costs incurred in connection with patient support services, including, but not limited to, insurance benefits investigations, co-pay assistance, and provision of free or low cost drug to patients demonstrating financial need, co-insurance assistance or other coupons directly related to the sale of the US Product, accrued, paid or deducted pursuant to an agreement: and



- (gg) [information redacted]
- (hh) [information redacted]
- (ii) [information redacted]
- (jj) "Party" or "Parties" means Teva or Buyer or both, as applicable.
- (kk) "PDUFA" means the US Prescription Drug User Fee Act of 1992, as amended.
- (II) "<u>Permitted Encumbrances</u>" means (i) any minor imperfections of title or similar Encumbrance that do not, and would not reasonably be expected to, individually or in the aggregate, materially impair the value or materially interfere with the use of, the Purchased Assets, (ii) Encumbrances for Taxes that are not yet due and payable, (iii) the [information redacted], and (iv) with respect to the Ex-US Product Marketing Authorizations, the [information redacted].
- (mm) "Person" means any individual, partnership (general or limited), association, corporation, limited liability company, joint venture, trust, estate, limited liability partnership, unincorporated organization, Governmental Entity or other legal person or organization.
 - (nn) [information redacted]
 - (oo) [information redacted].
 - (pp) "Pre-Closing Tax Period" shall mean any taxable period (or portion thereof) ending on or before the Effective Date.
- (qq) "Product" or "Products" means one or more, as applicable, of the Products set forth on Schedule I hereto next to the US Product NDA and Ex-US Product Marketing Authorizations.
- (rr) "Product Marketing Authorization(s)" means, individually or collectively as the context requires, (i) the US Product NDA; and/or (ii) the Ex-US Product Marketing Authorizations.

- (ss) "Product Seller" means Buyer and any Person other than Buyer (including, without limitation, any permissible assignee, successor, licensee and sublicensee of any of the foregoing), in each case, that sells Product, other than Teva or its Affiliates.
 - (tt) "Purchase Price" has the meaning ascribed to the term in Section 5(a) of this Agreement.
 - (uu) "Purchased Assets" means the following:
 - the Product Marketing Authorizations;
 - ii. all Adverse Event reports and other data, information and materials relating to adverse experiences and other safety issues submitted to any Governmental Entity with respect to the Products and safety databases, as well as all material correspondence with any Governmental Entity relating to the Products, including any correspondence with the FDA, directly relating to the US Product NDA ("<u>US Product FDA Correspondence</u>"), in each case, as set forth in <u>Schedule I</u>, as may be in Teva's possession and readily accessible to Teva, and as may be existing as of the Effective Date;
 - iii. all customer lists maintained by Teva and related to the US Product;
 - iv. the contracts set forth on Schedule I (including all rights and obligations arising thereunder);
 - v. those Internet domain names and social media account names or identifiers that are related to the US Product as set forth on Schedule I;
 - vi. the trademarks, trade names, brand names, logotypes, symbols, service marks, trade dress and their corresponding registrations or applications set forth on Schedule I, together with all goodwill symbolized by the foregoing;
 - vii. all trade secret and other know-how rights, and all other intellectual property or proprietary rights of any kind, owned or controlled by Teva, solely to the extent used in connection with the Products; and
 - viii. all Current Inventory.
 - (vv) [information redacted]
 - (ww) [information redacted]
 - (xx) [information redacted]
 - (yy) [information redacted]

- (zz) [information redacted]
- (aaa) [information redacted]
- (bbb) "Retained Inventory" means the Teva labeled, finished Product inventory set forth on Schedule VI.
- (ccc) "Retained Inventory Value" means Teva's value, on the Effective Date, of the Retained Inventory, as set forth on Schedule VI.
- (ddd) "Tax(es)" means (a) any and all U.S. federal, state, local, or foreign taxes, assessments, charges, duties, fees, imports, levies or other charges from any Governmental Entity (including interest, penalties or additions associated therewith), including (but not limited to) income, franchise, capital stock, real property, personal property, tangible, withholding, employment, payroll, social security (or similar tax), social contribution, unemployment compensation, unclaimed property escheat, disability, transfer, sales, bulk sales, use, excise, license, occupation, registration, stamp, premium, environmental, customs duties, alternative or add-on minimum, estimated, gross receipts, value-added, ad valorem, profits, estimated, and all other taxes of any kind for which either Party may have any Liability imposed by any Governmental Entity, whether disputed or not, and any charges, interest or penalties imposed by any Governmental Entity, and (b) any Liability in respect of any items described in clause (a) payable by reason of contract, assumption, transferee liability, operation of Law, Treasury Regulations section 1.1502-6(a) (or any predecessor or successor thereof or any analogous or similar provision under Law) or otherwise.
 - (eee) "Tax Authority" means any Governmental Entity responsible for the administration or the imposition of any Tax.
- (fff) "Tax Return" means any report, return (including any estimated return or amended return), election, notice, estimate, declaration, information statement, claim for refund, and other forms and documents (including all schedules, exhibits and other attachments thereto) relating to and filed or required to be filed with a Tax Authority in connection with any Taxes (including estimated Taxes).
 - (ggg) "Territory" means the US and the [information redacted]
 - (hhh) "Teva Indemnified Parties" has the meaning ascribed to the term in Section 9(a) of this Agreement.
 - (iii) "Teva Selling End Date" has the meaning ascribed to the term in Section 2(g) of this Agreement.

- (jjj) "Trademark Assignment Agreement" means a trademark assignment agreement to be executed and delivered by each Party on the Effective Date, substantially in the form of Exhibit A-3.
- (kkk) "<u>Trademark License Agreement</u>" means a trademark license assignment agreement to be executed and delivered by each Party on the Effective Date, substantially in the form of <u>Exhibit A-4</u>.
 - (III) "Transition Services Agreement" has the meaning ascribed to the term in Section 4(f) of this Agreement.

(mmm)" <u>US</u>" means the United States of America, including its districts, military bases, territories, commonwealths and possessions.

- (nnn) "US Product" has the meaning set forth on Schedule I.
- (000) "US Product NDA" means the United States NDA set forth on Schedule I.
- (ppp) "US Product NDA Transfer Date" has the meaning ascribed to the term in Section 14 of this Agreement.

2. Purchase and Sale.

- (a) Upon the terms and subject to the conditions of this Agreement, on the Effective Date, Teva hereby transfers, sells, conveys, assigns and delivers to Buyer, and Buyer hereby purchases, acquires, accepts and assumes, all of Teva's right, title and interest in, within the Licensed Territory, to and under the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances, for the consideration set forth herein. To the extent that any Affiliate of Teva has any right, title and interest in, within the Territory, to and under the Purchased Assets, Teva shall cause such Affiliate to transfer, sell, convey, assign and deliver to Buyer all of such Affiliate's right, title and interest in, within the Licensed Territory, to and under the Purchased Assets, free and clear of all Encumbrances, other than Permitted Encumbrances.
- (b) Teva and Buyer expressly agree and acknowledge that the Purchased Assets do not include any assets of any kind, nature, character or description (whether real, personal or mixed, whether tangible or intangible, whether absolute, accrued, contingent, fixed or otherwise, and wherever situated) that are not expressly included within the definition of Purchased Assets (the "Excluded Assets"). For purposes hereof, it is agreed that the Excluded Assets include, without limitation, (i) information or data relating to any assets of Teva and its Affiliates other than the Purchased Assets, (ii) the inventory and other rights and assets (including receivables) specifically related to [information redacted], and (iii) any and all trademarks, trade names, brand names, logotypes, symbols, service marks, and trade dress, and any registrations or applications for any of the foregoing.

