UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**65-0643773**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
2 University Plaza, Suite 100, Hackensack, NJ	**07601**
(Address of principal executive offices)	**(Zip Code)**

(201) 696-9345
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	PLX	NYSE American

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting common stock held by non-affiliates of the Registrant as of June 30, 2025 was approximately $113.1 million, based on the closing price for shares of the Registrant's common stock reported by the NYSE American for such date.

On March 1, 2026, approximately 80,571,642 shares of the Registrant's common stock, par value $0.001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement related to its 2026 Annual Stockholders' Meeting to be filed subsequently are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the registrant's proxy statement shall not be deemed to be part of this report.

PROTALIX BIOTHERAPEUTICS, INC.
2025 FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

Except where the context otherwise requires, the terms "we," "us," "our" or "the Company," refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiary, and "Protalix" or "Protalix Ltd." refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the sections entitled "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," and other statements included elsewhere in this Annual Report on Form 10-K, particularly with respect to our plans and strategy for our business and related financing, include forward-looking statements within the meanings of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and other words or phrases of similar import, as they relate to our company, our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

- risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease;

- risks relating to Elfabrio's market acceptance, competition, reimbursement, and regulatory actions, including as a result of the boxed warning contained in the approval received from the U.S. Food and Drug Administration, or FDA, for the product;

- risks related to the regulatory approval and commercial success of our other product and product candidates, if approved;

- risks related to our expectations with respect to the projected market of our products and product candidates;

- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and/or inability to monitor patients adequately during or after treatment;

- the risk that the results of the clinical trials of our product candidates will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics;

- the possible disruption of our operations due to the regional conflict in Iran and the military actions between Israel and Iran, the Hamas terrorist organization located in the Gaza Strip, Hezbollah, the Houthis terrorist group that controls parts of Yemen, and others, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers, and the risk that the current hostilities will result in increased regional conflict;

- delays in the approval or potential rejection of any applications we file with the FDA, European Medicines Agency, or EMA, or other health regulatory authorities for our other product candidates, and other risks relating to the review process;

- risks associated with global conditions and developments such as new or increased tariffs, new or changed trade restrictions, supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations, and ability to raise additional financing if and as required and on terms acceptable to us;

- risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses, and working capital;

- risks relating to our evaluation and pursuit of strategic partnerships;

- risks relating to our ability to manage our relationship with our collaborators, distributors, and partners, including, but not limited to, Pfizer Inc., or Pfizer, and Chiesi Farmaceutici S.p.A., or Chiesi;

- risks related to the amount and sufficiency of our cash, cash equivalents, and short-term bank deposits;

- risks relating to changes to interim, top-line, or preliminary data from clinical trials that we announce or publish;

- risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MoH, with its purchase obligations under the Supply and Technology Transfer Agreement that we entered into with Fiocruz in June 2013, or the Brazil Agreement, which may have a material adverse effect on us and may result in our terminating such agreement;

- risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector;

- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services;

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;

- the impact of development of competing therapies and/or technologies by other companies;

- risks related to our supply of drug products to Pfizer;

- potential product liability risks, and risks of securing adequate levels of related insurance coverage;

- the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; and

- risks relating to changes in healthcare laws, rules, and regulations in the United States or elsewhere.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the FDA or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These and other risks and uncertainties are detailed under the "Risk Factors" section of this Annual Report and are described from time to time in the reports we file with the U.S. Securities and Exchange Commission, or the Commission.

PART I

Item 1. Business

We are a commercial stage biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs. We are the first and only company to gain FDA approval of a protein produced through plant cell-based expression in suspension. ProCellEx®, our unique, proprietary plant cell-based protein expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Our corporate strategy includes development of treatments for rare and orphan diseases. To execute on our strategy, we are turning our focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. We believe our treatments of interest will address both genetic and non-genetic diseases. We currently intend to use our ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities.

Consistent with this strategy, we are developing PEGylated uricase, or PRX-115, for the treatment of uncontrolled gout, Long Acting (LA) DNase I, or PRX-119, for the treatment of NETs-related diseases, and a number of other technologies and preclinical assets. We have completed a Phase 1 First-in-Human clinical trial of PRX-115. Currently, we are actively recruiting for, and the first patients have been randomized in a Phase 2 clinical trial of PRX-115 for the treatment of uncontrolled gout which we refer to as the RELEASE study.

To date, we have successfully developed two commercial products, both of which are enzyme replacement therapies (ERTs): Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and older with Gaucher disease and Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease.

Elelyso, our first commercial product, is our proprietary recombinant form of glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. Elelyso was approved by the FDA in 2012 for injection as an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in more than 40 markets including the United States, Brazil, Israel and others. It is not approved in the European Union (EU). In August 2014, the FDA approved Elelyso for injection for children four years of age and greater. We have licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer pursuant to the terms of an amended and restated exclusive license and supply agreement, or the Amended Pfizer Agreement, which is in effect until 2030. We sell drug substance to Pfizer for the production of Elelyso, subject to certain terms and conditions, and Pfizer retains the revenues generated from its sales of the product. In Brazil, we have licensed rights to commercialize Elelyso to Fiocruz. Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil. We retain distribution rights to Elelyso in Brazil. See Commercialization of Approved Products--Elelyso – Pfizer and --Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz).

Our sales of Elelyso to Pfizer and Fiocruz are made at a fixed price directly to Pfizer and Fiocruz who maintain product in inventory, and we recognize revenue from those sales upon delivery. The timing of such sales do not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by each of Pfizer and Fiocruz resulting in variability in our period-to-period results. There may be periods during which no orders are placed by either Pfizer or Fiocruz, whether as a result of inventory de-stocking or other factors. We do not anticipate that these ordering patterns will change until the demand characteristics for Elelyso stabilize, the launch of Elelyso matures and Elelyso's share of the market for Fabry disease treatment increases globally.

Elfabrio, our second commercial product, for the treatment of adult patients with Fabry disease, is our proprietary, chemically modified, stabilized plant cell culture expressed recombinant α-Galactosidase-A protein, a lysosomal enzyme. It was approved by the European Commission, or the EC, for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease, and subsequently in more than 10 additional markets. These approvals cover the 1 mg/kg every-two-weeks (E2W) dosage.

On March 5, 2026, the EC ratified the positive opinion issued in January 2026 by the Committee for Medicinal Products for Human Use, or the CHMP, of the European Medicines Agency, or the EMA. The EC decision approves, in the EU, the 2 mg/kg E4W dosing regimen for pegunigalsidase alfa (Elfabrio) in Fabry disease adult patients stable with an ERT treatment.

We have partnered with Chiesi for the development and commercialization of Elfabrio for the treatment of Fabry disease through two exclusive global licensing and supply agreements; the Exclusive License and Supply Agreement dated as of October 17, 2017, by and between Protalix Ltd. and Chiesi, or the Chiesi Ex-US Agreement, and the Exclusive License and Supply Agreement dated as of July 23, 2018, by and between Protalix Ltd. and Chiesi, or the Chiesi US Agreement. The Chiesi Ex-US Agreement and the Chiesi US Agreement are referred to herein collectively as the Chiesi Agreements. Under these two agreements, we have received certain upfront payments and development cost reimbursements, and remain entitled to potential milestone payments and payments for drug product purchased by Chiesi from Protalix Ltd. See Commercialization of Approved Products--Elfabrio (pegunigalsidase alfa/PRX-102) – Chiesi Farmaceutici.

Under the terms of the Chiesi Agreements, Chiesi is solely responsible for the global commercialization and medical programs of Elfabrio, including patient acquisition and retention, and distribution of Elfabrio to patients. We manufacture Elfabrio drug substance and, after the fill\finish process is complete, we sell the resulting drug product to Chiesi. Operationally, Chiesi conducts its own internal commercial forecasting to guide inventory needs. To date, Chiesi has placed bulk orders for Elfabrio. As a result, the orders we receive from Chiesi may not be timed precisely to Chiesi's pace of patient acquisition and retention. Accordingly, our sales of Elfabrio to Chiesi may not reflect patient demand for Elfabrio as we sell the fulfilled orders to Chiesi's inventory. In addition, on a period-to-period basis, there may be variations in the orders placed by Chiesi resulting in variability in our period-to-period results as we, in turn, recognize revenues from sales of Elfabrio upon delivery of the drug product to Chiesi. There may be periods during which no orders are placed by Chiesi, whether as a result of inventory de-stocking or other factors. We do not anticipate that these Chiesi ordering patterns will change until the demand characteristics for Elfabrio stabilize, the launch of Elfabrio matures and Elfabrio's share of the market for Fabry disease treatment increases globally.

2025 and Recent Company Developments

*2025 Developm*ents

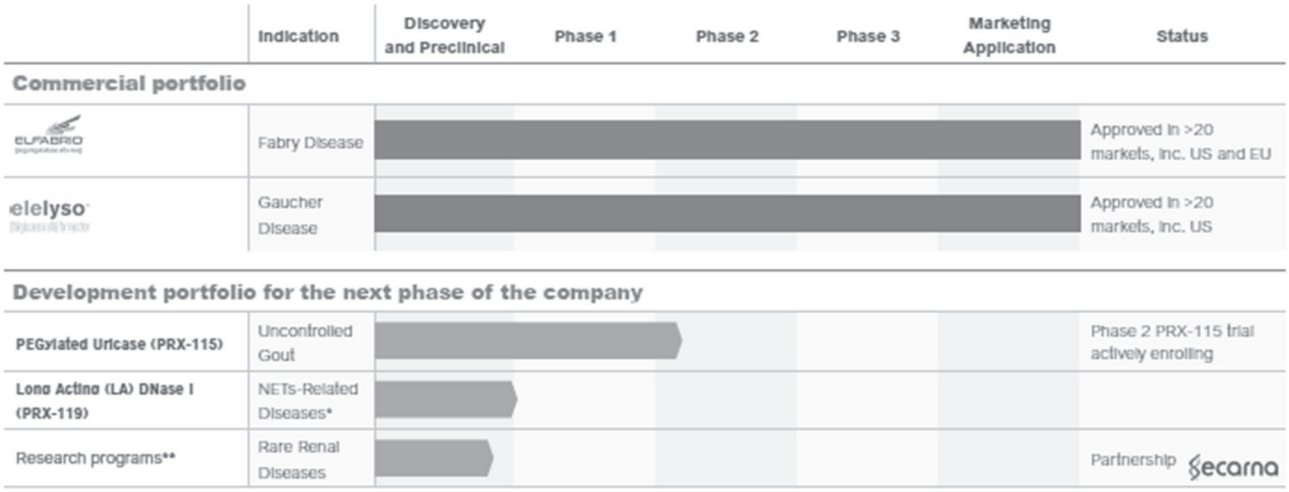
- On June 30, 2025, we announced that we had been added to the Russell 3000® and Russell 2000® Indexes, effective as of the U.S. market close on June 27, 2025, as part of the 2025 Russell indexes annual reconstitution.

- On August 24, 2025, Gilad Mamlok succeeded Eyal Rubin as our Senior Vice President and Chief Financial Officer.

- On October 6, 2025, we submitted an Investigational New Drug (IND) application to the FDA in connection with our planned RELEASE Phase 2 clinical trial of PRX-115 which became effective following the FDA's standard 30-day review period.

- On March 5, 2026, the EC ratified the CHMP positive opinion issued in January 2026. The EC decision approves, in the EU, the 2 mg/kg E4W dosing regimen for pegunigalsidase alfa in Fabry disease adult patients stable with an ERT treatment. The CHMP's positive opinion is the result of an appeal submitted after the CHMP issued a negative opinion in October 2025.

Product Pipeline



Our proprietary ProCellEx platform is being used to manufacture both our approved and marketed products as well as PRX-115 and PRX-119.

We are committed to leveraging our track record of success as we progress with the development of treatments for rare and orphan diseases. In addition, we continuously work on the further development and enhancement of our ProCellEx technology. Accordingly, we are turning our focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. We believe that our treatments of interest will address both genetic and non-genetic diseases. We currently intend to use our ProCellEx platform and PEGylation/chemical capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. We are also exploring novel platform technologies to expand our pipeline.

ProCellEx: Our Proprietary Protein Expression System

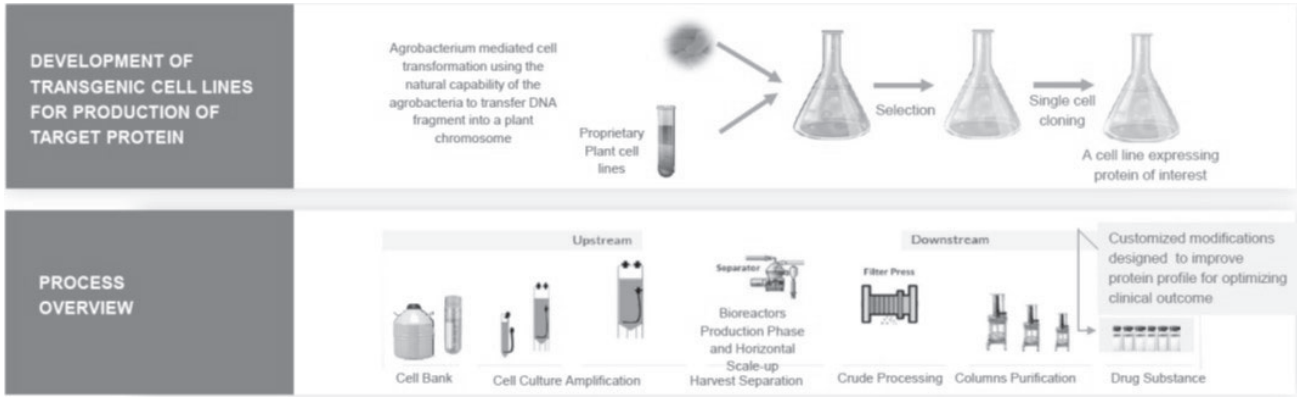
ProCellEx is our proprietary platform used to produce and manufacture recombinant proteins through plant cell-based expression in suspension. We are the first and only company to receive FDA approval of a complex human protein produced through plant cell-based expression, and with the approval of Elfabrio, we now produce two commercial proteins through our platform.

