

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

SCHEDULE TO

**Tender Offer Statement under Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934
(Amendment No. 1)**

PREVAIL THERAPEUTICS INC.

(Name of Subject Company (Issuer))

TYTO ACQUISITION CORPORATION
(Offeror)
a wholly-owned subsidiary of

ELI LILLY AND COMPANY
(Parent of Offeror)
(Names of Filing Persons)

Common Stock par value \$0.0001 per share
(Title of Class of Securities)

74140Y101
(CUSIP Number of Class of Securities)

Anat Hakim
Senior Vice President, General Counsel and Secretary
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Telephone: (317) 276-2000

Copies to:

Raymond O. Gietz, Esq.
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767 Fifth Avenue
New York, NY 10153
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(Name, address, and telephone number of person authorized to receive notices and communications on behalf of filing persons)

CALCULATION OF FILING FEE

Transaction Valuation*	Amount of Filing Fee**
\$895,944,268.62	\$97,747.52

* Estimated for purposes of calculating the filing fee only. The transaction valuation was calculated as (a) an amount equal to the product of (i) \$22.88, the average of the high and low sales prices per share of Prevail Therapeutics Inc. ("Prevail") common stock, par value \$0.0001 per share (each such share, a "Share"), on December 16, 2020, as reported by NASDAQ, and (ii) 40,899,855 Shares, which consist of (A) 34,248,033 Shares outstanding (inclusive of Shares that are subject to vesting or forfeiture restrictions granted pursuant to a Prevail equity incentive plan, program or arrangement) and (B) 6,651,822 Shares issuable pursuant to outstanding options with an exercise price less than \$22.50 (the "Closing Amount"), less (b) an amount equal to the product of (i) 6,651,822 Shares issuable pursuant to outstanding options with an exercise price less than the Closing Amount and (ii) the weighted average exercise price for such options of \$5.99 per Share. The calculation of the filing fee is based on information provided by Prevail as of December 14, 2020.

** The filing fee was calculated in accordance with Rule 0-11 under the Securities Exchange Act of 1934, as amended, and Fee Rate Advisory No. 1 for Fiscal Year 2021 beginning on October 1, 2020, issued August 26, 2020, by multiplying the transaction value by 0.00010910.

Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

Amount Previously Paid: \$97,747.52

Filing Party: Tyto Acquisition Corporation
Eli Lilly and Company

Form or Registration No.: Schedule TO-T

Date Filed: December 22, 2020

Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

- Third-party tender offer subject to Rule 14d-1.
- Issuer tender offer subject to Rule 13e-4.
- Going-private transaction subject to Rule 13e-3.
- Amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer:

If applicable, check the appropriate box(es) below to designate the appropriate rule provision(s) relied upon:

- Rule 13e-4(i) (Cross-Border Issuer Tender Offer)
 - Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)
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This Amendment No. 1 (this “Amendment”) amends and supplements the Tender Offer Statement on Schedule TO filed with the Securities and Exchange Commission on December 22, 2020 (together with any subsequent amendments and supplements thereto, the “Schedule TO”), by Tyto Acquisition Corporation, a Delaware corporation (“Purchaser”) and a wholly-owned subsidiary of Eli Lilly and Company, an Indiana corporation (“Lilly”). This Schedule TO relates to the offer by Purchaser to purchase all of the issued and outstanding shares of common stock, par value, \$0.0001 per share (the “Shares”) of Prevail Therapeutics Inc., a Delaware corporation (“Prevail”), in exchange for (a) \$22.50 per Share, net to the seller in cash, without interest and less any applicable tax withholding, plus (b) one non-tradable contingent value right (a “CVR”), which CVR represents the contractual right to receive a contingent payment of up to \$4.00 per share, net to the seller in cash, without interest and less any applicable tax withholding, which amount (or such lesser amount as determined in accordance with the terms and conditions of such contingent value rights agreement to be entered into with a rights agent mutually agreeable to Lilly and Prevail) will become payable, if at all, if a specified milestone is achieved prior to December 1, 2028 (the “Offer Price”), on the terms and subject to the conditions set forth in the Offer to Purchase and in the related Letter of Transmittal, copies of which are attached hereto as Exhibits (a)(1)(A) and (a)(1)(B), respectively.