- Shared Assets. The Parties acknowledge that the Purchased Assets may include Confidential Information, trade secrets, processes, know-how, technology, data and other information (whether or not confidential) that is or may be used or usable in connection with the business of Teva or its Affiliates with respect to products other than the Products (collectively, "Shared Assets"). Nothing in this Agreement shall be deemed to create or effect a transfer of any right, title or interest in any Shared Asset, except that Teva hereby grants Buyer a fully paid-up, royalty-free, non-exclusive, perpetual, irrevocable, transferrable and assignable license, with the right to grant sublicenses through multiple tiers, to practice, use and exploit the Shared Assets in the Licensed Territory solely to the extent necessary or useful to make, have made, use, import, market, promote, distribute, offer for sale, sell, and otherwise exploit the Products. In addition, as of the Effective Date, Buyer grants to Teva a fully-paid, royalty free, non-exclusive, perpetual license in and to the US Product NDA, including a right to access the contents of the US Product NDA, solely for the purpose of Teva performing its obligations under [information redacted].
- (d) Buyer acknowledges and agrees that Teva may retain such copies of all or any part of the documentation that is included in the Purchased Assets, which Teva delivers to Buyer pursuant to <u>Section 2(a)</u>, as may be reasonably necessary for archival purposes and for purposes of complying with applicable Law and for legal and regulatory purposes as a seller of pharmaceutical products.
- (e) To minimize the possibility of a delay in available supply of the US Product in the US, commencing on the Effective Date and continuing until such time that Buyer (or another Product Seller, if applicable) makes its first commercial sale of its US Product in the US (the "Buyer Selling Start Date"), the Parties will periodically discuss in good faith Buyer's (or another Product Seller's, if applicable) projected launch of its US Product in the US.
- (f) [information redacted] (such period, as extended pursuant to this <u>Section 2(f)</u>, the "<u>Post-Closing Selling Period</u>"), Teva shall continue to sell any of Teva's inventory of the US Product into the US consistent with its past practice as reasonably necessary to meet demand; <u>provided</u>, that if Buyer is not prepared to make its first commercial sale of its Product in the US by the end of the Post-Closing Selling Period, then Buyer may extend the Post-Closing Selling Period up to three times by an additional thirty (30) days each time by delivering written notice of any such extension to Teva no later than thirty (30) days prior to the end of the Post-Closing Selling Period. Teva will pay Buyer the Net Profit of Teva's sales of its US Product during the Post-Closing Selling Period in accordance with the terms set forth in the Transition Services Agreement. For the avoidance of doubt, nothing in this <u>Section</u> 2 shall permit Buyer to sell any Teva-branded inventory of the Product.
- Upon Teva ceasing its sale of Product in the US (the "<u>Teva Selling End Date</u>"), Teva shall sell and transfer to Buyer, and Buyer shall purchase from Teva, any remaining finished goods Retained Inventory, owned by Teva as of the Teva Selling End Date, that is in sellable condition and has a shelf life of at least one (1) year following the Teva Selling End Date (a schedule of which Teva shall provide to Buyer no later than thirty (30) days following the Teva Selling End Date), at the Retained Inventory Value for such Retained Inventory, pursuant to a bill of sale to be executed within fifteen (15) days of Buyer's receipt of the foregoing schedule and that is substantially similar to the Bill of Sale and mutually agreed upon by the Parties. Any terms contained in <u>Sections 7</u> to <u>29</u> of this Agreement that apply to the Current Inventory shall apply to any Retained Inventory transferred pursuant to this <u>Section 2(g)</u>, *mutatis mutandis*, as of the date of such transfer. Within thirty (30) days after the Parties execute a Bill of Sale for any Retained Inventory, Buyer will pay to Teva, by wire transfer of immediately available funds into an account designated in writing by Teva, an amount equal to the Retained Inventory Value for such Retained Inventory.

- (h) [information redacted].
- (i) Within thirty (30) days after the Teva Selling End Date, Teva shall notify First Data Bank, Gold Standard, Redbook and Medi-Span in writing of Teva's discontinuation of all the active NDC numbers for the US Product, and Teva shall send written notice to the Buyer once all active NDC numbers are thereafter discontinued.
- (j) Teva shall provide such reasonable assistance, as may be reasonably necessary, in an effort to ensure a smooth transition from Teva to Buyer of sales of US Product by Buyer in the US, including sending customer communications regarding Product availability following the Teva Selling End Date in the form attached hereto as Schedule II.
- 3. Assumption of Liabilities and Obligations. Buyer agrees that from and after the Effective Date, Buyer shall be responsible for and shall pay, perform and/or otherwise discharge when due those Liabilities, including any Liabilities arising in respect of Taxes that are not Excluded Taxes, arising from and after the Effective Date with respect to the Purchased Assets, including, without limitation: (i) Liabilities arising on or after the Effective Date from any patent infringement claim or other lawsuit brought by any third party, the FDA or any other Governmental Entity relating to Product sold by or on behalf of any Product Seller on or after the Effective Date; (ii) Liabilities arising on or after the Effective Date from any FDA or any other Governmental Entity action or notification filed on or after the Effective Date, in all cases only to the extent they relate to Product sold by or on behalf of any Product Seller on or after the Effective Date; (iii) Liabilities arising on or after the Effective Date from any product liability claims relating to Product sold by or on behalf of any Product Seller on or after the Effective Date; and (iv) state and federal Medicaid/Medicare rebates and payments, and all credits, chargebacks, rebates, discounts, allowances, incentives and similar payments in connection with the sale of Product by or on behalf of any Product Seller on or after the Effective Date (collectively, the "Assumed Liabilities"). It is understood and agreed that the Assumed Liabilities do not include, and Buyer shall not be responsible for and shall not pay, perform or otherwise discharge, any Liabilities that arose prior to the Effective Date with respect to the Purchased Assets, including any amounts accrued prior to the Effective Date or that arise from and after the Effective Date that relate to the Purchased Assets or any other Liabilities set forth in clauses (i) through (iv) above in each case that relate to or arise in respect of the period prior to the Effective Date. Teva agrees to reasonabl

4. <u>Assumption of Regulatory Commitments</u>.