ProCellEx consists of a comprehensive set of proprietary technologies and capabilities, including the use of advanced genetic engineering and plant cell culture technology, enabling us to produce complex, proprietary proteins for a variety of human diseases. Our protein expression system facilitates the creation and selection of high-expressing, genetically-stable cell lines capable of expressing recombinant proteins. The system plays an important role in the execution of our corporate strategy as it allows us to develop and produce tailored complex recombinant therapeutic proteins and to genetically engineer and/or chemically modify such proteins pre- and/or post-production. The engineering and modification of the therapeutic proteins have the potential to provide added clinical benefits by improving the biological characteristics (e.g., glycosylation, half-life, immunogenicity).

Our ProCellEx technology allows for many unique advantages, including: biologic optimization; an ability to handle expression of complex proteins; flexible manufacturing with improvements through efficiencies, enhancements and/or rapid horizontal scale-ups; a simplified production process; elimination of the risk of viral contaminations from mammalian components; and intellectual property advantages.

We developed ProCellEx based on our plant cell culture technology for the development, expression and manufacture of recombinant proteins that are the essential foundation of modern biotechnology. We develop new, recombinant therapeutic proteins by using the natural capability of agrobacterium to transfer a DNA fragment into the plant chromosome, allowing the genome of the plant cell to code for specific proteins of interest. The agrobacterium-mediated

transformed cells are then able to produce specific proteins, which are extracted and purified and can be used as therapies to treat a variety of diseases.

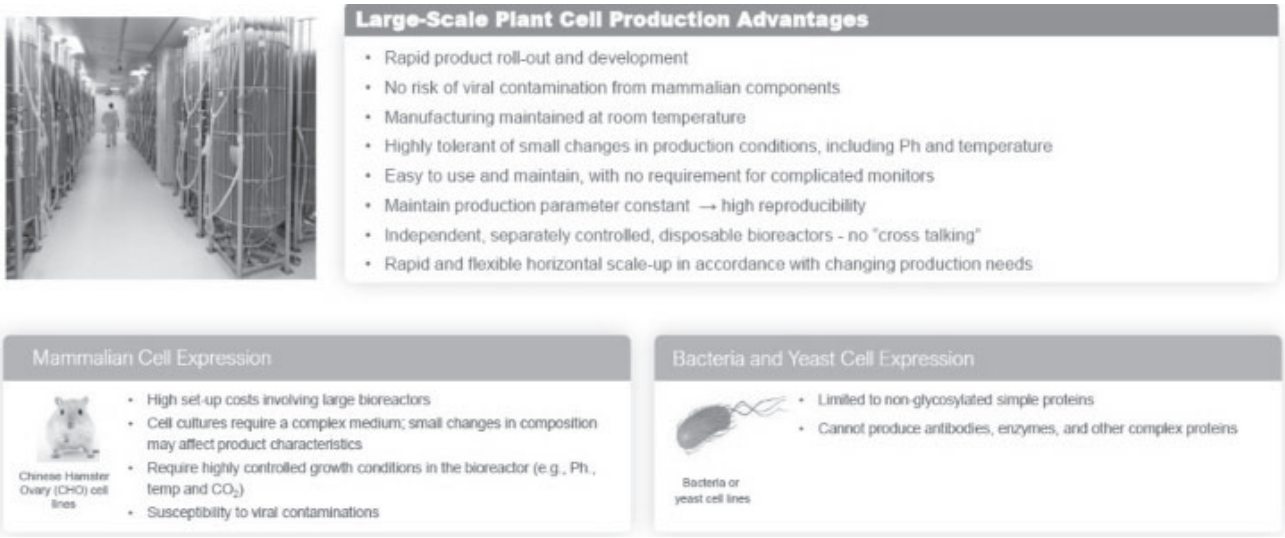


Our ProCellEx technology can be utilized to express complex therapeutic proteins belonging to different drug classes, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. The entire protein expression process, from initial nucleotide cloning to large-scale production of the protein product, occurs under Current Good Manufacturing Practice-, or cGMP-, compliant, controlled processes. Our plant cell culture technology uses cells, such as carrot and tobacco (BY-2) cells, which undergo advanced genetic engineering and/or chemical modifications, and are grown on an industrial scale in a disposable, flexible bioreactor system. Our system does not involve mammalian or animal-derived components or transgenic field-grown or whole plants at any point in the production process.

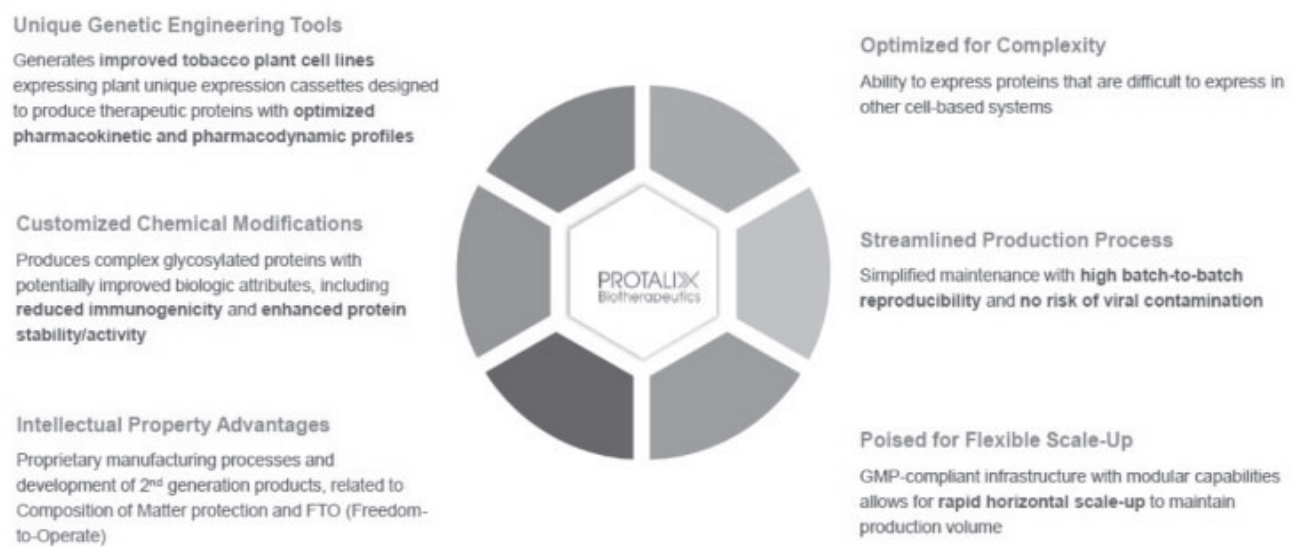
Cell growth, from initiating scale-up steps from a cell-bank through large-scale production, takes place in a clean-room environment in flexible, sterile, custom-designed polyethylene bioreactors, and does not require the use of large stainless-steel bioreactors commonly used in mammalian-based systems for recombinant protein production. Unlike these bioreactors, the ProCellEx reactors are easy to use and maintain, allow for rapid horizontal scale-up and do not involve the risk of mammalian viral contamination. Our bioreactors are well-suited for plant cell growth using a simple, inexpensive, chemically defined growth medium. The reactors, which are custom-designed and optimized for plant cell cultures, require low initial capital investment and are rapidly scalable at a low cost.

In addition, we continuously work on the further development and enhancement of our ProCellEx technology.

Plant Cell Production Advantages



ProCellEx®: Protalix's Differentiated Plant Cell Protein Expression Platform



Our Marketed Products

Both of our commercial products, Elelyso and Elfabrio, are ERTs.

Elelyso for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, was approved by the FDA in 2012 for injection as an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. In August 2014, the FDA approved Elelyso for injection for children four years of age and greater. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in more than 40 markets including the United States, Brazil, Israel, and others. It is not approved in the EU.

Gaucher disease, also known as glucocerebrosidase, or GCD, deficiency, is a rare genetic autosomal recessive disorder and one of the most common Lysosomal Storage Disorders, or LSDs, in the world. It is one of a group of disorders that affect specific enzymes that normally break down fatty substances for reuse in the cells. If the enzymes are missing or do not work properly, the substances can build up and become toxic. Gaucher disease occurs when a lipid called glucosylceramide accumulates in the cells of the bone marrow, lungs, spleen, liver, and sometimes the brain. Gaucher disease symptoms can include fatigue, anemia, easy bruising and bleeding, severe bone pain and easily broken bones, and distended stomach due to an enlarged spleen and thrombocytopenia. Epidemiology of Gaucher disease varies; recent literature provides that prevalence of Gaucher disease ranges from 0.70 to 1.75 per 100,000 in the general population. In people of Ashkenazi Jewish heritage, estimates of occurrence vary from approximately 1 in 400 to 1 in 850 people.

The global market for therapies for Gaucher disease, including Sanofi's Cerezyme®, Shire's (acquired by Takeda Pharmaceutical Company Limited) Vpriv® and Sanofi's Cerdelga®, among others, was $1.65 billion in 2025, is forecasted to be approximately $1.6 billion in 2026 and is forecasted to grow at a compound annual growth rate (CAGR) of approximately 0.5% from 2025-2031.

The current standard of care for Gaucher disease is ERT, which is a medical treatment where recombinant enzymes are injected into patients to replace the lacking or dysfunctional enzyme. In Gaucher disease, recombinant GCD is infused to replace the mutated or deficient natural GCD enzyme. Elelyso is the only alternative ERT treatment of Gaucher disease to Cerezyme and Vpriv.

Elfabrio for the Treatment of Fabry Disease

Elfabrio, our second commercial product, was approved by the EC for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg E2W dosage.

On March 5, 2026, the EC ratified the CHMP positive opinion issued in January 2026. The EC decision approves, in the EU, the 2 mg/kg E4W dosing regimen for pegunigalsidase alfa in Fabry disease adult patients stable with an ERT treatment. The CHMP's positive opinion is the result of an appeal submitted after the CHMP issued a negative opinion in October 2025.

Elfabrio was approved by the FDA with a boxed warning for hypersensitivity reactions/anaphylaxis, consistent with ERT class labeling, and warnings/precautions providing guidance on the signs and symptoms of hypersensitivity and infusion-associated reactions seen in the clinical studies as well as treatments to manage such events should they occur. The warnings/precautions for membranoproliferative glomerulonephritis (MPGN) alert prescribers to the possibility of MPGN and provide guidance for appropriate patient management. Overall, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease. Since the approvals by the FDA and the EMA, Elfabrio has been approved for marketing in more than 10 additional markets for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.

Fabry disease, also one of the most common LSDs, is a serious x-linked life-threatening rare genetic disorder. Fabry patients lack or have low levels of α-galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide, or Gb_3, in blood vessel walls throughout their body. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure, particularly of the kidneys, but also of the heart and the cerebrovascular system. Fabry disease occurs in one person per 40,000 to 60,000 males.

The global market for therapies for Fabry disease, that includes agalsidase alfa, agalsidase beta, and Amicus Therapeutics' Galafold®, among others, is forecasted to be approximately $2.3 billion in 2026 and is forecasted to grow at a CAGR of 6.3% from 2025-2031 reaching approximately $3.2 billion in annual sales in 2031.

The standard of care for Fabry disease is ERT. Currently, the marketed ERTs for Fabry disease are agalsidase alfa (Takeda's (Shire) Replagal®) agalsidase beta (Sanofi Genzyme's Fabrazyme®), and pegunigalsidase alfa (Elfabrio). Through an ERT, the missing α-galactosidase-A is replaced with a recombinant form of the protein via intravenous, or IV, infusion once every two weeks. Fabry disease, if left untreated, will progress from a less severe condition to a more serious one. It can have a significant impact on quality of life due to presence of serious, chronic and debilitating complications, including cardiovascular and renal complications, and comorbidities such as pain can have a significant impact on the psychological well-being of Fabry patients and their social functioning. Fabry disease often involves substantial reduction in life expectancy. Causes of death are most often cardiovascular disease and, to a lesser extent, cerebrovascular disease and renal disease. The life expectancy of Fabry patients is significantly shorter compared to the general population. Untreated male Fabry patients may experience shortened lifespans to approximately 50 years, and 70 years for untreated female patients with Fabry disease. This represents a 20- and 10-year reduction of their respective lifespans.

Key Trials and Design for Elfabrio

Our clinical development program for Elfabrio, or PRX-102, was designed to show that PRX-102 has a potential clinical benefit in all adult Fabry patient populations when compared to two marketed Fabry disease enzymes, agalsidase alfa and agalsidase beta. In preclinical studies, PRX-102 showed significantly longer half-life due to higher enzyme stability, enhanced activity in Fabry disease affected organs leading to reduction of the accumulated substrate and reduced immunogenicity, which together can potentially lead to improved efficacy through increased substrate clearance and significantly lower formation of anti-drug antibodies, or ADAs.

The Phase 3 clinical program included three individual studies; the BALANCE study, the BRIDGE study and the BRIGHT study. In the Phase 3 clinical program overall, two potential dosing regimens for PRX-102 were analyzed; 1 mg/kg E2W, with the potential for improved efficacy and safety offering a potential alternative to existing enzyme replacement therapies, and 2 mg/kg E4W. In addition, the Phase 3 clinical trials, a dose range finding study program included two extension studies in which subjects that participated in our Phase 1/2 clinical trials and Phase 3 clinical trials had the opportunity to enroll and continue to be treated with PRX-102.