Except as otherwise set forth in this Amendment, the information set forth in the Schedule TO remains unchanged and is incorporated herein by reference to the extent relevant to the items in this Amendment. Capitalized terms used but not defined herein have the meanings ascribed to them in the Schedule TO.

Items 1 through 9 and Item 11.

The disclosure in the Offer to Purchase and Items 1 through 9 and Item 11 of the Schedule TO is hereby amended and supplemented by adding the following under the heading “*What is the CVR and how does it work?*” in the Summary Term Sheet of the Offer to Purchase:

Adding the following new paragraph as the penultimate paragraph:

“Holders of CVRs are intended third party beneficiaries of the CVR Agreement. Furthermore, the CVR Agreement provides that, other than the rights of the Rights Agent as set forth in the CVR Agreement, holders of at least 30% of outstanding CVRs (the “Acting Holders”) have the sole right, on behalf of the holders of CVRs, by virtue or under any provision of the CVR Agreement, to institute any action or proceeding with respect to the CVR Agreement, and no individual holder or other group of holders will be entitled to exercise such rights. The Acting Holders may request a written update in reasonable detail describing the process, status and anticipated trajectory of the development of the protocols applicable to the Milestone, which Parent shall not be obligated to provide more than once during any consecutive 12-month period. Additionally, the CVR Agreement grants Lilly and Purchaser the right to amend, without the consent of the CVR holders, the CVR Agreement in certain instances which include (i) providing for a successor to Lilly or to Purchaser, (ii) adding to the covenants of Lilly and Purchaser for the protection of the holders (provided that such provisions do not adversely affect the interests of the CVR holders), (iii) curing any ambiguities, correcting or supplementing any provisions of the CVR Agreement that may be defective or inconsistent therein, making any provisions with respect to matters or questions arising under the CVR Agreement (provided that such provisions do not adversely affect the interests of the CVR holders), (iv) amendments as may be necessary or appropriate to ensure that the CVRs are not subject to registration under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any similar registration or prospectus requirement under applicable securities laws outside the United States (provided that such provisions do not adversely affect the interests of the CVR holders), (v) providing for a successor rights agent, and (vi) any other amendments for the purpose of adding, eliminating or changing any provisions of the CVR Agreement, unless such addition, elimination or change is adverse to the interests of the CVR holders. Lilly or Purchaser may also amend the CVR Agreement in a manner that is materially adverse to your interests as a CVR holder provided that Lilly and Purchaser obtain the written consent of the Acting Holders.”

Adding the following statement after the last paragraph:

“Under the terms of the CVR Agreement, Lilly shall, and shall cause its subsidiaries, licensees and rights transferees to, use commercially reasonable efforts (as defined in the CVR Agreement) to achieve the Milestone as promptly as practicable following the Effective Time, provided, that use of commercially reasonable efforts does not guarantee that Lilly will achieve the Milestone at all or by a specific date. Whether the Milestone required for payment of the Milestone Payment is met will depend on many factors, some within control of Lilly and its subsidiaries and others outside the control of Lilly and its subsidiaries.”

The disclosure in the Offer to Purchase and Items 1 through 9 and Item 11 of the Schedule TO is hereby amended and supplemented by adding the following under the heading “*Is Purchaser’s financial condition relevant to my decision to tender my Shares in the Offer?*” in the Summary Term Sheet of the Offer to Purchase:

Adding the following sentence at the end of the first paragraph:

“While, for the reasons stated above, we do not believe Purchaser’s financial condition to be relevant to your decision to tender your Shares, you should consider the following in connection with your decision to tender your Shares and accept the Offer:

- Lilly’s future financial condition could deteriorate such that Lilly would not have the necessary cash or cash equivalents to pay, or cause to be paid, the Milestone Payments;
- holders of CVRs will have no greater rights against Lilly or the Surviving Corporation than those accorded to general unsecured creditors of Lilly or the Surviving Corporation under applicable law;
- the CVRs will be effectively subordinated in right of payment to all of Lilly’s and the Surviving Corporation’s secured obligations to the extent of the collateral securing such obligations;
- the CVRs will be effectively subordinated in right of payment to all existing and future indebtedness, claims of holders of capital stock and other liabilities, including trade payables, of Lilly’s subsidiaries (other than the Surviving Corporation); and
- the filing of a bankruptcy petition by, or on behalf of, Lilly or the Surviving Corporation may prevent Lilly or the Surviving Corporation from making some or all payments that may become payable with respect to the CVRs.”

The disclosure in the Offer to Purchase and Items 1 through 9 and Item 11 of the Schedule TO is hereby amended and supplemented by adding the following in Section 9 – “Source and Amount of Funds” of the Offer to Purchase:

Deleting the current paragraph and replacing it with the following:

“The Offer is not conditioned upon Lilly’s or Purchaser’s ability to finance the purchase of Shares pursuant to the Offer. We estimate that we will need approximately \$880 million to purchase all of the Shares pursuant to the Offer and to complete the Merger. Lilly will provide us with sufficient funds to purchase all Shares validly tendered (and not properly withdrawn) in the Offer and to provide funding for the Merger. In addition, Lilly will need approximately \$160 million to pay the maximum aggregate amount that the holders of the CVRs may be entitled to receive if the Milestone is achieved. Lilly has, or will have, available to it, through a variety of sources, including cash and cash equivalents on hand and borrowings at prevailing effective rates under Lilly’s commercial paper program, funds necessary to satisfy all of Purchaser’s payment obligations under the Merger Agreement and resulting from the Transactions. As of September 30, 2020, Lilly had approximately \$3.60 billion in cash and cash equivalents on hand. In the event that Lilly determines to issue commercial paper in connection with the purchase of Shares pursuant to the offer and to complete the Merger, such commercial paper will be issued at a discount to principal amount resulting in an effective yield determined by the market for commercial paper at the time of each such issuance, the maturities of such commercial paper and Lilly’s commercial paper rating. Lilly currently anticipates the maturities of such commercial paper to be between 30 and 90 days. We have no specific alternative financing arrangements or alternative financing plans in connection with the Offer or the Merger.

While, for the reasons stated above, we do not believe our financial condition to be relevant to your decision to tender your Shares and accept the Offer, you should consider the fact that Lilly’s future financial condition could deteriorate such that Lilly would not have the necessary cash or cash equivalents to pay, or cause to be paid, the Milestone Payments. Furthermore, you should also consider the fact that: (i) holders of CVRs will have no greater rights against Lilly or the Surviving Corporation than those accorded to general unsecured creditors of Lilly or the Surviving Corporation under applicable law; (ii) the CVRs will be effectively subordinated in right of payment to all of Lilly’s and the Surviving Corporation’s secured obligations to the extent of the collateral securing such obligations; (iii) the CVRs will be effectively subordinated in right of payment to all existing and future indebtedness, claims of holders of capital stock and other liabilities, including trade payables, of Lilly’s subsidiaries (other than the Surviving Corporation); and (iv) the filing of a bankruptcy petition by, or on behalf of, Lilly or the Surviving Corporation, may prevent Lilly or the Surviving Corporation from making some or all payments that may become payable with respect to the CVRs.”

The disclosure in the Offer to Purchase and Items 1 through 9 and Item 11 of the Schedule TO is hereby amended and supplemented by adding the following under the heading “CVR Agreement” in Section 11 – “The Merger Agreement; Other Agreements” of the Offer to Purchase:

Adding the following statement after the end of the second paragraph:

“Under the terms of the CVR Agreement, Lilly shall, and shall cause its subsidiaries, licensees and rights transferees to, use commercially reasonable efforts (as defined in the CVR Agreement) to achieve the Milestone as promptly as practicable following the Effective Time, provided, that use of commercially reasonable efforts does not guarantee that Lilly will achieve the Milestone at all or by a specific date. Whether the Milestone required for payment of the Milestone Payment is met will depend on many factors, some within control of Lilly and its subsidiaries and others outside the control of Lilly and its subsidiaries.”