- (a) From and after the US Product NDA Transfer Date and the Effective Date, respectively, Buyer will be in control of, and responsible for, all costs and Liabilities arising from or related to any commitments or obligations to any Governmental Entity relating to the applicable Product or the applicable Product Marketing Authorization, or otherwise related to the applicable Purchased Assets, including, those obligations set forth on Schedule III attached hereto.
- (b) From and after the US Product NDA Transfer Date and the Effective Date, respectively, Buyer will be responsible for communications with any Governmental Entity involving the applicable Product Marketing Authorization or any batches of Product manufactured after the US Product NDA Transfer Date and the Effective Date, as applicable. Teva shall promptly forward to Buyer any correspondence received by Teva after the US Product NDA Transfer Date and the Effective Date, respectively, from any Governmental Entity solely to the extent related to the applicable Purchased Assets.
- (c) For the avoidance of doubt, from and after the US Product NDA Transfer Date, Buyer (as the holder of the US Product NDA) shall, as further set forth on Schedule V hereto, have the responsibility for the reporting of pharmacovigilance data, including adverse events ("AE" or "Adverse Events") processing and submission to the FDA and preparation and submission to FDA of any other pharmacovigilance data reports such as Periodic Adverse Drug Experience Report (PADER). After the US Product NDA Transfer Date and until the expiry of the last batch of US Product commercially sold by Teva in the US, Teva shall forward to Buyer all AE reports (as source documents) within three (3) Business Day after receipt of such AE report by Teva, and until expiry of the [information redacted], Buyer shall forward to Teva, to the following email address: [information redacted], all serious AE reports (as processed cases) of Product within five (5) calendar days after receipt of such AE report by Buyer. From and after the Effective Date, Buyer will be responsible for ensuring the reporting, processing and submission to the applicable Governmental Entity of any other pharmacovigilance data reports. Except with respect to Japan, the term for which has previously expired, Teva shall provide written notice to Buyer of the expiration of the [information redacted] in any country within the [information redacted] no later than five (5) Business Days prior to such expiration.
- (d) From and after the US Product NDA Transfer Date, Buyer will be responsible for responding to and maintaining a database of all medical inquiry records and Product quality complaints for Product commercially sold by Teva in the US. If Teva receives by phone, any medical inquiries, Adverse Events as noted above or Product quality complaints, Teva will warm transfer such medical inquiry, Adverse Events or Product quality complaints to [information redacted]. If Teva receives, in writing, any medical inquiries, Adverse Events or Product quality complaints from consumers or HCPs, Teva will send such medical inquiries or Product quality complaints for action to Eton Pharmaceuticals, Inc. (Quality Department), 21925 W Field Parkway, Suite 235, Deer Park, IL 60010 within one (1) Business Day from date of Teva's receipt. Additionally, any medical inquiries, Adverse Events or Product quality complaints received via email will be forwarded to redacted] within one (1) Business Day from date of Teva's receipt. In addition, if Teva receives by phone or in writing any questions or requests regarding availability of a Product, the location at which a Product can be purchased or otherwise obtained, or such other questions or requests for information, other than those medical inquiries, Adverse Events or Product quality complaints addressed above in this Section 4(d), Teva will transfer such questions or requests to [information redacted]. From and after the Effective Date, Buyer will be responsible for ensuring that a Product Seller of the [information redacted] is responding to and maintaining a database of all medical inquiry records and Product quality complaints.

- (e) For the avoidance of doubt, on and after the Effective Date, Buyer will assume and be responsible for all regulatory, quality, compliance and other requirements set forth in the [information redacted], in Buyer's capacity as a party to the [information redacted], and as otherwise may be required by Law with respect to the [information redacted].
 - (f) [information redacted].
- (g) <u>Transition Services Agreement</u>. If applicable, on the Effective Date, the Parties will enter into a transition services agreement, in substantially the form attached hereto as <u>Exhibit A-5</u> (the "<u>Transition Services Agreement</u>"), whereby the Parties will discuss in good faith, coordinate and align on certain finance, quality, regulatory and pharmacovigilance matters, as more specifically set forth therein, to ensure the Parties satisfy their respective obligations with respect to Teva's sale of the US Product in the US after the Effective Date.
 - 5. <u>Purchase Price; Royalty</u>. The Parties covenant and agree as follows:
- (a) <u>Purchase Price</u>. In consideration for transfer of the Purchased Assets to Buyer, on the Effective Date, Buyer shall pay to Teva, by wire transfer of immediately available funds into an account designated in writing by Teva to the Buyer, a non-refundable payment of an amount equal to the sum of Seven Million United States dollars (\$7,000,000.00) *plus* the Current Inventory Value (the "<u>Purchase Price</u>").

(b) Royalty on US Sales of Buyer's Product.

- i. Within forty five (45) days after the close of each calendar quarter commencing with the calendar quarter during which the Buyer Selling Start Date occurs and continuing up to and including the calendar quarter during which the tenth (10th) anniversary of the Buyer Selling Start Date (the "Royalty Term"), Buyer (or the Product Seller, if applicable) shall (i) furnish to Teva a report in reasonable detail showing for the US Product: (A) the aggregate gross invoiced amount of all US Product sold by such Product Seller, its Affiliates and distributors during such calendar quarter (the "Reporting Period"); and (B) the deductions taken in calculating Net Sales and the US Net Sales for the US Product during the Reporting Period and (ii) pay to Teva an amount equal to[information redacted] of the US Net Sales of the US Product for such calendar quarter (the "Royalty Payment"). [information redacted]
- ii. During the period of time from the Buyer Selling Start Date and for a period of two (2) years thereafter, Buyer shall keep, and shall cause each Product Seller, as applicable, to keep, complete and accurate books and records of account containing all information required for the computation and verification of Net Sales.

- iii. At Teva's request (not to be made more than once in any twelve (12) month period (other than for cause audits) and not more than two (2) years after delivery of the report setting forth such computation) and expense, Buyer will, and will cause each Product Seller to, permit a reputable firm of independent accountants that has substantial experience auditing generic pharmaceutical companies (which accountants shall not have been hired or paid on a contingency basis and which accountants shall have experience auditing generic pharmaceutical companies) and is reasonably acceptable to Buyer, to have access at Buyer's offices in the United States upon reasonable written advanced notice and during ordinary working hours to such records as may be necessary to audit any computation of Net Sales. Such accountants shall sign a confidentiality agreement and shall in no event provide any product pricing, product costs or other competitively sensitive information to Teva. Such independent accountants shall simply provide a report to Teva stating whether Product Seller's determination of Net Sales is accurate or inaccurate, and if inaccurate, the amount of such inaccuracy. If as a result of any inaccuracies set forth in such report, Teva was underpaid, Buyer shall pay such unpaid amount to Teva together with interest on such amount at the then prime rate (as reported in the Wall Street Journal) per annum for each day such payment was delayed. In the event of any dispute between the Parties regarding the findings of any such inspection or audit, the Parties shall initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within a commercially reasonable period of time, such dispute shall be resolved by an accountant from an internationally recognized independent accounting firm that is mutually agreeable to both of the Parties, and such accountant's determination shall be binding. Further, in the event it is determined that Teva was underpaid by ten percent (10%) or more of the total amount that should have been paid, Buyer shall pay for the costs and expenses of the audit, including by reimbursement to Teva of any and all such amounts to the extent Teva previously paid such amounts. Notwithstanding anything contained herein to the contrary, neither Party shall disclose to the other Party, and neither Party shall have access to the other Party's, product pricing, products cost or other competitively sensitive information.
 - (c) All currency amounts referred to in this Agreement are in U.S. Dollars, unless otherwise specified.
- (d) Buyer shall allocate the Purchase Price (along with all other items of consideration for income tax purposes) among the Purchased Assets as of the Effective Date in accordance with applicable Law (including in accordance with Section 1060 of the Code) and as set forth in Schedule IV (the "Allocation"). Each of the Parties shall report (and cause its respective Affiliates to report) the transactions contemplated by this Agreement in a manner consistent with applicable Law and the terms of this Agreement, including the Allocation, and agrees not to take any position inconsistent therewith in any Tax Return, in any Tax refund claim, in any litigation or otherwise.
- (e) All transfer, sales, value added, registration, documentary, stamp duty and similar Taxes solely and directly related to payment of the Purchase Price ("<u>Transaction Taxes</u>") which are payable in connection with the transactions contemplated hereby will be borne by Teva. If applicable Laws require that any Transaction Taxes be withheld from any amounts due to Teva under this Agreement, Buyer shall pay such additional amounts as shall be required to ensure that the net amount received by Teva will equal the full amount which would have been received and retained by Teva had no such deduction or withholding been made. Teva shall cooperate with Buyer in claiming exemptions from such deductions or a reduced withholding tax rate as allowable under any agreement or treaty from time to time in effect.

6. <u>Competition</u>.