Extension Studies

Two long-term open-label extension studies were available for patients who completed the BALANCE, BRIDGE, and BRIGHT studies, and the extension of the Phase 1/2 study. Overall, 126 patients who participated in our PRX-102 clinical program initially opted, with the advice of the treating physician, to enroll in one of the extension studies: 97 patients in the 1 mg/kg E2W extension study (PB-102-F60, NCT03566017) (10 patients who completed an extension study from the Phase 1/2 study, 18 patients who completed the BRIDGE study; 69 patients who completed the BALANCE study), and 29 patients who completed the BRIGHT study in the 2 mg/kg E4W extension study (PB-102-F51, NCT03614234). Two of the patients in the 2 mg/kg E4W extension study were treated with 1 mg/kg E2W.

After the approval of Elfabrio in the US and the EU, sponsorship and administration of the extension studies was transferred to Chiesi. Over time, and as Elfabrio is approved for marketing in different jurisdictions, patients routinely switch-out of the open-label extension studies. Most such patients have transferred to a commercial setting; others withdrew for other reasons. Accordingly, the 1 mg/kg E2W dosage extension study is now closed as most patients have transferred to commercial or expanded access programs. In addition, the US-based patients that enrolled in the 2 mg/kg E4W dosage extension study are now being treated with Elfabrio on a commercial basis; EU-based patients remain on the extension study.

Over the course of the PRX-102 clinical development program, 142 Fabry disease subjects, in the aggregate, were exposed to treatment with PRX-102. Patients contributing to the integrated safety dataset included subjects from the Phase 1/2 study, each of the BALANCE, BRIDGE and BRIGHT studies, and the Phase 3 extension studies. The safety and immunogenicity profile of PRX-102 are in line with the safety and immunogenicity profiles of other ERTs.

Pediatric FLY Study

Chiesi is sponsoring a clinical trial entitled “Multi-Centre, Open-label Trial to Assess the Safety, Pharmacodynamics, Efficacy and Pharmacokinetics of pegunigalsidase alfa in Patients From 2 Years to Less Than 18 Years of Age With Confirmed Fabry Disease” (NCT06328608). Recruitment is ongoing. The design of the study is based on the Initial Pediatric Study Plan (iPSP) agreed to with the FDA and the paediatric investigation plan (PIP) for Elfabrio, which has been accepted, as amended, by the Paediatric Committee (PDCO) of the EMA. The study involves the 1 mg/kg E2W dosage regimen.

Japanese RISE Study

Chiesi is currently recruiting patients for its clinical trial entitled “A Multicenter Open-Label Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Pegunigalsidase Alfa (PRX-102) in Japanese Patients With Fabry Disease,” or the *RISE* study (NCT05710692). The aim of the *RISE* study is to evaluate the safety and efficacy of pegunigalsidase alfa in Japanese patients (adults and adolescents) affected by Fabry disease. It is planned that a total of approximately 16 male and female Fabry disease patients between the ages of 13 and 70 years will be enrolled in the study which is being conducted in Japan. The study will evaluate both the 1 mg/kg E2W and the 2 mg/kg E4W dosage regimens.

Our Pipeline – Clinical Programs

PEGylated Uricase (PRX-115)

PRX-115 is our proprietary recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme under development for the potential treatment of patients with uncontrolled gout.

Currently, we are actively recruiting for the RELEASE study, a Phase 2 clinical trial of PRX-115 entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study Assessing the Efficacy, Safety, and Dosing Regimen Selection of Multiple Intravenous Infusions of PRX-115 With and Without Methotrexate Versus Placebo in Adult Patients with Gout." The RELEASE study is a multicenter, randomized, double-blind, placebo-controlled Phase 2 study assessing the efficacy, safety, and dosing regimen selection of multiple IV infusions of PRX-115 over 24 weeks, with or without the immunomodulator methotrexate (MTX), versus the respective placebos in adult patients with gout. Participants will receive PRX-115 by intravenous (IV) infusions according to different treatment schedules, with and without MTX. We expect to enroll approximately 150 adult patients in the study in clinical sites located in the United States, Georgia, and Israel.

Gout is the most common inflammatory arthritis, affecting a projected 11.9 million adults in the United States alone. Based on market research we have commissioned, we estimate that approximately 25% of the gout population in the US and Western Europe does not have their gout controlled. Some of those patients cannot be treated with existing therapies; others stop treatment with existing therapies due to adverse events. In addition, such research presents that there are gout patients treated with existing therapies that continue to suffer from tophi despite having reached urate target levels. The risk of gout increases with age, and is more common in males. Gout results from sustained elevation of serum urate levels (hyperuricaemia). Urate levels may increase due to diet, genetic predisposition and environmental factors leading to the deposition of monosodium urate crystals and\or tophi in joints, tendons and other tissues, which triggers recurrent episodes of pronounced acute inflammation, known as gout flares. Gout leads to substantial morbidity, severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with a number of comorbidities, including hypertension, cardiovascular disease, renal impairment, diabetes, obesity, hyperlipidaemia and frequently occurs in a combination known as metabolic syndrome.

Uncontrolled gout is when serum urate (sUA) levels are above the maximum medically appropriate level (6.8 mg/dL), as well as tophi formation and/or flares that cannot be treated with available urate lowering therapies. Currently available Urate-lowering therapies (ULTs) can be effective in treating gout. However, factors such as low adherence, under dosing, disease progression that causes high patient burden or patients that are not suitable for available therapy, require new, effective and safe therapies to treat these underserved uncontrolled gout patients.

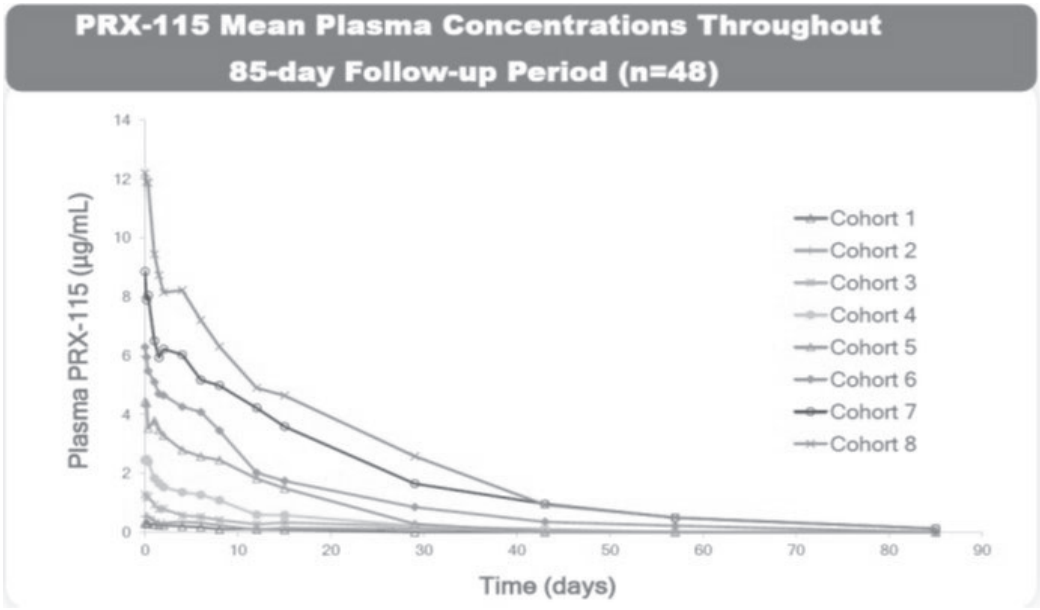
The uricase enzyme, which does not exist naturally in humans, converts urate to allantoin, which is easily eliminated through urine. PRX-115, our recombinant uricase enzyme, expressed via our ProCellEx system, is designed to lower urate levels and improve clinical manifestation of the disease while having low immunogenicity and increased half-life of the drug in the blood. Pre-clinical data demonstrates long half-life, reduced immunogenic risk and high specific activity support the potential of PRX-115 to be a safe and effective treatment for patients with uncontrolled gout.

We completed a Phase 1 clinical trial of PRX-115 for the potential treatment of uncontrolled gout entitled "A Double-blind, Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Properties of PRX-115 in Adult Volunteers With Elevated Uric Acid Levels" (NCT05745727), or the FIH study. The FIH study was conducted at New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines. The completed study included eight sequential dosing cohorts, each composed of eight subjects (six active and two placebo), a 3:1 ratio. Subjects in each cohort, males and females aged 18 through 65, received a single dose of PRX-115 and were analyzed for safety, pharmacokinetics (PK), pharmacodynamics (PD) (concentrations of plasma urate) and immunogenicity for 85 days. Overall, 64 randomized subjects were enrolled across the eight cohorts; 48 subjects were treated with PRX–115 and 16 subjects were treated with placebo.

Key results from the full FIH study are as follows:

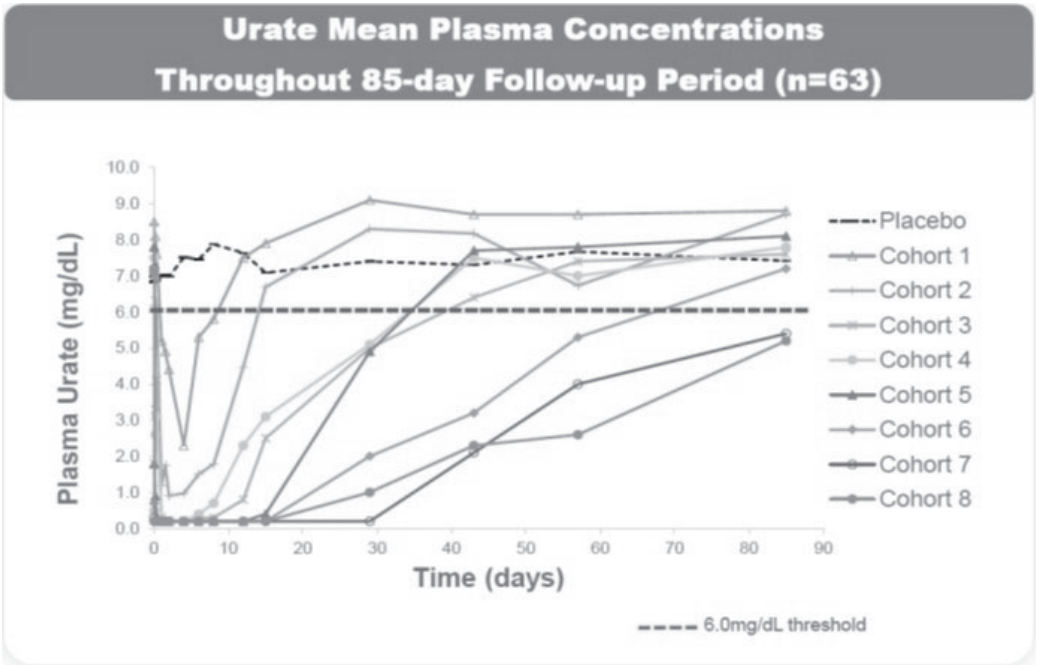
- Exposure to PRX-115 increased in a dose-dependent manner. Detectable PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7, and 8. See Figure 1.

Figure 1



- In all tested doses, a single dose of PRX-115 rapidly reduced plasma urate levels. The effect and duration of response were found to be dose dependent. Following a single dose, mean plasma urate levels remained below 6.0 mg/dL for up to 12 weeks at the highest doses. See Figure 2.

Figure 2



- All randomized participants completed the study. PRX-115 was found to be well-tolerated. See Figure 3.

Figure 3. Overall Summary of Treatment Emergent Adverse Events*

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	Cohort 7	Cohort 8	Pooled PRX-115	Pooled Placebo
N	6	6	6	6	6	6	6	6	48	16
TEAE n(%)	5(83.3)	6(100.0)	5(83.3)	3(50.0)	6(100.0)	5(83.3)	3(50.0)	4(66.7)	37(77.1)	13(81.3)
Related TEAE n(%)	1(16.7)	5(83.3)	3 (50.0)	1(16.7)	1(16.7)	0	0	1(16.7)	12(25.0)	3(18.8)
Serious Related TEAE n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.4)	0
TEAE Leading to Study Drug Discontinuation n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.1)	0
TEAE Leading to Study Discontinuation n(%)	0	0	0	0	0	0	0	0	0	0

*Number of subjects reporting at least one adverse event.

Only 25% of the subjects treated with PRX-115 in the study (12/48) reported study drug-related adverse events. The majority of such adverse events were mild to moderate and transient in nature. One subject experienced an anaphylactic reaction in cohort 2 immediately following the commencement of the infusion (6 minutes) and, accordingly, was exposed to approximately 5% of the applicable PRX-115 dose. The reaction resolved completely and the subject continued in the study for follow-up safety assessments. Premedication with anti-histamines and steroids were administered to all subjects following the anaphylaxis event. No other subjects experienced a similar reaction and no other serious adverse events were reported in the study. No related adverse events were reported for subjects treated in cohorts 6 and 7, and only for one patient per cohort in cohorts 4, 5 and 8. Approximately 50% of the subjects developed ADAs. The incidence of ADAs showed a negative relationship with the applicable PRX-115 dose, with the highest incidence observed in Cohort 1 and lower incidences in the higher PRX-115 dose cohorts.

These results suggest that PRX-115 has the potential to be a promising treatment option for patients with gout. The results demonstrate that PRX-115 may offer an effective urate-lowering treatment with an added benefit of a potentially wide dosing interval, which may enhance patient compliance and treatment flexibility. Further studies are needed to confirm the long-term safety and efficacy of PRX-115 in the gout patient population.

To date, two variants of recombinant uricases are approved for marketing: (i) Krystexxa® (pegloticase) for treatment of chronic gout refractory to conventional therapy (gout patients who have contraindication/failure of other lowering urate treatments) and (ii) Elitek®, indicated for the treatment of tumor lysis syndrome but not gout. Both have a black box warning for anaphylaxis and other major side-effects. The FDA label of Krystexxa was amended in 2022 to include co-treatment of methotrexate to prolong efficacy and increase tolerability in patients with refractory gout. Krystexxa is marketed only in the US.