Adding the following new paragraphs before the current last paragraph:

“Section 6.4 of the CVR Agreement provides that the CVR holders are intended third-party beneficiaries of the CVR Agreement. Furthermore, pursuant to Section 6.4 of the CVR Agreement, other than the rights of the Rights Agent as set forth in the CVR Agreement, holders of at least 30% of the CVRs (the “Acting Holders”) have the sole right, on behalf of the holders of CVRs, by virtue or under any provision of the CVR Agreement, to institute any action or proceeding with respect to the CVR Agreement, and no individual holder or other group of holders will be entitled to exercise such rights. The Acting Holders may request a written update in reasonable detail describing the progress, status and anticipated trajectory of the development of the products applicable to the Milestone, which Parent shall not be obligated to provide more than once during any consecutive 12-month period.

Additionally, the CVR Agreement grants Lilly and Purchaser the right to amend, without the consent of the CVR holders, the CVR Agreement in certain instances which include (i) providing for a successor to Lilly or to Purchaser, (ii) adding to the covenants of Lilly and Purchaser for the protection of the holders (provided that such provisions do not adversely affect the interests of the CVR holders), (iii) curing any ambiguities, correcting or supplementing any provisions of the CVR Agreement that may be defective or inconsistent therein, making any provisions with respect to matters or questions arising under the CVR Agreement (provided that such provisions do not adversely affect the interests of the CVR holders), (iv) providing, as may be necessary or appropriate, to ensure that the CVRs are not subject to registration under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any similar registration or prospectus requirement under applicable securities laws outside the United States (provided that such provisions do not adversely affect the interests of the CVR holders), (v) providing for a successor rights agent, and (vi) any other amendments for the purpose of adding, eliminating or changing any provisions of the CVR Agreement, unless such addition, elimination or change is adverse to the interests of the CVR holders. Lilly or Purchaser may also amend the CVR Agreement in a manner that is materially adverse to your interests as a CVR holder provided that Lilly and Purchaser obtain the written consent of the Acting Holders of the CVRs.”

The disclosure in the Offer to Purchase and Item 11 of the Schedule TO is hereby amended and supplemented by adding the following in Section 16 – “Certain Legal Matters; Regulatory Approvals” of the Offer to Purchase:

Adding the following new sub-heading and paragraph at the end of the last paragraph:

“Certain Litigation

On December 30, 2020, Lori Karson, a purported stockholder of Prevail, filed a putative class action lawsuit in the Supreme Court of the State of New York, County of New York, captioned *Lori Karson v. Prevail Therapeutics Inc., et al.*, against Prevail and the Prevail Board (the “Karson Complaint”). The Karson Complaint asserts a breach of fiduciary duty claim against the individual defendants and an aiding and abetting claim against Prevail in connection with the proposed transaction between Prevail, Purchaser and Lilly. The Karson Complaint alleges, among other things, that (i) defendants engaged in an unfair sales process and agreed to inadequate consideration in connection with the proposed transaction, and (ii) the Schedule 14D-9 filed with the SEC on December 22, 2020 in connection with the proposed transaction is materially misleading. The Karson Complaint seeks, among other things, to enjoin the proposed transaction, rescind the transaction or award rescissory damages to the extent it is consummated, and an award of attorneys’ fees and expenses.