- (a) [information redacted]
- (b) Nothing contained in this Agreement will be construed as prohibiting either Party or any of its Affiliates from: (i) acquiring (whether by merger, asset or stock acquisition or otherwise) another company, business or line of products (including by license thereof or through investment therein), which makes, has made, sells, has sold, markets, has marketed, distributes or has distributed or otherwise represents a product which is substantially similar to or equivalent to the Product that is not a Competitive Product and continuing to operate such company, business or line of products following such acquisition; or (ii) entering into a joint venture, alliance or other similar collaborative arrangement with any third party which joint venture makes, has made, sells, has sold, markets, has marketed, distributes or has distributed a product which is substantially similar to or equivalent to the Product that is not a Competitive Product and continuing to participate in such collaboration.
- (c) Teva acknowledges that a breach or threatened breach of this <u>Section 6</u> could give rise to irreparable harm to Buyer, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by Teva of any such obligations, Buyer shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to seek equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond). In the event of a violation or breach by Teva or any of its Affiliates, of any agreement set forth in this <u>Section 6</u>, the term of the obligations set forth in this <u>Section 6</u> shall be extended by a period equal to the duration of such violation or breach.
- (d) Teva acknowledges that the geographic boundaries, scope of prohibited activities and the duration of the provisions of this Section 6 are reasonable and are no broader than are necessary to protect the legitimate business interests of Buyer, including the ability of Buyer to realize the benefit of its bargain under this Agreement and to enjoy the goodwill of the business related to the Products, and that such restrictions constitute a material inducement to Buyer to enter into this Agreement and consummate the transactions contemplated by this Agreement. In the event that any covenant contained in this Section 6 should ever be adjudicated to exceed the time, geographic, product or service, or other limitations permitted by applicable Law in any jurisdiction, then any court is expressly empowered to reform such covenant, and such covenant shall be deemed reformed, in such jurisdiction to the maximum time, geographic, product or service, or other limitations permitted by applicable Law. The covenants contained in this Section 6 and each provision hereof are severable and distinct covenants and provisions. The invalidity or unenforceability of any such covenant or provision as written shall not invalidate or render unenforceable the remaining covenants or provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such covenant or provision in any other jurisdiction.

(e) [information redacted].

7. Representations and Warranties; Covenants.

- (a) Each of the Parties represents and warrants to the other Party that:
- i. such Party has the requisite corporate or other organizational as applicable power and authority to enter into this Agreement and the other documents and instruments delivered hereunder and to consummate the transactions contemplated hereby and thereby;
- ii. such Party is duly organized, validly existing and in good standing under the laws of the state of its incorporation and is qualified to do business in each jurisdiction where such qualification is necessary;
- iii. neither the execution and delivery of this Agreement or any other document or instrument delivered hereunder by such Party, nor its performance hereunder or thereunder, conflicts with or will result in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, indenture, license, agreement or other instrument or obligation to which it is a party or by which it or any of its properties or assets may be bound; or to its best knowledge, violates any applicable Law;
- iv. this Agreement is a legal, valid and binding agreement of such Party, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at law;
- v. to the knowledge of such Party, there are no claims, suits, actions or other proceedings pending or threatened against such Party at law or in equity before or by any Governmental Entity, which may in any way materially adversely affect the performance of such Party's obligations under this Agreement or the other documents and instruments delivered hereunder or the transactions contemplated hereby or thereby;
- vi. such Party has not, and will not, directly or indirectly, enter into any contract or any other transaction with any third party that conflicts or derogates from its undertakings hereunder; and
- vii. such Party has not been debarred, is not subject to debarment, and will not use, in any capacity in connection with the obligations to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the Federal Food, Drug and Cosmetic Act.

- (b) In addition, Teva hereby represents and warrants to Buyer that, as of the Effective Date:
 - i. it has the requisite corporate power and authority to own and to use the Purchased Assets in the Territory;
- ii. to its knowledge, (A) there is no proceeding, material suit, claim or similar action pending or threatened in the Territory against the Purchased Assets; (B), no proceeding or inquiry is pending in the Territory, or has been threatened or made in the Territory, as applicable, in writing, by any Governmental Entity relating to any Product Marketing Authorization; (C) Teva is in compliance with the written procedures, record-keeping and FDA reporting requirements for Adverse Event reporting requirements set forth in 21 C.F.R. Part 314 regarding Product, and (D) no third party has challenged or has threatened to challenge Teva's sole and exclusive right, title or interest in, to or under the Purchased Assets in the Territory;
- iii. except as set forth in this Agreement, it is not necessary for Teva to take any action or to obtain any approval, consent or release by or from any third party, governmental or other, to enable Teva to enter into or perform this Agreement;
- iv. to its knowledge, it is in compliance with, and is not in violation of any, applicable Law in the Territory, the violation of or noncompliance with which could have a material adverse effect on the Purchased Assets;
- v. to its knowledge, (A) no event has occurred that would reasonably be expected to require or result in the termination, material adverse modification, suspension, revocation or cancellation of any Product Marketing Authorization; and (B) any copies of applications, approvals, written notices of inspectional observations, establishment inspection reports and any other material correspondence received from any Governmental Entity in the Territory, including the FDA, with respect to a Product provided by Teva are accurate and complete in all material respects;
- vi. (A) it has good, valid and marketable title in the Territory to the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances, (B) the Current Inventory includes raw materials necessary for the manufacture of Product after the Effective Date, (C) the tangible assets included in the Purchased Assets are maintained in accordance with normal industry practice and in good operating condition and repair (subject to normal wear and tear), and (D) to its knowledge, there are no Liabilities in the Territory relating to the Purchased Assets other than amounts payable in the ordinary course of business;

- vii. (A) Schedule 7(b) sets forth a true, complete and accurate list of Current Inventory in the possession or control of Teva, or otherwise owned by Teva, existing as of the Effective Date, classifying such Current Inventory by, as applicable, lot number, status, expiration date, unit number, material, units, and age and Teva's value, for such Current Inventory (the "Current Inventory Value"); and (B) Teva has not introduced or sold Product in the US in a manner inconsistent with the actual demand of the market for Product (i.e., "channel stuffing" or "trade loading"). For the purposes of clause (A) herein, "control" shall include Current Inventory held by [information redacted] on behalf of Teva.
- viii. to its knowledge, none of the Purchased Assets nor any use thereof infringe upon or misappropriate the intellectual property or proprietary rights of any third party in the Territory;
- ix. to its knowledge, (A) there are no material contracts related to the Products, other than the [information redacted], which is being assigned by Teva, and assumed by Buyer, on the Effective Date pursuant to the Bill of Sale, (B) no party to the [information redacted] is in violation of or in default under such contract;
- x. (A) it has timely filed all material Tax Returns that it was required to file in the Territory relating to the Purchased Assets, and such Tax Returns are true, correct and complete in all material respects; (B) it has withheld and timely paid all Taxes due and payable relating to the Purchased Assets in the Territory (whether or not shown on any Tax Returns); (C) there are no liens for Taxes in the Territory on the Purchased Assets, and to its knowledge there is no Tax Authority in the Territory in the process of imposing any liens for Taxes on any of the Purchased Assets, other than liens for Taxes not yet due and payable; (D) to its knowledge, it is not a party to any action or audit in the Territory by any Tax Authority with respect to the Purchased Assets, nor has it received written notice of any pending or threatened audits or actions by any Tax Authority in the Territory with respect to the Purchased Assets; (E) all deficiencies asserted, or assessments made, against it with respect to the Purchased Assets as a result of any examinations by a Tax Authority in the Territory have been fully paid; (F) no claim has ever been made by any Governmental Entity in a jurisdiction where it does not file Tax Returns relating to the Purchased Assets that it is or may be subject to taxation by that jurisdiction; and (G) it has not treated any of the Purchased Assets as stock, partnership interest or any other equity interest for any Person for U.S. federal income tax purposes; and
- xi. all items made available to Buyer at any time before the Effective Date in the virtual data room established in connection with the transactions contemplated by this Agreement are materially accurate and complete in all material respects.
 - (c) Buyer hereby represents and warrants to Teva that:
- i. Buyer has conducted its own independent investigation, review, and analysis of the Purchased Assets, the Products and the Assumed Liabilities, has formed an independent judgment concerning the Purchased Assets, the Products, and the Assumed Liabilities and acknowledges that it has been provided adequate access to the personnel, assets, and applicable documents and data of Teva, for such purpose;