Our Pipeline – Preclinical and Research Programs

PRX-119

PRX-119 is our plant cell-expressed PEGylated recombinant human DNase I product candidate which we are designing to have an elongated half-life in the circulation for the potential treatment of NETs-related diseases. NETs, or Neutrophil extracellular traps, are web-like structures released by activated neutrophils that trap and kill a variety of microorganisms. NETs are composed of DNA, histones, antimicrobial and pro-inflammatory proteins. Excessive formation or ineffective clearance of NETs can cause different pathological effects. NETs formation has been observed in various autoimmune, inflammatory and fibrotic conditions, diverse forms of thrombosis, cancer and metastasis. According to scientific literature, animal studies have demonstrated that DNase treatment reduce NETs toxicity. Our proprietary modified DNase I, which we have designed for long and customized systemic circulation in the bloodstream, may potentially enable effective treatment for these conditions.

The administration of PRX-119 resulted in a decrease in circulating of DNA levels and significantly enhanced the survival of mice in both a CLP-induced sepsis model and an ARDS model.

Antisense oligonucleotide (ASO) therapies for rare renal indications

We are currently engaged in a collaborative research project with Secarna Pharmaceuticals GmbH & Co. KG, or Secarna, through which we are partnering in the discovery of novel antisense oligonucleotide (ASO) therapies against multiple targets for rare renal indications. We have selected pharmaceutical targets with fundamental biological roles in rare renal indications, and Secarna plans to apply OligoCreator®, its proprietary AI-empowered oligonucleotide discovery and development platform, to design and profile ASO candidates against those targets. It is our mutual goal to advance the programs from discovery stage to clinical trials. As part of the collaboration, Secarna granted to us an option to an exclusive, worldwide milestone and royalty bearing license to further develop, market, and commercialize therapeutic programs.

Commercialization of Approved Products

Elelyso – Pfizer

We have licensed to Pfizer the global rights to market and sell Elelyso in all markets, excluding Brazil, pursuant to the Amended Pfizer Agreement. Pursuant to such agreement we have agreed to sell drug substance to Pfizer for the production of Elelyso for a fixed cost, subject to certain terms and conditions, through 2030. Any failure to comply with our supply commitments may subject us to substantial financial penalties. The Amended Pfizer Agreement includes customary provisions regarding cooperation for regulatory matters, patent enforcement, termination, indemnification and insurance requirements. We retain distribution rights to taliglucerase alfa in Brazil.

Our sales of Elelyso to Pfizer are made at a fixed price directly to Pfizer who maintains product in inventory, and we recognize revenue from those sales upon delivery. The timing of such sales does not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by Pfizer resulting in variability in our period-to-period results. There may be periods during which no orders are placed by Pfizer, whether as a result of inventory de-stocking or other factors.

Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz)

Elelyso, marketed as BioManguinhos alfataliglicerase in Brazil, is commercialized in Brazil through the Brazil Agreement with Fiocruz which became effective in January 2014. Gaucher patients in Brazil are entitled to receive ERT paid for by the Brazilian MoH. The Brazilian MoH clinical treatment guidelines (PCDT) state that BioManguinhos alfataliglicerase is the therapy of choice for newly diagnosed patients. BioManguinhos alfataliglicerase is currently estimated to be used by approximately 25% of Gaucher patients in Brazil.

The Brazil Agreement provides for a staged technology transfer that is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of BioManguinhos alfataliglicerase. Fiocruz has not satisfied certain purchase commitments under the Brazil Agreement. We continue to sell BioManguinhos alfataliglicerase for a fixed price through purchase orders and, on a continuous basis, we discuss with Fiocruz potential steps to maximize sales of BioManguinhos alfataliglicerase to the Brazilian MoH.

Our sales of BioManguinhos alfataliglicerase to Fiocruz are made at a fixed price directly to Fiocruz who maintains product in inventory, and we recognize revenue from those sales upon delivery. The timing of such sales does not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by Fiocruz resulting in variability in our period-to-period results. There may be periods during which no orders are placed by Fiocruz, whether as a result of inventory de-stocking or other factors.

Elfabrio (pegunigalsidase alfa/PRX-102) – Chiesi Farmaceutici

Elfabrio is commercialized worldwide by Chiesi under the Chiesi Agreements. Under the Chiesi Ex-US Agreement, we granted to Chiesi an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. At execution of the Chiesi Ex-US Agreement, Chiesi made an upfront, non-refundable, non-creditable payment to Protalix Ltd. of $25.0 million, followed by additional payments of $25.0 million to cover development costs in the aggregate. Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $270.0 million,

in the aggregate and including the $25.0 million currently payable, subject to the satisfaction of certain regulatory and commercial milestones. Protalix Ltd. agreed to manufacture all of the pegunigalsidase alfa needed for all purposes under the agreement, subject to certain exceptions, and Chiesi agreed to purchase the pegunigalsidase alfa from Protalix Ltd., subject to certain terms and conditions. Chiesi is required to make payments to Protalix Ltd. ranging from 15% to 35% of its net sales under the Chiesi Ex-US Agreement, depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply. The agreement shall remain in effect until the later of (i) the expiration of the last enforceable Protalix patent right thereunder or (ii) the 15th anniversary of the launch on a country-by-country basis, subject to certain terms and conditions, unless earlier terminated in accordance with the terms and conditions thereof.

Under the Chiesi US Agreement we granted to Chiesi the exclusive license to develop and commercialize pegunigalsidase alfa in the United States. Protalix Ltd. received from Chiesi an upfront, non-refundable, non-creditable payment of $25.0 million from Chiesi and additional payments of $20.0 million to cover development costs. To date, we have received the complete amount of such development costs, and, following the approval of Elfabrio by the FDA, we received a milestone payment equal to $20.0 million. Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $740.0 million, in the aggregate, subject to the satisfaction of certain regulatory and commercial milestones. Chiesi is required to make payments to Protalix Ltd. ranging from 15% to 40% of its net sales under the Chiesi US Agreement to Protalix Ltd., depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply. The agreement shall remain in effect until the later of (i) the expiration of the last enforceable Protalix patent right thereunder or (ii) the 15th anniversary of the launch in the US, unless earlier terminated in accordance with the terms and conditions thereof.

We manufacture Elfabrio drug substance and, after the fill\finish process is complete, we sell the resulting drug product to Chiesi under both agreements. Operationally, Chiesi conducts its own internal commercial forecasting to guide inventory needs. To date, Chiesi has placed bulk orders for Elfabrio. As a result, the orders we receive from Chiesi may not be timed in relation to Chiesi's pace of patient acquisition and retention. Accordingly, our sales of Elfabrio to Chiesi may not reflect patient demand for Elfabrio as we sell the fulfilled orders to Chiesi's inventory. In addition, on a period-to-period basis, there may be variations in the orders placed by Chiesi resulting in variability in our period-to-period results as we, in turn, recognize revenues from sales of Elfabrio upon delivery of the drug product to Chiesi. There may be periods during which no orders are placed by Chiesi, whether as a result of inventory de-stocking or other factors. We do not anticipate that these Chiesi ordering patterns will change until the demand characteristics for Elfabrio stabilize, the launch of Elfabrio matures and Elfabrio's share of the market for Fabry disease treatment grows both inside the US and outside the US.

On August 29, 2022, we entered into a Fill/Finish Agreement, or the F/F Agreement, and a Letter Agreement, or the Letter Agreement, in each case with Chiesi. Under the F/F Agreement, we agreed to supply Chiesi with drug substance for pegunigalsidase alfa and, following relevant technology and technical information transfer activities, Chiesi has agreed, among other things, to provide us with commercial fill/finish services for pegunigalsidase alfa, including to support the anticipated global launch of pegunigalsidase alfa. The Letter Agreement changed the obligations of both us and Chiesi under the Chiesi Agreements with respect to, among other things, the evaluation, selection and establishment of an initial alternate source of commercial fill/finish services for pegunigalsidase alfa. In addition, the Letter Agreement amended certain provisions of the Chiesi Agreements to reflect the appointment of Chiesi as a supplier to our company of commercial fill/finish services, and the potential establishment of an initial alternate source of commercial fill/finish services. Subsequently, in November 2024, we agreed that a different Chiesi facility may act as a secondary supplier of such services and that the F/F Agreement shall have an initial term of 10 years, unless terminated earlier in accordance with the terms thereof. Prior to expiration of the initial term, the term may be extended by mutual agreement for an additional period of seven years upon mutual written agreement.

Intellectual Property

We have a robust patent portfolio, which is a key element of our overall strategy. We work to continually enhance, strengthen, and protect our intellectual property and now hold a broad portfolio of approximately 70 patents globally, including in Europe, the US, Israel and additional countries worldwide. Our patents are designed to protect our proprietary technology, proprietary products and product candidates, and their methods of use. Additionally, we have approximately 45 pending patent applications.

During the year ended December 31, 2025, we received the following:

- New patents in each of USA, and Australia for the patent family named "Therapeutic Regimen For the Treatment of Fabry Using Stabilized Alpha-galactosidase, adding to the single previously granted patent in such family.

- A new patent in USA for the patent family named "Removal of Constructs from Transformed Cells."

Our competitive position and future success depend, in part, on our ability, and that of our licensees, to obtain and leverage the intellectual property rights covering our product candidates, know-how, methods, processes and other technologies, to protect our trade secrets, to prevent others from using our intellectual property and to operate without infringing on the intellectual property rights of third parties. We seek to protect our competitive position by filing United States, EU, Israeli and other foreign patent applications covering our technology, including both new technology and improvements to existing technology. Our patent strategy includes obtaining patents on methods of production, compositions of matter and methods of use. We also rely on know-how, continuing technological innovation, licensing and partnership opportunities to develop and maintain our competitive position. With respect to Elfabrio, we continuously seek to have the patent term extended in those countries in which it has been approved for marketing.

As of December 31, 2025, our patent portfolio consisted of several patent families (consisting of patents and/or patent applications) covering our technology, protein expression methodologies and system, products and product candidates, as follows:

Patent Name/Int. App. No.	Global Pending Jurisdictions	Granted Jurisdictions	Nominal Expiry
Production of High Mannose Proteins in Plant Culture/PCT/ Il2004 000181	N/A	Russian Federation, Australia	2029(1) (3)
Large Scale Disposable Bioreactor/PCT/Il2008/000614	N/A	Australia, Canada, China, Europe, Hong Kong, India, Israel, Republic of Korea, Russian Federation, Singapore, South Africa, USA, Brazil	2028
Stabilized Alpha-galactosidase and uses thereof/PCT/Il2011/ 000209	Brazil	Canada, South Africa, Russian Federation, Singapore, Israel, India, New Zealand, Republic of Korea, Australia, China, Japan, USA, Europe, Hong Kong, India, Brazil	2031(3)
Nucleic Acid Construct for Expression of Alpha-galactosidase in Plants and Plant Cells/PCT/ Il2011/000719	N/A	India, China, Republic of Korea, Japan, Israel, Europe, Hong Kong, USA, Brazil	2031(2)
Therapeutic Regimen For The Treatment of Fabry Using Stabilized Alpha-galactosidase/ PCT/Il2018/050018	Europe, Brazil, Japan, Canada, Israel, Republic of Korea, China, Hong Kong	South Africa, New Zealand, Russian Federation, USA, Chile, Mexico, Australia	2038
Dry Powder Formulations of DNase 1/PCT/Il2013/050094	N/A	Israel, USA	2033
DNase I Polypeptides, Polynucleotides Encoding Same, Methods of Producing DNase I and uses thereof in Therapy/PCT/ Il2013/050097	N/A	Europe, Israel, Brazil	2033

Inhalable Liquid Formulations of DNase I/PCT/Il2013/050096	N/A	Israel, USA	2033
Removal of Constructs from Transformed Cells/PCT/IL2019/ 051266	USA, Israel, New Zealand, Australia	Japan, USA	2040
Long-Acting DNase/PCT/IL2021/051207	Canada, Israel, USA, Japan, Europe, Hong Kong, Republic of Korea, China	N/A	2041
Dicer-Like Knock-Out Plant Cells/ PCT/IL2021/051194	Israel, USA, Japan, Europe, Hong Kong, Republic of Korea, China	N/A	2041
Modified Uricase and Uses Thereof/PCT/IL2021/051305	Japan, Canada, Brazil, USA, Israel, Mexico, Europe, Republic of Korea, China	N/A	2041
Methods of treating diseases associated with elevated uric acid	USA	N/A	N/A

(1) Patent granted in Australia expires in 2029.
(2) Patent granted in the United States expires in 2032.
(3) PTE/SPC applications were submitted for some of the patents.

We are aware of U.S. patents, and corresponding international counterparts of such patents, owned by third parties that contain claims covering methods of producing glucocerebrosidase. We do not believe that, if any claim of infringement were to be asserted against us based upon such patents, taliglucerase alfa would be found to infringe any valid claim under such patents. However, there can be no assurance that a court would find in our favor or that, if we choose or are required to seek a license to any one or more of such patents, a license would be available to us on acceptable terms or at all.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and significant competition. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. Most of these companies have large, established research and development, manufacturing, marketing, financial, technological personnel and managerial resources. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with our current and future product candidates and technologies. Acquisitions of competing companies by large pharmaceutical or biotechnology companies could further enhance such competitors' financial, marketing and other resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize competitive products or technologies on their own through collaborations with pharmaceutical and biotechnology companies.