On January 4, 2021, a complaint was filed in the United States District Court for the Southern District of New York captioned *Stephen Bushansky v. Prevail Therapeutics Inc., et al.*, Case No. 1:21-cv-00040, against Prevail and the Prevail Board (the “Bushansky Complaint”). The Bushansky Complaint alleges, among other things, that the defendants violated Sections 14(d), 14(e), and 20(a) of the Securities and Exchange Act of 1934 by omitting certain material facts related to the transaction from the Schedule 14D-9 filed by Prevail. The Bushansky Complaint seeks, among other things, to enjoin the defendants from proceeding with, consummating, or closing the transaction, rescissory damages should the transaction not be enjoined, and an award of attorneys’ and experts’ fees.

The outcome of the lawsuits described above cannot be predicted with certainty. However, Prevail believes the claims asserted in the complaints described above are without merit. Additional complaints may be filed against Prevail, the Prevail Board, Lilly and/or Purchaser in connection with the transactions contemplated by the Merger Agreement, the Schedule TO and the Schedule 14D-9. If such additional complaints are filed, absent new or different allegations that are material, Lilly and Purchaser will not necessarily announce such additional complaints.”

SIGNATURES

After due inquiry and to the best knowledge and belief of the undersigned, each of the undersigned certifies that the information set forth in this statement is true, complete and correct.

Date: January 5, 2021

Tyto Acquisition Corporation

By: /s/ Kenneth L. Custer

Name: Kenneth L. Custer

Title: President

Eli Lilly and Company

By: /s/ Joshua L. Smiley

Name: Joshua L. Smiley

Title: Senior Vice President and Chief
Financial Officer

EXHIBIT INDEX

- (a)(1)(A) Offer to Purchase, dated December 22, 2020.*
- (a)(1)(B) Letter of Transmittal (including Guidelines for Certification of Taxpayer Identification Number on IRS Form W-9).*
- (a)(1)(C) Letter to Brokers, Dealers, Commercial Banks, Trust Companies and Other Nominees.*
- (a)(1)(D) Letter to Clients for use by Brokers, Dealers, Commercial Banks, Trust Companies and Other Nominees.*
- (a)(1)(E) Summary Advertisement, dated December 22, 2020.*
- (a)(5)(A) Joint Press Release issued by Lilly and Prevail on December 15, 2020 (incorporated by reference to Exhibit 99.1 to the Schedule TO-C filed by Lilly on December 15, 2020).*
- (b) Not applicable.
- (d)(1) Agreement and Plan of Merger, dated December 14, 2020, by and among Eli Lilly and Company, Tyto Acquisition Corporation and Prevail Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by Prevail on 15, 2020 (File No. 001-38939)).*
- (d)(2) Tender and Support Agreement, dated December 14, 2020, by and among Eli Lilly and Company, Tyto Acquisition Corporation and OrbiMed Private Investments VI L.P. (incorporated by reference to Exhibit 2.2 to the Current Report on Form 8-K filed by Prevail on December 15, 2020 (File No. 001-38939)).*
- (d)(3) Tender and Support Agreement, dated December 14, 2020, by and among Eli Lilly and Company, Tyto Acquisition Corporation, Pontifax (Cayman) V L.P., Pontifax (China) V L.P., Pontifax (Israel) V L.P. and Pontifax Late Stage Fund L.P. (incorporated by reference to Exhibit 2.3 to the Current Report on Form 8-K filed by Prevail on December 15, 2020 (File No. 001-38939)).*
- (d)(4) Tender and Support Agreement, dated December 14, 2020, by and among Eli Lilly and Company, Tyto Acquisition Corporation and Asa Abeliovich, M.D., Ph.D. (incorporated by reference to Exhibit 2.4 to the Current Report on Form 8-K filed by Prevail on December 15, 2020 (File No. 001-38939)).*
- (d)(5) Form of Contingent Value Rights Agreement (incorporated by reference to Annex IV to Exhibit 2.5 to the Current Report on Form 8-K filed by Prevail on 15, 2020 (File No. 001-38939)).*
- (d)(6) Amended and Restated Mutual Confidentiality Agreement between Prevail and Lilly, dated October 1, 2020.*
- (g) Not applicable.
- (h) Not applicable.

* Previously filed.