- ii. (A) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, Buyer has relied solely upon its own investigation and the express representations and warranties of Teva set forth in this Agreement (including the related portions of any disclosure schedules attached hereto) and any other document or instrument delivered hereunder, including the contents in the data room; and (B) neither Teva nor any other Person has made, and Buyer is not relying on, any representation or warranty, express or implied, as to the accuracy or completeness of any information regarding Teva, its Affiliates, the Purchased Assets, the Products or the Assumed Liabilities (including any information, documents and materials made available to Buyer in any data room or any repository of information, management presentations, or in any other form in expectation of the transactions contemplated hereby) not expressly set forth in this Agreement, and, other than the indemnification obligations of Teva, neither Teva nor any other Person will have or be subject to any Liability to Buyer or any other Person resulting from the distribution to Buyer or its representatives or Buyer's use of any such information; and
- iii. Buyer acknowledges and agrees that Teva does not guarantee that FDA or other Governmental Entity approval will be obtained for any initial filing of or supplemental filing to any NDA or other Product Marketing Authorization and makes no representation or warranty hereunder with respect thereto.

(d) Buyer hereby covenants that:

- i. if not already applied for, as soon as reasonably possible following the Effective Date, it shall apply for and initiate applicable processes to obtain and establish new NDC Numbers for Product sold by a Product Seller in the US and notify Teva thereof;
- ii. to the extent required by the [information redacted], Buyer shall not, and shall not permit a Product Seller to, under any circumstances, directly or indirectly, (A) market, distribute, offer for sale or sell any Product or cause or permit any Product to be marketed, distributed, offered for sale or sold in or for any place in the world other than the Licensed Territory for such Product; or (B) market, distribute, offer for sale or sell any Product or cause or permit any Product be marketed, distributed, offered for sale or sold to any Person who intends to, or could reasonably be expected to, market, distribute, offer for sale or sell a Product any place in the world other than the Licensed Territory of such Product;
- iii. Buyer shall not, and shall not permit any Product Seller to, use in any manner any trademark, tradename or service mark of Teva not transferred hereunder;
- iv. Buyer shall, at its own cost and expense, (A) obtain its own NDCs for the Teva labeled, finished product inventory included in the Current Inventory or Retained Inventory transferred pursuant to Section 2(g), (B) apply "blackout labels" to such inventory to obscure Teva's name, marks and related NDC numbers on such inventory, and (C) relabel all such inventory exclusively into Buyer-identified labeling, prior to selling or delivering any such inventory into the US;

- v. Buyer shall use commercially reasonable efforts to request a waiver of any PDUFA fees paid by Teva for sale of the US Product in the US during fiscal year 2025, and shall remit the net benefits of such waiver, if any, to Teva following Buyer's receipt thereof;
- vi. after the Effective Date, respectively, it shall assume all responsibility for responding to any medical inquiries or complaints about such Product; and
- vii. it hereby waives compliance by Teva with the provisions of any so-called "bulk transfer law" of any jurisdiction in connection with the transfer of the Purchased Assets, it being understood that any Liabilities arising out of the failure of Teva to comply with the requirements of any provisions of any so-called "bulk transfer law" of any jurisdiction shall be retained by Teva.
 - (e) [information redacted].
- (f) All representations and warranties contained in this Section 7 shall survive the Effective Date and shall remain operative and in full force and effect for a period of nine (9) months following the Effective Date. Notwithstanding anything herein to the contrary, any breach of a representation or warranty that is the subject of a claim that is asserted in writing prior to the time at which it would otherwise terminate pursuant to this Section 7(e) shall survive with respect to such claim or any dispute with respect thereto until the final resolution thereof.
- 8. EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER PARTY IS NOT MAKING AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS, ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NON-INFRINGEMENT. WITHOUT DEROGATING FROM THE GENERALITY OF THE FOREGOING, EXCEPT AS EXPRESSLY SET FORTH HEREIN, BUYER ACKNOWLEDGES AND AGREES THAT TEVA IS SELLING THE PURCHASED ASSETS ON AN "AS IS" AND "WHERE IS" BASIS AND TEVA MAKES NO REPRESENTATION OR WARRANTY HEREUNDER WITH RESPECT TO THE PURCHASED ASSETS OR THE PRODUCTS INCLUDING, WITHOUT LIMITATION, ANY GUARANTEE THAT FDA APPROVAL WILL BE OBTAINED, RELATING TO THE MANUFACTURE AND/OR MARKETING OF THE PRODUCT.

9. <u>Indemnification</u>.

(a) Subject to Section 10, Buyer shall indemnify, defend and hold Teva and its Affiliates and their respective officers, directors, employees, agents and subcontractors ("Teva Indemnified Parties") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees and expenses) ("Losses") arising out of or resulting from (i) Buyer's breach of any of its representations and warranties set forth in this Agreement, (ii) Buyer's breach of any of its covenants or agreements set forth in this Agreement or in any certificate, instrument or other document delivered pursuant to this Agreement and (iii) any and all Assumed Liabilities.

(b) Subject to Section 10, Teva shall indemnify, defend and hold Buyer and its Affiliates and their respective officers, directors, employees, agents and subcontractors ("Buyer Indemnified Parties") harmless from and against any and all Losses arising out of or resulting from (i) Teva's breach of any of its representations and warranties obligations set forth in this Agreement, (ii) Teva's breach of any of its covenants or agreements set forth in this Agreement and (iii) any and all Liabilities relating to the Excluded Assets or Excluded Liabilities.

Buyer Indemnified Parties and Teva Indemnified Parties are sometimes referred to herein as "Indemnified Parties".

Limitations on Liability.

- (a) The amount of any Losses for which either Teva or Buyer, as the case may be, is liable shall be reduced by the aggregate amount actually recovered under any indemnity agreement, contribution agreement, or any other agreement between any of the Indemnified Parties, on the one hand, and any third party, on the other hand, with respect to such Losses, net of any actual and documented (which will be provided to Teva upon written request) expenses incurred in recovering such amounts.
- (b) Notwithstanding the other provisions of Section 9 and Section 10, except for claims based on fraud, Teva shall not have any indemnification obligations for any individual Losses arising out of or resulting from Section 9(b)(i) unless and until the aggregate amount of all such Losses exceed seventy thousand US dollars (US\$70,000.00) (the "Deductible"), in which event Teva shall be required to pay the full amount of such Losses in excess of the Deductible, but only up to a maximum aggregate amount of ten percent (10%) of the sum of the Purchase Price and the Royalty Payments actually received by Teva. Notwithstanding the other provisions of Section 9 and Section 10, except for claims based on fraud, Teva shall not have any indemnification obligations for any individual Losses arising out of or resulting from Section 9(b)(ii) unless and until the aggregate amount of all such Losses, but only up to a maximum aggregate amount of ten percent (10%) of the sum of the Purchase Price and the Royalty Payments actually received by Teva.
- (c) Except for claims based on fraud or a breach of <u>Section 13</u>, in no event shall either Party or its Affiliates have any liability to the other Party for indirect, incidental, special or consequential damages (including lost profits) of the other arising out of the performance or failure to perform any obligations set forth herein, irrespective of whether attributable to breach of contract, breach of warranty, negligence, strict liability or otherwise; provided that the foregoing does not limit any of the obligations or Liability of either Party or its Affiliates under <u>Section 9</u> with respect to claims of unrelated third parties.