With respect to Gaucher disease, we face competition primarily from two ERTs, Sanofi Genzyme's Cerezyme and Takeda's (Shire) Vpriv. In addition, Actelion markets a small molecule drug for the treatment of mild to moderate Type 1 Gaucher disease (Zavesca or miglustat), an oral treatment approved by the FDA only for patients for whom ERT is not a therapeutic option. In addition, Sanofi Genzyme markets a small molecule oral drug, Cerdelga®, approved for Gaucher patients with certain CYP2D6 metabolizer status. We are aware of other treatments, such as venglustat which completed a Phase 3 clinical trial for the treatment of Type 3 Gaucher disease, and gene therapies in clinical development and later stage clinical development for the treatment of Gaucher disease.

With respect to Fabry disease, we face competition primarily from Sanofi Genzyme (Fabrazyme), Takeda (Replagal) and Amicus (Galafold®). In addition, we are aware of other late clinical stage, early clinical stage and experimental drugs that are being developed by other companies for the treatment of Fabry disease. In particular, Sangamo Therapeutics, Inc. has initiated a rolling Biologics License Application (BLA) submission to the FDA for accelerated approval of ST-920, its gene therapy in development for the treatment of Fabry disease.

With respect to uncontrolled gout, we face competition from Amgen Inc.'s Krystexxa, which is indicated for treatment of chronic gout in adult patients refractory to conventional therapy. In addition, we are aware of other clinical stage, early clinical stage and experimental refractory or chronic gout treatments. For example, Swedish Orphan Biovitrum AB (Sobi) has developed Pegadriscase (NASP) for the treatment of chronic refractory gout that recently completed a Phase 3 clinical trial, and the FDA has set a Prescription Drug User Fee Act (PDUFA) target action date in June 2026 for its review and decision on NASP. We are also aware of another product candidate that is the subject of a Phase 2 clinical trial for hyperuricemia in gout patients with advanced CKD.

We also face potential competition to our ProCellEx system from companies that are developing other platforms for the expression of recombinant therapeutic pharmaceuticals. We are aware of companies that are developing alternative technologies to develop and produce therapeutic proteins in anticipation of the expiration of certain patent claims covering marketed proteins. A number of companies have developed or are developing alternative expression technologies. Examples include Crucell N.V.'s (acquired by Johnson & Johnson) expression system based on human-cell technology, Dyadic International Inc.'s expression system based on a fungus, Pfenex Inc.'s (acquired by Ligand Pharmaceuticals Incorporated) bacteria-based expression system, and others. Companies developing alternate plant-based technologies include iBio, Inc., Medicago, Inc., and Eleva Biologics. Unlike ProCellEx, these alternate technologies are not cell-based. These companies base their product development on transgenic plants or whole plants.

Manufacturing

We use our manufacturing facility in Carmiel, Israel, which has approximately 1,466 sq/m of clean rooms built according to industry standards, to manufacture drug substance for Elfabrio and Elelyso for commercial purposes. We maintain an approximately 316 sq/m pilot plant for protein development and to manufacture supplies for clinical trials (Phase 1 and Phase 2). Elelyso, Elfabrio, PRX-115 and our other drug product candidates must be manufactured in a clean environment and in compliance with cGMPs set by the FDA and other relevant foreign regulatory authorities. We intend to use our manufacturing space to produce all of the drug substance needed in connection with the clinical trials for our other product candidates.

Our manufacturing facility is an approved multi-product facility. Our facility's current capacity can serve all of our current commercial and clinical needs and we are preparing to expand the manufacturing space within our current facility to add additional purification capabilities in anticipation of future needs with respect to the potential commercialization of PRX-115.

Our manufacturing facilities are subject to inspections by various regulatory authorities from time to time. We have undergone successful in-person and virtual inspections by the FDA, the Irish Medicines Board (under the EMA's centralized marketing authorization procedure), the Brazilian National Health Surveillance Agency (ANVISA), the Israeli Ministry of Health, the Turkish Ministry of Health, the Australian Therapeutic Goods Administration (TGA), Health Canada, and the South Korean Ministry of Health and Welfare.

Raw Materials and Suppliers

We believe that the raw materials that we require throughout the manufacturing process of Elfabrio and Elelyso, and our current and potential drug product candidates, are widely available from numerous suppliers and are generally considered to be generic industrial biological supplies. We rely on a single, approved supplier for certain materials relating to the current expression of our proprietary biotherapeutic proteins through ProCellEx. We have identified additional suppliers for most of the materials required for the production of our product candidates.

Development and regulatory approval of our pharmaceutical products are dependent upon our ability to procure active ingredients (DS) and certain packaging materials from sources approved by the FDA and other regulatory authorities.

The FDA and other regulatory approval processes require manufacturers to specify their proposed suppliers of active ingredients (which is not relevant to our company), intermediate material and certain packaging materials in their applications. From time to time, we intend to continue to identify alternative approved suppliers to ensure the uninterrupted supply of necessary raw materials.

Government Regulations

U.S. Drug Development Process

The FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act, or the FFDCA, and the implementing regulations thereto. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FFDCA, Section 351 of the Public Health Service Act, and related regulations and other federal, state and local laws and regulations. Biological products include a wide variety of products including vaccines, blood and blood components, gene therapies, tissue and proteins. Unlike most prescription products made through chemical processes, biological products generally are made from human and/or animal materials. To be lawfully marketed in interstate commerce, a recombinant protein biologic product must be the subject of a BLA issued by the FDA on the basis of a demonstration that the product is safe, pure and potent, and that the facility in which the product is manufactured meets standards to assure that the product continues to be safe, pure and potent. The FDA has developed, and is continuously updating, the requirements and has issued documents concerning the regulation of cellular and tissue-based products. Manufacturers of cell and tissue-based products must comply with the FDA's current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease.

The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state and local statutes and regulations in the United States, and foreign statutes and regulations, requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a biological product or drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies, with certain studies conducted in accordance with Good Laboratory Practice regulations, or GLPs, and other applicable regulations;
- Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials according to Good Clinical Practices, or GCPs, to establish the safety and efficacy of a proposed drug candidate, and the safety, purity and potency of a proposed biological product candidate, for its intended use;
- Submission to the FDA of a BLA for a new biological product or a new drug application, or NDA, for a new drug;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;

- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and

- FDA review and approval of the BLA or NDA.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit, among other things, the results of the preclinical tests, together with manufacturing information and analytical data appropriate to the development stage, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND review time is 30 days unless there are deficiencies and/or the FDA, within the 30-day time period, places the IND on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with FDA requirements, in which case clinical trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. FDA may also place a trial on a partial clinical hold. A partial clinical hold is a delay or suspension of only part of the clinical work requested or ongoing under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only begin or resume after the FDA has notified the sponsor that the investigation may proceed.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all subjects participating in the clinical trial provide their informed consent regarding the trial. Further, an IRB must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject, or his or her legal representative, and must monitor the clinical trial until completed. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval.

Human clinical trials are typically conducted in three sequential Phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients having the specific disease.

- *Phase 2.* Phase 2 clinical trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and the optimal dosage and schedule.

- *Phase 3.* Phase 3 clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Post-approval studies, also called Phase IV trials, may be conducted after initial marketing approvals. These studies are used to obtain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the trial sponsor

may suspend or terminate a clinical trial at any time on various grounds, including a finding that the study subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the applicable product candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product candidate, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees which may be waived under certain limited circumstances.

The testing and approval processes require substantial time and effort, and may not result in approval on a timely basis, if at all. The FDA may refuse to approve a BLA or NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Generally, it takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's or biologic's safety and effectiveness after BLA or NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA imposes other conditions, including distribution restrictions or other risk management mechanisms, including a risk evaluation and mitigation strategy, or REMS, which can materially affect the potential market and profitability of the product.

In addition, the Pediatric Research Equity Act, or the PREA, requires a sponsor to conduct pediatric clinical trials for most biologics and drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under the PREA, original NDAs and BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness, or safety, purity, and potency, of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective, or safe, pure and potent. The sponsor may request or the FDA may grant a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional data need to be collected before the pediatric clinical trials begin.

Orphan Drug Designation

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs and biological products intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 persons in the United States but that sales in the United States are not expected to recover the costs of developing and marketing a treatment drug. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Among the benefits of orphan drug designation are possible funding and tax savings to support clinical trials, other financial incentives and a waiver of the marketing application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not

approve any other applications to market the same treatment for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan drug status in the EU has similar but not identical benefits in the EU.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between (a) the effective date of an IND and the submission date of a BLA or an NDA plus (b) the time between the submission date of a BLA or an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The U.S. Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. We anticipate that we will apply for restorations of the patent term for certain of patents covering our product candidates.

Fast Track Designation; Breakthrough Therapy Designation

The FDA has a fast track program that is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, the purpose being to make important new drugs available to patients earlier. A drug candidate that receives Fast Track designation from the FDA is eligible for some or all of the following: more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; more frequent written communication from the FDA about such things as the design of the proposed clinical trials; eligibility for the FDA's Accelerated Approval and Priority Review, if relevant criteria are met; and eligibility for Rolling Review, which allows a drug company to submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the BLA or NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Accelerated Approval; Breakthrough Therapy Designation

Section 901 of the U.S. Food and Drug Administration Safety Innovations Act amends the FFDCA to allow the FDA to base Accelerated Approval for drugs for serious conditions that fill an unmet medical need on whether the drug has an effect on a surrogate or an intermediate clinical endpoint. A surrogate endpoint used for Accelerated Approval is a marker; that is, a laboratory measurement, radiographic image, physical sign or other measure, that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. The FDA bases its decision on whether to accept the proposed surrogate or

intermediate clinical endpoint on the scientific support for that endpoint. Studies that demonstrate a drug's effect on a surrogate or intermediate clinical endpoint must be "adequate and well controlled" as required by the FFDCA.

The Accelerated Approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Under subpart H of the Accelerated Approval pathway, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. The Accelerated Approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA, which could adversely impact the timing of the commercial launch of the product.

Post-Approval Requirements

Drugs approved by the FDA are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse effects with the product, reporting of changes in distributed products which would require field alert reports (FARs), drugs and biological product deviation reports (BPDRs) providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post marketing studies and clinical trials (PMRs and PMCs), labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies (REMS), approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs and biologics must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug and biologic manufacturers and other entities involved in the manufacturing and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP applicable to biologics, and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Discovery of previously unknown problems with a product subsequent to its approval, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new

legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our development efforts. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

Pharmaceutical products are subject to regulations and product registration requirements in many foreign countries, including in the areas of product standards, packaging requirements, labeling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Pharmaceutical products may not be imported into, or manufactured or marketed in, the State of Israel absent drug registration. The three basic criteria for the registration of pharmaceuticals in Israel is quality, safety and efficacy of the pharmaceutical product and the Israeli Ministry of Health requires pharmaceutical companies to conform to international developments and standards. Regulatory requirements are constantly changing in accordance with scientific advances as well as social and ethical values.

The relevant legislation of the EU requires that medicinal products, including generic versions of previously approved products, and new strengths, dosage forms and formulations, of previously approved products, shall have a marketing authorization before they are placed on the market in the EU. Authorizations are granted after the assessment of quality, safety and efficacy by the respective health authorities. In order to obtain an authorization, an application must be made to the competent authority of the member state concerned or in a centralized procedure to the EMA. Besides various formal requirements, the application must contain the results of pharmaceutical (physico-chemical, biological or microbiological) tests, of preclinical (toxicological and pharmacological) tests as well as of clinical trials. All of these tests must have been conducted in accordance with relevant EU regulations and must allow the reviewer to evaluate the quality, safety and efficacy of the medicinal product.

Orphan drug designation in the EU is granted to medicinal products intended for the diagnosis, prevention and treatment of life-threatening diseases and very serious conditions that affect not more than five in 10,000 people in the EU. Orphan drug designation is generally given to medicinal products that treat conditions for which no current therapy exists or are expected to bring a significant benefit to patients over existing therapies. To obtain marketing approval of a drug under EU regulatory systems, marketing authorization applications may be submitted either under a centralized, decentralized or national procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU and EEA member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases, and optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Products and product candidates that have received or will receive orphan designation in the EU qualify for this centralized procedure under which each product's marketing authorization application will be submitted to the EMA.

Third Party Payor Coverage and Reimbursement

Coverage and reimbursement status of any approved therapy carries uncertainty and risk for the market application holder. Commercialization of drug products in both the United States and foreign markets, our ability to commercialize our product and product candidates successfully, and the ability to attract commercialization partners, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as Medicare, Medicaid and the Veterans Affairs Health programs, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often

rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position most drug products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we, our commercialization partners or our customers seek reimbursement for our product candidates may be subject to challenge, reduction or denial by the government and other payors.

Possible legislation at the federal and state levels in the United States focused on cost containment and price transparency may impact our ability, or the ability of our commercialization partners, to sell our products and product candidates for maximum profitably. It appears likely that the pressure on pharmaceutical pricing will continue, especially under the Medicare program, which may also increase our regulatory burdens and operating costs. Moreover, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product and product candidates.

Some third-party payors also require pre-approval of coverage for new or innovative devices, biologics or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability, or the ability of our commercialization partners, to obtain adequate prices for our product candidates and operate profitably.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities and those of our commercialization partners are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney General offices within the Department of Justice, and state and local governments. These regulations include, among others:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services

information related to physician payments and other transfers of value and physician ownership and investment interests;

- the FFDCA, which among other things, strictly regulates drug and biologic product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- the Foreign Corrupt Practices Act of 1977, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Compliance with Environmental, Health and Safety Laws

In addition to FDA regulations, we are also subject to evolving federal, state and local environmental, health and safety laws and regulations. Compliance with environmental, health and safety laws and regulations has not had a material effect on our capital expenditures. Compliance with environmental, health and safety laws and regulations in the future may require additional capital expenditures.