Except for claims based on fraud or breach of Section 13, the rights of the Buyer Indemnified Parties and the Teva Indemnified Parties under Section 9 shall be the sole and exclusive monetary remedy of the Buyer Indemnified Parties and the Teva Indemnified Parties, as the case may be, with respect to matters covered hereunder, including, but not limited to, claims relating to the Product Marketing Authorizations, the Products, the Purchased Assets or the Assumed Liabilities, and no Indemnified Party shall have any other cause of action or remedy at law, in equity for breach of contract, rescission, tort, or otherwise against the other Party arising under or in connection with this Agreement and the matters and transactions contemplated hereby. Without limiting the generality of the preceding sentence, except in the case of specific performance and for claims based on fraud or breach of Section 13, no legal action sounding in contribution, tort, or strict liability (in each case, other than claims made or contemplated by Section 9) may be maintained by an Indemnified Party, or any of its officers, directors, other governing bodies, employees, equity holders, owners, agents, successors, or assigns, against Teva or Buyer or any of their Affiliates with respect to any matter that is the subject of Section 9, and Buyer and Teva, for themselves and the other Indemnified Parties and each of their respective officers, directors, other governing bodies, employees, equity holders, owners, Affiliates, representatives, agents, successors, and assigns, hereby waive any and all statutory rights of contribution or indemnification (other than rights of indemnification hereunder) that any of them might otherwise be entitled to under any Law with respect to any matter that is the subject of Section 9.

11. <u>Indemnification Procedure</u>.

In order for an Indemnified Party to be entitled to any indemnification provided for under this Agreement, such Indemnified Party will, within a reasonable period of time following the discovery of the matters giving rise to any Losses, notify the indemnifying party under this Section 11 (the "Indemnifying Party") in writing of its claim for indemnification for such Losses, specifying in reasonable detail the nature of such Losses and the amount of the liability estimated to accrue therefrom; provided, however, that failure to give such notification will not affect the indemnification provided hereunder, except to the extent the Indemnifying Party will have been prejudiced as a result of such failure. Thereafter, the Indemnified Party will deliver to the Indemnifying Party, within a reasonable period of time after the Indemnified Party's receipt of such request, all information and documentation reasonably requested by the Indemnifying Party with respect to such Losses.

- If the indemnification sought pursuant hereto involves a claim made by a third party against the Indemnified Party (a "Third Party (b) Claim"), the Indemnifying Party will be entitled to assume the defense of such Third Party Claim at its own expense with counsel selected by the Indemnifying Party. Should the Indemnifying Party so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. If the Indemnifying Party assumes such defense, the Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense (which expense shall not constitute a Loss), separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable and documented fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Third Party Claim as provided above). If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, all of the Parties will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, it will defend or prosecute it diligently and the Indemnifying Party will obtain the prior written consent of the Indemnified Party (not to be unreasonably withheld, conditioned or delayed) before entering into any settlement, compromise or discharge of such Third Party Claim if (i) such settlement, compromise or discharge does not relate solely to monetary damages, (ii) such settlement, compromise or discharge does not expressly unconditionally and completely release the Indemnified Party from all Losses and liabilities with respect to such Third Party Claim and (iii) the Indemnifying Party is not directly paying the full amount of the Losses in connection with such Third Party Claim. Whether or not the Indemnifying Party will have assumed the defense of a Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party's prior written consent (not to be unreasonably withheld, conditioned or delayed).
- (c) Each Indemnified Party shall take, and shall cause its Affiliates to take, all commercially reasonable steps to mitigate any Loss upon becoming aware of any event or circumstance that would reasonably be expected to, or such Indemnified Party believes does, give rise thereto, including incurring costs only to the minimum extent necessary to remedy the breach that gives rise to such Loss; provided, that such failure to use such efforts in accordance with the foregoing shall not relieve the Indemnifying Party of its indemnification obligations under Section 9 except and only to the extent that the Indemnifying Party is prejudiced thereby.
- (d) All indemnification payments made pursuant to <u>Section 9</u> shall be treated as an adjustment to the Purchase Price by the Parties for Tax purposes, unless otherwise required by applicable Law.
- 12. <u>Insurance</u>. At all times for three (3) years after the Effective Date, Buyer shall maintain product liability and other insurance (or self-insurance) for itself in amounts which are reasonable and customary in the US pharmaceutical industry, provided in no event shall the product liability insurance amounts be less than ten million United States dollars (\$10,000,000.00) per occurrence and ten million United States dollars (\$10,000,000.00) in the aggregate limit of liability per year. Buyer shall cause Teva to be named an "additional insured" under the policy. Buyer shall provide written proof, in the form of a certificate of insurance, of such insurance and additional insured status to Teva upon request. Buyer agrees to provide prompt written notice to Teva, upon becoming aware of any cancellation, material change in, or non-renewal, of required insurance which prevents compliance with the requirements set forth herein. Failure to maintain required insurance may be deemed a material breach of this Agreement. Required insurance shall be placed with carriers having a minimum A.M. Best (or equivalent) rating of A- or better.

13. <u>Confidentiality</u>. Each of the Parties agrees that:

- (a) Except as required by Law, order of a Governmental Entity or the rules of any applicable stock exchange: (i) it will not disclose any Confidential Information, as defined herein, of the other Party to any third party at any time without the prior written consent of the disclosing Party; (ii) it will not make use of any Confidential Information of the other Party for any purpose other than for the purposes set forth in, or in furtherance of the transactions contemplated by, this Agreement; and (iii) without limitation, it will use all Commercially Reasonable Efforts to prevent unauthorized publication or disclosure by any Person of such Confidential Information; provided that each Party may, without the consent of the other Party, make announcements regarding the status and terms (including price terms) of this Agreement or the transactions contemplated hereby to their respective representatives and indirect current or prospective limited partners or investors or otherwise in the ordinary course of their respective businesses, in each case, so long as such recipients are obligated to keep such information confidential.
- (b) With respect to any Confidential Information required to be disclosed by Law, order of a Governmental Entity or the rules of any applicable stock exchange by a Party that has received such Confidential Information from the other Party, the receiving Party shall promptly notify the disclosing Party as to the demand for such disclosure and shall reasonably assist the disclosing Party in seeking to limit the scope of such disclosure or ensuring that the same is accorded confidential treatment. Any such disclosure by the receiving Party shall in no event otherwise change, alter or diminish the confidential and/or proprietary, status of such Confidential Information, or treatment as such by the receiving Party, under this Agreement. In addition, each Party shall have the right to disclose information related to the existence and/or terms and conditions of this Agreement as follows: (i) pursuant to the Closing Press Release, (ii) to the extent necessary (as reasonably determined by its legal counsel) to be disclosed in order to comply with the rules and regulations of the United States Securities and Exchange Commission (or another similar securities exchange authority in Territory), and (iii) with respect to Buyer, to the extent reasonably necessary for the manufacture, commercialization and other exploitation of the Purchased Assets.
- (c) All Confidential Information in any form will be returned to the Party who disclosed the Confidential Information within thirty (30) days after written request by the disclosing Party; provided that the Parties may retain: (i) one (1) copy of such Confidential Information with its legal counsel as a record of the receiving Party's ongoing confidentiality obligations under this Agreement and as expressly provided in Section 2(e) hereof; (ii) a backup in electronic form in backup tapes, servers or other sources as a result of receiving Party's normal back up procedures for electronic data, provided that no attempt is made to recover such Confidential Information from back-up tapes, servers or other sources (except for legal or compliance purposes).

- (d) For purposes of this Agreement, the term "Confidential Information" means all information disclosed by a Party related to the subject matter herein, including, but not limited to, know-how, trade secrets, formulae, data, inventions, US Product NDA, technology and other information, including financial information, in whatever form, related to the registration, manufacture, sale or marketing of the Products, marketing strategies or business of the disclosing Party, related to this Agreement, provided that, subject only to the exception in clause (i) below and Section 2(c)(ii), all information regarding the Purchased Assets constitutes solely Buyer's Confidential Information and Buyer shall constitute the disclosing Party therefor. Without limiting the generality of the foregoing, the existence of this Agreement and each of its provisions shall be considered Confidential Information of each Party. Confidential Information shall not include any information that (i) is or becomes public knowledge through no fault of the receiving Party; (ii) rightfully was in the receiving Party's possession at the time of disclosure (as evidenced by written records); (iii) was independently created by the receiving Party (as evidenced by written records) without use or reference to any Confidential Information; or (iv) is received from a third party having the lawful right to disclose the information. Notwithstanding anything to the contrary set forth in clause (ii) above, it is understood and agreed that in no event will the Confidential Information retained by Teva under Section 2(e), be deemed to be excluded from the term "Confidential Information." Confidential Information shall not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information and any combination of features shall not be deemed to be within the foregoing exceptions merely because individual features are known.
- 14. <u>FDA Notice of Transfer of US Product NDA</u>. Within ten (10) Business Days after the Effective Date, Teva shall dispatch (and shall cause the applicable Affiliate to dispatch) one (1) or more letters to the FDA, in substantially the form set forth in <u>Exhibit B</u>, with respect to the US Product NDA. The letter should indicate that a copy of the US Product NDA and applicable regulatory correspondence has been, or will be in accordance with the terms of this Agreement, submitted to Buyer to satisfy the transfer. A copy of the letter(s) shall be provided by Teva to Buyer upon submission to the FDA. Within five (5) Business Days of receipt by Buyer of the letter and confirmation of its delivery to FDA, Buyer will dispatch an Acceptance Letter(s) to the FDA in the form set forth in <u>Exhibit C</u> with respect to the US Product NDA (such date of dispatch, the "<u>US Product NDA Transfer Date</u>").

15. <u>Transfer of Documentation</u>.

- (a) Teva shall take all reasonably necessary actions to transfer all documentation, via electronic copies, included in the Purchased Assets to Buyer as reasonably practicable after the Effective Date, and US Product FDA Correspondence (including the pharmacovigilance data) shall be transferred no later than ninety (90) calendar days after the US Product NDA Transfer Date. At the Effective Date, Teva shall deliver to Buyer electronic versions of the contents of the virtual data room (as of immediately prior to the Effective Date) established in connection with the transactions contemplated by this Agreement, except for any contents that may not be delivered by Teva to a third-party pursuant to the [information redacted].
- (b) As further set forth on <u>Schedule V</u> hereto, after the US Product NDA Transfer Date, Buyer (as the US Product NDA holder) shall have the responsibility for the reporting of pharmacovigilance data, including AE processing and submission to the FDA, and preparation and submission to FDA of any other pharmacovigilance data reports such as Periodic Adverse Drug Experience Report (PADER). After the US Product NDA Transfer Date, Teva shall forward to Buyer all AE reports (as source documents) within three (3) Business Day after receipt of such AE report by Teva.

16. <u>Closing</u>.

- (a) The closing of the purchase and sale of the Purchased Assets is being consummated simultaneously with the exchange of signatures to this Agreement by the Parties by electronic transmission.
 - (b) Teva shall deliver or cause to be delivered to Buyer (unless previously delivered), the following on the Effective Date:
 - i. duly executed counterparts of the Bill of Sale, Domain Assignment Agreement, Trademark Assignment Agreement, Trademark License Agreement and Transition Services Agreement; and
 - ii. a properly completed and duly executed IRS Form W-9.
 - (c) Buyer shall deliver or cause to be delivered to Teva, the following on the Effective Date:
 - i. the Purchase Price;
 - ii. duly executed counterparts of the Bill of Sale, Domain Assignment Agreement, Trademark Assignment Agreement, Trademark License Agreement and Transition Services Agreement; and
 - iii. [information redacted].
- 17. <u>Maintenance of Records</u>. Buyer will preserve all books and records included within the Purchased Assets for applicable periods of time required by the FDA and any other applicable Governmental Entity and, subject to the confidentiality restrictions contained herein, make such books and records available for inspection and copying by Teva or its agents upon reasonable request and upon reasonable notice.
- 18. <u>Governing Law; Jurisdiction; Venue</u>. This Agreement shall be governed, interpreted and construed in accordance with the substantive laws of the State of Delaware, U.S.A., without regard to its conflict of laws principles. Each of the Parties irrevocably submits to the exclusive jurisdiction and venue of the United States District Court for State of Delaware over any action or proceeding arising out of or relating to this Agreement, and each hereby waives the defense of any inconvenient forum for the maintenance or such action or proceeding. To the extent that it may otherwise be applicable, the Parties expressly agree to unconditionally waive and exclude from the operation of this Agreement the United Nations Convention on Contracts for the International Sale of Goods, concluded at Vienna, on 11 April 1980, as amended and as may be amended further from time to time.

- 19. WAIVER OF JURY TRIAL. BUYER AND TEVA HEREBY WAIVE, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION (I) ARISING UNDER THIS AGREEMENT OR (II) IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO IN RESPECT OF THIS AGREEMENT OR ANY OF THE TRANSACTIONS RELATED HERETO, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER IN CONTRACT, TORT, EQUITY, OR OTHERWISE. THE PARTIES TO THIS AGREEMENT EACH HEREBY AGREE AND CONSENT THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OF A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.
- 20. <u>Notices</u>. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (a) on the date delivered, if personally delivered; (b) on the Business Day after being sent overnight by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery; or (c) three (3) Business Days after mailing, if mailed by U.S. postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable Party at the address set forth below; provided that a Party may change its address for receiving notice by the proper giving of notice hereunder:

if to Teva, to:

Teva Pharmaceuticals USA, Inc. 400 Interpace Parkway Parsippany, NJ 07054 Attention: Vice President, Business Development

With a copy (which shall not constitute notice) to: General Counsel, Global Operations

Teva Pharmaceuticals USA, Inc.

400 Interpace Parkway Parsippany, NJ 07054 [information redacted]

if to Buyer, to:

Eton Pharmaceuticals, Inc. 21925 Field Pkwy Suite 235 Deer Park, IL 60010 Attention: Chief Executive Officer

With a copy (which shall not constitute notice) to:

Morrison & Foerster LLP 12531 High Bluff Drive, Suite 100 San Diego, CA 92130 [information redacted]