Israeli Government Programs

The following is a brief summary of the current principal Israeli tax laws applicable to us and Protalix Ltd., and of the Israeli Government programs from which Protalix Ltd. benefits. Some parts of this discussion are based on new tax legislation that has not been subject to judicial or administrative interpretation. Therefore, the views expressed in the discussion may not be accepted by the tax authorities in question. This summary is based on laws and regulations in effect as of the date hereof, and should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

General Corporate Tax Structure in Israel

The income of Protalix Ltd., other than income from "Approved Enterprises," is taxed in Israel at regular rates. Pursuant to the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016, the corporate tax rate in 2018 and thereafter is 23%. Capital gains on the sale of assets are subject to capital gains tax according to the corporate tax rate in effect in the year which the assets are sold.

Law for the Encouragement of Capital Investments, 1959

The Law for the Encouragement of Capital Investments, 1959, as amended, or the Investment Law, provides certain incentives for capital investments in a production facility (or other eligible assets). Generally, an investment program that is implemented in accordance with the provisions of the Investment Law, referred to as an "Approved Enterprise," is entitled to benefits. These benefits may include cash grants from the Israeli government and tax benefits, based upon, among other things, the location within Israel of the facility in which the investment is made and specific elections made by the grantee. In order to qualify for these incentives, an Approved Enterprise is required to comply with the requirements of the Investment Law, and Letter of approval received by Protalix Ltd.

Protalix Ltd. will continue to enjoy the tax benefits under the pre-revision provisions of the Investment Law. If any new benefits are granted to Protalix Ltd. in the future, Protalix Ltd. will be subject to the provisions of the amended

Investment Law with respect to these new benefits. Therefore, the following discussion is a summary of the Investment Law prior to its amendment as well as the relevant changes contained in the new legislation.

Under the Investment Law prior to its amendment, a company that wished to receive benefits had to receive approval from the Authority for the Investment and Development of the Industry and Economy, or the Investment Center. Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset, e.g., the equipment to be purchased and utilized pursuant to the program.

An Approved Enterprise may elect to forego any entitlement to the grants otherwise available under the Investment Law and, instead, participate in an alternative benefits program under which the undistributed income (after deductions and offsets) from the Approved Enterprise is exempt from corporate tax for a defined period of time. Under the alternative package of benefits, a company's undistributed income derived from an Approved Enterprise will be exempt from corporate tax for a period of between two and 10 years from the first year of taxable income, depending upon the geographic location within Israel of the Approved Enterprise. Upon expiration of the exemption period, the Approved Enterprise is eligible for the reduced tax rates otherwise applicable under the Investment Law for any remainder of the otherwise applicable benefits period (up to an aggregate benefits period of either seven or 10 years, depending on the location of the company or its definition as a foreign investors' company). If a company has more than one Approved Enterprise program or if only a portion of its capital investments are approved, its effective tax rate is the result of a weighted combination of the applicable rates. The tax benefits from any certificate of approval relate only to taxable profits attributable to the specific Approved Enterprise and are contingent upon meeting the criteria set out in the certificate of approval. Income derived from activity that is not integral to the activity of the Approved Enterprises (including capital gain) does not enjoy these tax benefits.

A company that has an Approved Enterprise program is eligible for further tax benefits, as an alternative to exemption, if it qualifies as a foreign investors' company. A foreign investors' company eligible for benefits is essentially a company in which more than 25% of the share capital (in terms of shares, rights to profit, voting and appointment of directors) is owned (measured by both share capital and combined share and loan capital) by non-Israeli residents. A company that qualifies as a foreign investors' company and has an Approved Enterprise program is eligible for tax benefits for a 10-year benefit period and may enjoy a reduced corporate tax rate of 10% to 23%, depending on the amount of the company's shares held by non-Israeli shareholders.

If a company that has an Approved Enterprise program is a wholly-owned subsidiary of another company, the percentage of foreign investments is determined based on the percentage of foreign investment in the parent company. The tax rates and related levels of foreign investments with respect to a foreign investor's company that has an Approved Enterprise program are set forth in the following table:

Percent of Foreign Ownership	Rate of Reduced Tax
Over 25% but less than 49%	23%
49% or more but less than 74%	20%
74% or more but less than 90%	15%
90% or more	10%

Our original facility in Israel has been granted "Approved Enterprise" status, and it has elected to participate in the alternative benefits program. Under the terms of its Approved Enterprise program, the facility is located in a Zone A area and, therefore, the undistributed income from that Approved Enterprise will be tax exempt in Israel for a period of 10 years, commencing with the year in which taxable income is first generated from the relevant Approved Enterprise.

A company that has elected to participate in the alternative benefits program and that subsequently pays a dividend out of the income derived from the portion of its facilities that have been granted Approved Enterprise status during the tax exemption period will be subject to corporate tax in respect of the amount of dividend distributed at the rate that would have been applicable had the company not elected the alternative benefits program (generally 10% to 23%, depending on the extent to which non-Israeli shareholders hold such company's shares). If the dividend is distributed within 12 years after the end of the benefits period (or, in the case of a foreign investor's company, without time limitation), the dividend recipient is taxed at the reduced withholding tax rate of 20% applicable to dividends from approved enterprises, or at the

lower rate under an applicable tax treaty. After this period, the withholding tax rate is 25% to 30%, or at the lower rate under an applicable tax treaty. In the case of a company with a foreign investment level (as defined by the Investment Law) of 25% or more, the 12-year limitation on reduced withholding tax on dividends does not apply. The company must withhold this tax at its source, regardless of whether the dividend is converted into foreign currency.

The Investment Law also provides that an Approved Enterprise is entitled to accelerated depreciation on its property and equipment that are included in an approved investment program. This benefit is an incentive granted by the Israeli government regardless of whether the alternative benefits program is elected.

The benefits available to an Approved Enterprise are conditioned upon terms stipulated in the Investment Law and its regulations and the criteria set forth in the applicable certificate of approval. If Protalix Ltd. does not fulfill these conditions in whole or in part, the benefits can be canceled and Protalix Ltd. may be required to refund the benefits received, linked to the Israeli consumer price index with interest. In addition, if we increase our activities outside of Israel, for example, by future acquisitions, such increased activities generally may not be eligible for inclusion in Israeli tax benefit programs. We believe that Protalix Ltd. currently operates in compliance with all applicable conditions and criteria.

Amendment of the Law for the Encouragement of Capital Investments, 1959

In recent years, several amendments have been made to the Investments Law which have enabled new alternative benefit tracks, subject to certain conditions. The Investments Law was amended as part of the Economic Policy Law for the years 2011-2012 (amendment 68 to the Encouragement of Capital Investments Law), which was passed by the Israeli Knesset on December 29, 2010. The amendment sets alternative benefit tracks to those currently in effect under the provisions of the Investments Law. On December 29, 2016, Amendment 73 to the Investments Law, or the Investments Law Amendment, was published. This amendment sets new benefit tracks, inter alia, "Preferred Technological Enterprise" and "Special Preferred Technological Enterprise." To date, we have elected not to have the Investments Law Amendment apply to our company.

Encouragement of Industrial Research, Development and Technology Innovation Law, 1984

To date, Protalix Ltd. has received grants from the Office of the Chief Scientist of the Israeli Department of Labor, or the OCS, under the Israeli Law for the Encouragement of Industrial Research, Development and Technology Innovation, 1984, and related regulations, or the Research Law. On January 1, 2016, the Israeli government established the National Authority for Technological Innovation, or NATI, which replaced many of the functions of the OCS. For purposes of clarity, references to NATI will include the OCS. NATI grants may be made available, from time to time, to finance a portion of Protalix Ltd.'s research and development expenditures in Israel. As of December 31, 2025, NATI approved grants in respect of Protalix Ltd.'s continuing operations totaling approximately $53.2 million (before interest, as described below), measured from inception. Protalix Ltd. is required to repay up to 100% of grants actually received (plus interest at the LIBOR rate applied to the grants received on or after January 1, 1999) to NATI through payments of royalties at a rate of 3% to 6% of the revenues generated from NATI-funded project, depending on the period in which revenues were generated. As of December 31, 2025, Protalix Ltd. either paid or accrued royalties payable of $20.8 million, and Protalix Ltd.'s contingent liability to NATI with respect to grants received was approximately $32.4 million.

Under the Research Law, recipients of grants from NATI are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals, although the Research Law does enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties. If Protalix Ltd. receives approval to manufacture the products developed with government grants outside of Israel, it will be required to pay an increased total amount of royalties (possibly up to 150% of the grant amounts plus interest), depending on the manufacturing volume that is performed outside of Israel, as well as at a possibly increased royalty rate.

Additionally, under the Research Law, Protalix Ltd. is prohibited from transferring NATI-financed technologies and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the approval of NATI Council or the Research Committee. Protalix Ltd. may not receive the required approvals for any

proposed transfer and, if received, Protalix Ltd. may be required to pay NATI a portion of the consideration that it receives upon any sale of such technology by a non-Israeli entity. The scope of the support received, the royalties that Protalix Ltd. has already paid to NATI, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which NATI grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to NATI. The payments to NATI may result in up to 600% of the grant amounts plus interest. Approval of the transfer of technology to residents of the State of Israel is required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurance can be made that approval of any such transfer, if requested, will be granted.

Under the Research Law and the regulations promulgated thereunder, the NATI Council may allow the transfer outside of Israel of know-how derived from an approved program and the related manufacturing rights in limited circumstances which are currently as follows:

- in the event of a sale of know-how itself to a non-affiliated third party, provided that upon such sale the owner of the know-how pays to NATI an amount, in cash, as set forth in the Research Law (and the regulations promulgated thereunder). In addition, the amendment provides that if the purchaser of the know-how gives the selling Israeli company the right to exploit the know-how by way of an exclusive, irrevocable and unlimited license, the research committee may approve such transfer in special cases without requiring a cash payment.

- in the event of a sale of a company which is the owner of know-how, pursuant to which the company ceases to be an Israeli company, provided that upon such sale, the owner of the know-how makes a cash payment to NATI as set forth in the Research Law (and the regulations promulgated thereunder).

- in the event of an exchange of know-how such that in exchange for the transfer of know-how outside of Israel, the recipient of the know-how transfers other know-how to the company in Israel in a manner in which NATI is convinced that the Israeli economy realizes a greater, overall benefit from the exchange of know-how.

The Research Committee may, in special cases, approve the transfer of manufacture or of manufacturing rights of a product developed within the framework of the approved program or which results therefrom, outside of Israel.

The State of Israel does not own intellectual property rights in technology developed with NATI funding and there is no restriction on the export of products manufactured using technology developed with NATI funding. The technology is, however, subject to transfer of technology and manufacturing rights restrictions as described above. For a description of such restrictions, please see "Risk Factors—Risks Relating to Our Operations in Israel." NATI approval is not required for the export of any products resulting from the research or development or for the licensing of any technology in the ordinary course of business.

Law for the Encouragement of Industry (Taxes), 1969

We believe that Protalix Ltd. currently qualifies as an "Industrial Company" within the meaning of the Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law. The Industry Encouragement Law defines "Industrial Company" as a company resident in Israel and incorporated in Israel, that derives 90% or more of its income in any tax year (other than specified kinds of passive income such as capital gains, interest and dividends) from an "Industrial Enterprise" operating in Israel (including Judea & Samaria territories and the Gaza strip), that it owns. An "Industrial Enterprise" is defined as an enterprise whose major activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization of the cost of purchased know-how and patents over an eight-year period for tax purposes;

- accelerated depreciation rates on equipment and buildings;

- under specified conditions, an election to file consolidated tax returns with other related Israeli Industrial Companies; and

- expenses related to a public offering are deductible in equal amounts over three years.

Eligibility for the benefits under the Industry Encouragement Law is not subject to receipt of prior approval from any governmental authority. It is possible that Protalix Ltd. may fail to qualify or may not continue to qualify as an "Industrial Company" or that the benefits described above will not be available in the future.

Tax Benefits for Research and Development

Under specified conditions, Israeli tax laws allow a tax deduction by a company for research and development expenditures, including capital expenditures, for the year in which such expenditures are incurred. These expenditures must relate to scientific research and development projects and must be approved by NATI. Furthermore, the research and development projects must be for the promotion of the company and carried out by or on behalf of the company seeking such tax deduction. However, the amount of such deductible expenditures is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. Research and development expenses which were not approved shall be deductible over a period of three years.

Employees

As of December 31, 2025, we had 226 employees, all of whom are full time employees, and of which 25 have a Ph.D. or an M.D. in their respective scientific fields. We believe that our relations with our employees are good. We believe that our success will greatly depend on our ability to identify, attract and retain capable employees. The Israeli Ministry of Labor and Welfare is authorized to make certain industry-wide collective bargaining agreements, or Expansion Orders, that apply to types of industries or employees including ours. These agreements affect matters such as cost of living adjustments to salaries, length of working hours and week, recuperation, travel expenses, and pension rights. Otherwise, our employees are not represented by a labor union or represented under a collective bargaining agreement. See "Risk Factors—We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

Set forth below is a chart showing the number of people we employed at the times indicated:

	As of December 31,		
	2023	2024	2025
Total Employees	208	213	226
Research and Development	47	48	62
General and Administrative	14	14	14
Operations	147	151	150

Company Background

We were originally incorporated in the State of Florida in April 1992, and reincorporated in the State of Delaware in March 2016. Protalix Ltd., our wholly-owned subsidiary and sole operating unit, is an Israeli company and was incorporated in Israel in 1993.

ProCellEx® is our registered trademark. Each of the other trademarks, trade names or service marks appearing in this Annual Report on Form 10-K belongs to its respective holder.

Available Information

Our main corporate website address is http://www.protalix.com. We make available on our website, free of charge, our Commission filings, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports, as soon as reasonably practicable after we electronically file these documents with, or furnish them to, the Commission. The Commission maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the Commission at

www.sec.gov. Additionally, from time to time, we provide notifications of material news including press releases and conferences on our website. Webcasts of presentations made by our company at certain conferences may also be available from time to time on our website, to the extent the webcasts are available. The content of our website is not intended to be incorporated by reference into this report or in any other report or document we file and any references to these websites are intended to be inactive textual references only. Interested persons may sign up on our website to automatically receive e-mail alerts when we post financial information and issue press releases, and to receive information about upcoming events.

Our website also includes printable versions of our Code of Business Conduct and Ethics and the charters for each of the Audit, Compensation and Nominating Committees of our Board of Directors. Each of these documents is also available in print, free of charge, to any stockholder who requests a copy by addressing a request to:

Protalix BioTherapeutics, Inc.
2 Snunit Street, Science Park
Carmiel 2161401, Israel
Attn: Gilad Mamlok, Sr. Vice President and Chief Financial Officer

Item 1A. Risk Factors

You should carefully consider the risks described below together with the other information included in this Annual Report on Form 10-K. Our business, financial condition and results of operations could be adversely affected by any of these risks. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, results of operations and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this Annual Report on Form 10-K. If any of these risks occur, the value of our common stock could decline. A summary of the risk factors included in this Item 1A are set forth below followed by a full set of risk factors described in greater detail. For further details on our forward-looking statements, see "Cautionary Statement Regarding Forward-Looking Statements" on page 1.

Summary of Risk Factors

Risks Related to the Commercialization and Continued Approval of our Products

- We currently depend heavily on the generation of revenues from the sales of Elfabrio and Elelyso.
- Any current products or future product candidates may cause serious adverse events or undesirable side effects.
- There may be safety issues regarding our products that were not known at the time of approval are discovered.
- Physicians, patients, third party payors and others in the medical community might not accept and use our current or future products.
- Coverage and reimbursement may not be available for our current or future products in all territories.

Risks Related to Our Business

- We have a limited commercial operating history.
- We may fail to supply drug substance to Chiesi or Pfizer.
- We may be unable to enhance our portfolio of product candidates.
- We or our providers may experience manufacturing problems.
- Reliance on third parties for final processing of our products and product candidates exposes us to a number of risks.
- Developments by competitors may render our products or technologies obsolete or non-competitive.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.
- Our internal computer systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches and expose our company to liabilities.
- We may face product liability claims.
- Our ability to utilize net operating loss carryforwards may be limited.

Risks Related to Clinical Trials and Regulatory Matters

- We may not obtain the necessary U.S., EMA, or other worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all.

- We may experience delays in obtaining regulatory approvals with respect to any drug candidate.

- Preclinical and clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs.

- If the results of our clinical trials do not support our claims relating to a drug candidate, or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether.

- We may find it difficult to enroll patients in our clinical trials or patients may discontinue their participation in our clinical trials.

- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

- Dependence upon third-party service providers in connection with our clinical trials expose us to risks.

Risks Related to our Financial Condition and Capital Requirements

- We may need to raise additional capital to operate our business, which may not be available on favorable terms, or at all.

Risks Related to Intellectual Property Matters

- We may fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, and the terms of certain of our patents are limited or have expired.

Risks Relating to our Operations in Israel

- Our results may be adversely affected by military, political and economic conditions in Israel.

- The Israeli government grants we have received for certain research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions.

Risks Related to Investing in our Common Stock

- The market price of our common stock may fluctuate significantly; future sales of our common stock could reduce our stock price.

- Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses or divert management's attention.

- Delaware law and our organizational documents contain certain anti-takeover provisions.

- Our Amended and Restated Bylaws provide for limits on our stockholders' ability to obtain a favorable judicial forum.

* * *

Risks Related to the Commercialization and Continued Approval of our Products

We currently depend heavily on the generation of revenues from the sales of Elfabrio and Elelyso. Any failure to successfully commercialize Elfabrio will have a material adverse effect on our business, results of operations, and financial condition.

We have invested a significant portion of our efforts and financial resources in the development of Elfabrio, and in the past, on the development of Elelyso. Our ability to generate significant product revenues in the future from sales of Elfabrio depends on Chiesi's successful commercialization of Elfabrio, which we do not control and may not be able to effectively influence, and on the actions and decisions of foreign regulatory authorities. Chiesi may experience delays in, or be unable to achieve, the commercial introduction of Elfabrio globally. Similarly, we generate revenues from sales of Elelyso which are depend on Pfizer's efforts (except in Brazil), which we do not control. Sales of BioManguinhos alfataliglicerase in Brazil are controlled by Fiocruz. The successful worldwide commercialization of Elfabrio and Elelyso depends on several factors, including the following:

- the effectiveness of Chiesi's commercial strategy and its execution of that strategy, including its pricing strategy, its development and maintenance of successful sales and marketing organizations, and the effectiveness of its efforts to obtain adequate third-party reimbursements and, to a lesser extent, Pfizer's and Fiocruz's commercial efforts;

- expansion by Chiesi and Pfizer of the scope of the countries in which our products are approved for marketing;

- maintaining the cGMP compliance of our manufacturing facility or establishing manufacturing arrangements with third parties;

- the willingness of patients with Fabry disease and Gaucher disease to switch from other treatments to Elfabrio or Elelyso, as the case may be;

- competition from other approved treatments of Fabry disease and Gaucher disease;

- the continued acceptable safety and efficacy profile of Elfabrio and Elelyso; and

- other risks described in these Risk Factors.

Any failure to continue or expand the commercialization of either Elfabrio or Elelyso globally or the experience of significant delays in doing so may have a material adverse effect on our business, results of operations, and financial condition.

Any current products or future product candidates may cause serious adverse events, or SAEs, undesirable side effects or have other properties that could halt their clinical development, prevent, delay, or cause the withdrawal of their regulatory approval, limit their commercial potential, or result in material negative consequences.

As with most infused products, use of our products or any current or future product candidates could be associated with undesirable side effects or adverse events which can vary in severity and frequency. From time to time, we have observed serious adverse events in clinical studies of our products and product candidates. For example, while conducting clinical trials of Elfabrio, we have observed treatable anaphylactic reactions. Specifically with respect to Elfabrio, as indicated in the boxed warning with which it was approved by the FDA, patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. There are postmarketing requirements under the FFDCA included with the approval of Elfabrio by the FDA. For example, the FDA requires that a worldwide descriptive study be conducted that collects prospective and retrospective data in women and their offspring exposed to Elfabrio during pregnancy and/or lactation to assess risk of pregnancy and material complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant. Furthermore, the approval of pharmaceutical products generally includes requirements related to the preparation of a Risk Evaluation and Mitigation Strategy, or REMS, or a risk management plan as required by the EMA, which could include a medication guide outlining the risks of such side

effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use. For example, Chiesi must follow a risk management plan agreed upon with the EMA with respect to Elfabrio, which includes risk minimization measures in connection with risks associated with hypersensitivity reactions and possible medication errors in the home infusion setting.

Our product candidates, if approved, may also be subject to certain post-authorization reporting requirements. As an example, the EMA has required that Chiesi submit pharmacovigilance documents intended to provide post-authorization evaluation of Elfabrio's risk-benefit balance at defined time points after authorization, beginning within six months of authorization, and that an educational program about home administration be agreed upon with the National Competent Authority (as defined by the EMA) prior to the use of Elfabrio in the home setting.

Any of the foregoing, including the boxed warning, could prevent us or our commercialization partners from achieving or maintaining market acceptance of a product or a particular product candidate and could materially harm our business, results of operations, and prospects, and could adversely impact our financial condition, results of operations, ability to raise additional financing or the market price of our common stock.

If safety issues regarding our products that were not known at the time of approval are discovered, or if we or the applicable marketing authorization holder fails to comply with continuing U.S. and applicable foreign regulations, commercialization efforts for our products could be adversely affected and the products could lose their approval or their sales could be suspended.

Drug products remain subject to continuing regulatory oversight after they are approved for marketing, including the review of additional safety information. Drugs are more widely used by patients once approved for sale and, therefore, side-effects and other problems may be observed after approval that were not seen or anticipated, or were not as prevalent or severe, during clinical trials or nonclinical studies. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause our stock price to decline or experience periods of volatility and may have a material adverse effect on our business, results of operations, and financial condition.

If we or the marketing authorization holder, or MAH, of any of our products fail to comply with applicable continuing regulatory requirements, we or such MAH may be subject to fines and/or criminal prosecutions, and the product may become subject to suspension or withdrawal of regulatory approval, product recalls and seizures and operating restrictions. In addition, the manufacturers we or an MAH engage to produce a product and the manufacturing facilities in which the product is made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in the facility becoming unable to manufacture the product or a determination that inventories are not safe for commercial sale, which may have a material adverse effect on our business, results of operations, and financial condition.

If physicians, patients, third party payors and others in the medical community do not accept and use Elfabrio, Elelyso or any other future products, our ability to generate revenue from product sales will be materially impaired.

Physicians and patients, and other healthcare providers, may not accept and use Elfabrio, Elelyso or any other products we may develop in the future. Future acceptance and use of any of our products will depend upon a number of factors including:

- perceptions by physicians, patients, third party payors and others in the medical community about the safety and effectiveness of Elfabrio or Elelyso, or any future product, if any;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the prevalence and severity of any side effects, including any limitations or warnings contained in our products' approved labeling, including the boxed warning associated with Elfabrio in the United States;
- pharmacological benefits of Elfabrio or Elelyso, or any future product, if any relative to competing products and products under development;
- the efficacy and potential advantages relative to competing products and products under development;
- relative convenience and ease of administration;
- effectiveness of education, marketing and distribution efforts by Chiesi, Pfizer and any other relevant licensees and distributors;
- publicity concerning Elfabrio or Elelyso, or any future product, if any, or concerning competing products and treatments; and
- the price for our products and competing products.

If the market opportunities for Elfabrio, Elelyso or any other future products are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

To date, our development efforts have focused mainly on relatively rare disorders with relatively small patient populations, in particular Gaucher disease and Fabry disease. Estimation of the prevalence of these diseases are based on studies of small subsets of the population of specific geographic areas and are often inexact and prone to error. As new studies are performed, the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of Gaucher disease or Fabry disease in the study populations, particularly in these newer studies, accurately reflect the prevalence of these diseases in the broader world population. If the market opportunities for our products or product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Coverage and reimbursement may not be available for Elfabrio, Elelyso, or any other future products in all territories, which could diminish sales of our products or adversely affect the profitably of such sales.

Market acceptance and sales of Elfabrio, Elelyso or any other future products, if any, will depend on coverage and reimbursement policies in the countries in which they are approved for sale. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Obtaining reimbursement approval for an approved product from individual governments and other third-party payors is a time consuming (six to 12 months or longer) and costly process that requires our collaborators or us, as the case may be, to provide supporting scientific, clinical and cost-effectiveness data for the use of our products, if and when approved, to every payor. Data sufficient to gain acceptance with respect to coverage and reimbursement might not be available, or post-marketing studies may be required in order to demonstrate the cost-effectiveness of approved products, if any, to such payors' satisfaction. Such studies might require our collaborators or us to commit a significant amount of management time and financial and other resources.

Even if a payor determines that an approved product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. For example, the U.S. Inflation Reduction Act allows Medicare to negotiate the prices of the prescription drugs. Such initiatives and legislation may cause added pricing pressure on our products. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from other countries, could have a material adverse effect by limiting our products' use and coverage. To the extent that private insurers or managed care programs in the United States or elsewhere follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules. In addition, full reimbursement may not be available for high priced products. Moreover, eligibility for coverage does not imply that any approved product will be reimbursed in all cases or at a rate

that allows us to make a profit or even cover our costs. Limited reimbursement amounts may reduce the demand for, or the price of, Elfabrio, Elelyso or any other future products. If coverage and reimbursement are not available or are available only to limited levels, the sales of Elfabrio, Elelyso or other future products, if any, may be diminished or we may not be able to sell such products profitably.

In addition, coverage or reimbursement generally may be revoked or modified. For example, pharmaceutical product reimbursement can change relatively easily because payers control coverage. In the EU, coverage or reimbursement decisions face the potential of revocation or modification through reassessment, price renegotiation or conditional reimbursement frameworks. Any renovation or reduction in the coverage or reimbursement of our products may have a material adverse effect on our business, results of operations, and financial condition.

The pricing of our products in different countries may vary widely, thus creating the potential for third-party trade in our products in an attempt to exploit price differences between countries. This third-party trade of our products could undermine our sales in markets with higher prices which could have a material adverse effect on our business, results of operations, and financial condition.

We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

All marketing activities associated with products that are approved for sale in the United States, if any, will be, directly or indirectly through our customers, subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products in the United States, including, without limitation, the federal Anti-Kickback Law, the federal False Claims Act and HIPAA. These laws may adversely impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Law prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments and deductibles, ownership interests and providing anything at less than its fair market value. Despite a series of narrow safe harbors, the federal Anti-Kickback Law prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Law include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other state or federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Law, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. Violations of the federal False Claims Act and the analogous state laws may result in substantial financial penalties, some as much as three times the actual damages sustained by the government.

HIPAA created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that Elfabrio, Elelyso or any other future products, if any, are sold in a foreign country, we and our collaborators may be subject to similar foreign laws and regulations. If we or any of our

collaborators are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring or our operations, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Risks Related to Our Business

We have a limited commercial operating history which may limit the ability of investors to make an informed investment decision.

Elfabrio and Elelyso are our only commercial products both of which are marketed by our commercialization partners. Our operations to date have been limited to acquiring, developing and securing our proprietary technology and undertaking, through third parties, preclinical and clinical trials of our drug candidates and advancing our drug candidates through the regulatory approval processes. These operations provide a limited basis for investors to assess our ability to commercialize our drug candidates and whether to invest in our company.

Any failure by us to supply drug substance to Chiesi or Pfizer may have a material adverse effect on our business, results of operations, and financial condition.