- 21. <u>Independent Contractors</u>. The status of the Parties under this Agreement shall be that of independent contractors, without the authority to act on behalf of or bind each other. Nothing in this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties hereto.
- 22. <u>Entire Agreement; No Third-Party Beneficiaries; Amendment.</u> This Agreement (including its Exhibits, Schedules and each additional document, instrument or other agreement to be executed and delivered pursuant hereto) constitutes the entire agreement between the Parties with respect to its subject matter, and supersedes all prior agreements, arrangements, dealings or writings between the Parties, both written and oral (including any letter of intent, memorandum of understanding or term sheet), with respect to the subject matter hereof. Except as specifically provided herein, this Agreement is not intended to confer upon any Person other than the Parties any rights or remedies hereunder. This Agreement may not be amended or modified except in writing executed by the duly authorized representatives of each Party.
- 23. <u>Severability</u>. Should any part or provision of this Agreement be held unenforceable or in conflict with applicable Law, the invalid or unenforceable part or provision shall, provided that it does not affect the essence of this Agreement, be replaced with a revision which accomplishes, to the greatest extent possible, the original commercial purpose of such part or provision in a valid and enforceable manner, and the balance of this Agreement shall remain in full force and effect and binding upon the Parties hereto.
- 24. <u>Assignment</u>. The terms and provisions hereof shall inure to the benefit of, and be binding upon the Parties and their respective successors and permitted assigns. Any Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, to an Affiliate or to a successor in interest of the assigning Party by reason of merger, sale of all or substantially all of its assets or portion of its business which relates to the Product, or any similar transaction. Any permitted assignee or successor-in-interest will assume all obligations of its assignor under this Agreement. No assignment will relieve either Party of its obligations of confidentiality or responsibility for the performance of any obligation.
- 25. <u>Waiver</u>. No waiver by one Party of the other Party's breach or default hereunder shall be considered valid unless such waiver is set forth in writing and signed by the Party giving such waiver, and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such Party.
- 26. <u>Further Assurances</u>. Without limitation, each of the Parties shall use its Commercially Reasonable Efforts to take, or cause to be taken, all such further actions and to do, or cause to be done, including by its Affiliates, all things necessary, proper or advisable to consummate and make effective as promptly as possible, the transactions contemplated by this Agreement including, without limitation, notices to the FDA regarding the transfer of the US Product NDA from Teva to Buyer. Each Party shall bear its own costs related thereto.

- 27. <u>Counterparts</u>. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original but all of which, taken together, shall constitute one and the same instrument. PDF and facsimile signatures shall constitute original signatures.
- 28. <u>Expenses</u>. Except as otherwise expressly provided herein, each Party shall bear its own costs and expenses, including attorney, accountant, consultant and broker's fees, incurred in connection with the negotiation and execution of this Agreement, the related agreements and the consummation of the transactions contemplated hereby and thereby.
- 29. <u>Interpretation; Headings</u>. As used in this Agreement, unless the context otherwise requires words describing the singular number include the plural, and vice versa; words denoting any gender include all genders; the word "including" means "including, without limitation"; and the words "hereof," "herein" and "hereunder," and words of similar import, refer to this Agreement as a whole and not to any particular provision of this Agreement. The headings contained herein are for the sole purpose of convenience of reference, and do not in any way limit or affect the meaning or interpretation of any of the provisions of this Agreement.

[The remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, by signature below, the Parties agree this Agreement is effective as of the Effective Date.

TEVA PHARMACEUTICALS USA, INC.

By:	Date:	
Name:		
Title:		
By:	Date:	
Name:		
Title:		
ETON PHARMACEUTICALS, INC.		
By:	Date:	
Name:		
Title		

Eton Pharmaceuticals Advances Its Commitment to Rare Disease with the Acquisition of Galzin®

- Adds an additional commercial and strategic rare disease product to Eton's portfolio
- Galzin® is FDA-approved for the treatment of the ultra-rare metabolic condition of Wilson Disease

DEER PARK, Ill., Jan. 3, 2025 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc ("Eton" or the "Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced that it has acquired Galzin® (zinc acetate).

"This acquisition furthers our mission of supporting life-saving treatments for conditions impacting ultra rare patient populations. Galzin® is a critical medication for patients with Wilson Disease, and we look forward to supporting these patients with our comprehensive Eton Cares patient support program," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Galzin® is FDA-approved as a maintenance treatment of patients with Wilson Disease who have been initially treated with a chelating agent. It is estimated that less than 5,000 patients in the United States are currently being treated for Wilson Disease.

Eton expects to assume the commercialization of the product in the United States in the first quarter of 2025 with its metabolic sales force supporting healthcare professionals who treat Wilson Disease. Once available, Eton plans to offer the product through its Eton Cares patient support program that provides high-touch, personalized service tailored for rare disease patients and their providers. The program will offer a \$0 co-pay for all qualified commercial patients, provide prescription fulfillment, insurance benefits investigation, educational support, and other services designed to help patients access treatment.

As part of the transaction, Eton has also acquired European rights to the product, where it is commercialized under the tradename Wilzin® by a third party. Under an existing agreement, Eton will continue to supply the product to the third party and the third party is responsible for all commercialization activities in Europe.

Stifel served as exclusive financial advisor to Eton on the transaction.

INDICATION AND IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION

INDICATION

Zinc acetate therapy is indicated for maintenance treatment of patients with Wilson's disease who have been initially treated with a chelating agent

Warning and Precautions

• Copper Deficiency: Several post-marketing cases reported that zinc acetate taken over extended periods of time (i.e., months to years) may result in decreased enteral copper absorption and copper deficiency. The cases reported the following complications of copper deficiency: anemia, granulocytopenia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, and myeloneuropathy.

If a patient develops signs and/or symptoms of copper deficiency during treatment with zinc acetate, interrupt zinc treatment and measure zinc, 24-hr urinary copper, and non-ceruloplasmin bound copper (NCC) levels. Consider restarting zinc acetate treatment based on periodic monitoring of 24-hr urinary copper and NCC levels.

• Gastric Ulcer: There have been postmarketing reports of gastric ulcers with long-term use of zinc acetate. The cases reported the complications of anemia and gastric ulcer perforation with peritonitis. In some cases, ulcers persisted after treatment until zinc acetate was discontinued.

If a patient develops signs and/or symptoms of gastric ulcer during treatment with zinc acetate, discontinue zinc treatment. Most patients showed improvement after cessation of zinc treatment.

- General: Zinc acetate is not recommended for the initial therapy of symptomatic patients because of the delay required for zinc-induced increase in enterocytic metallothionein and blockade of copper uptake. Symptomatic patients should be treated initially, using chelating agents. During initial therapy, neurological deterioration may occur as stores of copper are mobilized. Once initial therapy has been completed, and the patient is clinically stable, maintenance treatment with zinc acetate can be considered, but patients may be continued on initial therapy as clinically indicated.
- Information for Patients: Patients should take GALZIN® on an empty stomach, at least one hour before or two to three hours after meals. Capsules should be swallowed whole, not opened or chewed. In the rare event of gastric intolerance of zinc, generally occurring with the morning dose, this dose may be taken between breakfast and lunch. Patients must be clinically monitored to determine the adequacy of zinc acetate therapy. Since strict adherence to the zinc regimen is essential for optimal control of copper distribution and metabolism, the physician must reinforce the need for compliance at each contact with the patient.
- Monitoring Patients: Patients should be monitored primarily by assessment of existing signs and symptoms of Wilson's disease and 24-hour urine copper. Neuropsychiatric evaluations including speech as well as liver function tests including bilirubin and aminotransferases, should be done as appropriate.

Adverse Reactions

The following adverse reactions associated with the use of zinc acetate were identified from postmarketing reports. Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Investigations: elevations of serum alkaline phosphatase, amylase, and lipase lasting from weeks to months suggesting pancreatitis; the levels usually return to high normal within the first one or two years of zinc therapy.

Please see Full Prescribing Information for more information.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has six commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has three additional product candidates in late-stage development: ET-400, ET-600, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at www.etonpharma.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Eton to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding Eton's business strategy, Eton's plans to develop and commercialize its product candidates, the safety and efficacy of Eton's product candidates, Eton's plans and expected timing with respect to regulatory filings and approvals, and the size and growth potential of the markets for Eton's product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's development programs and financial position are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist

Investor Relations:

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