We have agreed to sell drug substance to Pfizer and Chiesi for the production of Elelyso and Elfabrio, respectively. With respect to Elelyso, our drug substance supply commitment is until 2030, subject to certain terms and conditions. As part of that obligation, we agreed to substantial financial penalties if we fail to comply with the supply commitments, or are delayed in doing so. The amounts of the penalties depend on when any such failure occurs and for how long it persists, if at all, and other considerations. Any failure to comply with the supply commitments to Pfizer and/or Chiesi may have a material adverse effect on our business, results of operations, and financial condition.

Our strategy, in certain cases, is to enter into collaboration agreements with third parties to develop product candidates. Failure to enter into such agreements, or non-compliance by us or our collaborators with such agreements, may have a material adverse effect on our business, results of operations, and financial condition.

Our strategy, in certain cases, is to enter into arrangements with pharmaceutical companies to develop additional product candidates. Our future revenues may depend, in part, on our ability to enter into and maintain arrangements with our existing partners and other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and pharmaceutical products on a global scale. Under these arrangements, we may grant to our partners rights to license and commercialize pharmaceutical products developed under the applicable agreements, as we have done with Elfabrio and Elelyso. Commercialization, marketing, distribution and other similar alliances with respect to our products and product candidates will subject us to a number of risks. We may be required to relinquish important rights to our products or product candidates, and the rights of our partners may limit our flexibility in considering alternatives for the commercialization of our products and product candidates. Our partners may control key decisions relating to the development of the products and we may depend on our partners' expertise and dedication of sufficient time and resources to develop and commercialize our products and product candidates. Our partners may experience financial difficulties which adversely affect their efforts with respect to our product and product candidates. If we or any of our current or future partners breach or terminate the agreements that make up such arrangements, our partners otherwise fail to conduct their obligations under such arrangements in a timely manner, there is a dispute about their obligations or if either party terminates the applicable agreement or elects not to continue the arrangement, we may not enjoy the benefits of the agreements or receive a sufficient amount of royalty or milestone payments from them, if any, which may have a material adverse effect on our business, results of operations, and financial condition.

Fiocruz is not complying, and we expect they will continue to not comply, with the terms and conditions of the Brazil Agreement.

We do not control and may not be able to effectively influence Fiocruz's ability to distribute BioManguinhos alfataliglicerase in Brazil. Fiocruz has not complied with the purchase requirements of the Brazil Agreement in the past, and we expect Fiocruz will continue to not comply and may otherwise materially breach the agreement. Continued non-

compliance may result in our decision to terminate the agreement, and may have a material adverse effect on our business, results of operations, and financial condition.

We face the risk of lower than anticipated purchases of BioManguinhos alfataliglicerase by the Brazilian MoH. In addition, we may fail to supply the intended amounts on time, if at all. We also cannot accurately predict the amount of revenues we will generate under the Brazil Agreement in future periods, if any. Any failure by the Brazilian MoH to purchase BioManguinhos alfataliglicerase or by Fiocruz to distribute BioManguinhos alfataliglicerase in Brazil, or the experience of significant delays in any of the foregoing, may have a material adverse effect on our business, results of operations, and financial condition.

We have limited experience in selling, marketing or distributing products and limited internal capability to do so.

We currently have very limited sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. Currently, the distribution of our commercial products are performed by Pfizer, Chiesi, and Fiocruz (in Brazil). The commercialization of a product requires the commitment of significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. If we elect to commercialize our products directly and without strategic partners we may be unable to recruit and retain adequate numbers of effective sales and marketing personnel. In addition, such sales personnel might not access an adequate number of physicians or persuade them to prescribe our products, or may lack complementary products to offer to such physicians. Commercialization by such sales personnel may expose our company to unforeseen costs and expenses.

If we are unable to enhance our portfolio of product candidates, our business may be adversely affected.

A key element of our business strategy is to establish a portfolio of product candidates, particularly in the rare and orphan disease spaces, as targets for development and eventual commercialization. We seek to do so through our internal research programs and strategic collaborations. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. A research program may initially show promise in identifying a potential product candidate, yet fail to immediately yield the product candidate for clinical development for many reasons, including the following:

- a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all;
- the research methodology used may not be successful in identifying potential product candidates; or
- a product candidate may, after further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory approval.

Any failure or delay in the establishment of a portfolio of product candidates may have a material adverse effect on our business, results of operations, and financial condition.

The manufacture of our products is an exacting and complex process, and any manufacturing problems encountered by us or certain of our providers may have a material adverse effect on our business, results of operations, and financial condition.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or certain of our services and materials providers, including our fill and finish service providers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the provider may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing. We or any such third-party manufacturer might be unable to formulate and manufacture our products in the volume and of the quality required to meet our preclinical, clinical and commercial needs. If we engage any contract manufacturers, such manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our preclinical, clinical or commercial needs. In addition, we and contract manufacturers are subject to the rules and regulations of the FDA and comparable

foreign regulatory authorities and face the risk that any of those authorities may find that they are not in compliance with applicable regulations. To date, our current facility has passed audits by the FDA and a number of other regulatory authorities but remains subject to audit by other foreign regulatory authorities. There can be no assurance that we or our contract manufacturers will be able to comply, or continue to comply, with FDA or foreign regulatory manufacturing requirements, and the failure to so comply, or continue to comply, may have a material adverse effect on our business, results of operations, and financial condition.

We rely on third parties for final processing of Elfabrio, Elelyso, and our other product candidates, which exposes us to a number of risks that may delay development, regulatory approval, and commercialization of Elfabrio, Elelyso, or our other product candidates or result in higher product costs.

We have no experience in the final filling and freeze drying steps of the drug manufacturing process. We rely on third-party service providers in the United States and Europe to perform fill and finish activities for Elelyso and Elfabrio, and have engaged other parties for our other product candidates. The number of potential fill and finish services providers is limited and we face the risk of being unable to identify manufacturers and/or replacement manufacturers on acceptable terms or at all. In addition, the FDA and other regulatory authorities, as applicable, must approve any manufacturer and/or replacement manufacturer, including us.

Any failure to identify and maintain fill and finish service providers could delay our preclinical and clinical trials, the approval, if any, of our potential drug candidates by the FDA, and other regulatory authorities, or the commercialization of our drug candidates, or could result in higher product costs or otherwise deprive us of potential product revenues.

Developments by competitors may render our products or technologies obsolete or non-competitive which would have a material adverse effect on our business, results of operations, and financial condition.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Our products compete, and our products candidates will compete, with existing therapies and therapies under development by our competitors. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our products. Other companies have drug candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. See “Business – Competition.”

Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, staff and facilities and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining marketing approvals from the FDA and other regulatory authorities;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

These organizations also compete with us to attract qualified personnel, acquisitions and joint ventures candidates and for other collaborations. Activities of our competitors may impose unanticipated costs on our business or adversely affect the market for our products which would have a material adverse effect on our business, results of operations, and financial condition.

If we in-license drug candidates, we may delay or otherwise adversely affect the development of our existing drug candidates, which may negatively impact our business, results of operations and financial condition.

In addition to our own internally developed drug candidates, we proactively seek opportunities to in-license and advance other drug candidates that are strategic and have value-creating potential to take advantage of our development know-how and technology. In-licensing additional drug candidates may significantly increase our capital requirements, and place a strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may have a material adverse effect on our business, results of operations, and financial condition.

If we acquire companies, products, or technologies, we may face integration risks and costs associated with those acquisitions that could potentially negatively impact our business, results of operations and financial condition.

If we are presented with appropriate opportunities, we may acquire or make investments in complementary companies, products or technologies. If we acquire companies or technologies, we will face risks, uncertainties, and disruptions associated with the integration process, including difficulties in the integration of the operations of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired business and impairment charges if future acquisitions are not as successful as we originally anticipate. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets. Any failure to successfully integrate other companies, products or technologies that we may acquire may have a material adverse effect on our business, results of operations, and financial condition.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our President and Chief Executive Officer, Dror Bashan, as well as the Chairman of our Board of Directors, Eliot R. Forster, Ph.D., our other directors, consultants and collaborating scientists. Many of these people have been involved with us for many years and have played integral roles in our progress, and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business, clinical development and regulatory programs. We have employment agreements with Mr. Bashan and our other executive officers that may be terminated by us or the applicable officer at any time with varying notice periods of 30 to 180 days. The loss of any of these persons' services may adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

We also depend in part on the continued service of our key scientific personnel and our ability to identify, hire, and retain additional personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Under current U.S. and Israeli laws, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered into non-competition agreements with substantially all of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under current U.S. and Israeli laws, we may be unable to enforce these agreements against most of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees acquired while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which may have a material adverse effect on our business, results of operations, and financial condition.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2025, our internal control over financial reporting was effective, we cannot predict the outcome of our testing or any subsequent testing by our auditor in future periods. Any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information and affect our reputation, which could have an adverse effect on the trading price of our common stock.

Our management is required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. However, for as long as we are a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal control could identify deficiencies in internal control over financial reporting that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Our internal computer systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches, resulting in liability and harm to our reputation, which could negatively affect our business, results of operation and financial condition. We may face liability if we breach our obligations related to the protection, security, nondisclosure of confidential information or disclosure of sensitive data or fail or are perceived to fail to comply with applicable data protection laws and regulations, or consumer protection laws, regulations and standards.

Despite the implementation of security measures, our internal computer systems and those of our present and future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We have a cybersecurity insurance policy to protect us from such risks. However, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability despite our insurance policy, and the further development and commercialization of our product candidates could be delayed.

Further, the global data protection landscape is rapidly evolving, and we are or may become subject to numerous local and foreign laws, requirements, and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect about individuals worldwide. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with local or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations

and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Our failure to adhere to or successfully implement processes in response to changing regulatory requirements in this area could result in legal liability or impairment to our reputation in the marketplace, which could have a material adverse effect on our business, results of operations, and financial condition.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. Any such litigation, could result in substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, results of operations, and financial condition.

If product liability claims are brought against us, it may result in reduced demand for our products and product candidates or damages that exceed our insurance coverage.

The use and marketing of our products and product candidates, including in connection with clinical trials, exposes us to product liability or similar claims if the use or misuse of those products or product candidates cause injury or disease, or results in adverse effects. We presently carry product liability and clinical trial liability insurance with coverages of up to $10.0 million per occurrence and $10.0 million in the aggregate, an amount we consider reasonable and customary. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. In the future, we may need to obtain additional product liability and clinical trial liability coverage; however, such insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, may adversely affect the availability of funds for other purposes, such as research and development, which may have a material adverse effect on our business, results of operations, and financial condition. Product liability claims, even if without merit, may result in reduced demand for our products, if approved, or result in adverse market reactions, which would have a material adverse effect on our business, results of operations, and financial condition.

Our ability to utilize net operating loss carryforwards may be limited.

Our NOL carryforwards as of December 31, 2025, are equal to approximately $219.8 million, of which approximately $20.0 million may be restricted under Section 382 of the Internal Revenue Code, or the IRC. IRC Section 382 applies whenever a corporation with NOLs experiences an ownership change. As a result of IRC Section 382, the taxable income for any post-change year that may be offset by a pre-change NOL may not exceed the fair market value of the pre-change entity multiplied by the IRC long-term tax exempt rate. Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, we considered all available evidence, including past operating results, the most recent projections for taxable income and prudent and feasible tax planning strategies. We reassess our valuation allowance periodically and if future evidence allows for a partial or full release of the valuation allowance, a tax benefit will be recorded accordingly. Any ownership change, or any other limitation on our utilization of NOLs, could have a material adverse effect on our business, results of operations, and financial condition.

Our corporate structure may create U.S. federal income tax inefficiencies.

Protalix Ltd. is our wholly-owned subsidiary and thus a controlled foreign corporation of our company for U.S. federal income tax purposes. This organizational structure may create inefficiencies, as certain types of income and investments of Protalix Ltd. that otherwise would not be currently taxable under general U.S. federal income tax principles may become taxable. These inefficiencies may require us to use more of our NOLs than we otherwise might and may result in a tax liability without a corresponding distribution from our subsidiaries which could have a material adverse effect on our business, results of operations, and financial condition.

We are a holding company with no operations of our own.

We are a holding company with no operations of our own. Accordingly, our ability to conduct our operations, service any current or future debt and pay dividends, if any, is dependent upon the earnings from the business conducted by Protalix Ltd. The distribution of those earnings or advances or other distributions of funds by our subsidiaries to us, as well as our receipt of such funds, are contingent upon the earnings of Protalix Ltd. and are subject to various business considerations and U.S. and Israeli laws. If Protalix Ltd. is unable to make sufficient distributions or advances to us, or if there are limitations on our ability to receive such distributions or advances, we may not have the cash resources necessary to conduct our corporate operations or service our debt which would have a material adverse effect on our business, results of operations, and financial condition.

Outbreaks of contagious disease or similar public health threats could materially and adversely affect our business, results of operations and financial condition.

Outbreaks of contagious disease or other adverse public health developments worldwide could have a material adverse effect on our business, financial condition and results of operations. Outbreaks of contagious disease or other adverse public health developments could affect our business in a number of ways, including but not limited to:

- Disruptions or restrictions on our employees' ability to work effectively due to illness;
- Temporary closures or disruptions at our facilities or the facilities of our contract manufacturers or suppliers could adversely affect our ability to timely meet our customer's orders and negatively impact our supply chain;
- Outbreaks of contagious disease could cause delays or disruptions in our supply chain;
- The failure of third parties on which we rely to meet their respective obligations to us, or significant disruptions in their ability to do so, which may be caused by their own financial or operational difficulties, could have an adverse impact on our business, financial condition or results of operations; and
- The impact of contagious disease or other adverse public health developments could also exacerbate other risks discussed elsewhere in these Risk Factors, any of which could have a material adverse effect on us.

Our operating costs and business operations could be adversely affected by climate-related events and increasing regulatory requirements and security.

The effects of climate change (such as drought, flooding, heat waves, wildfires, increased storm severity, and sea level rise, etc.) could affect our ability to continue our operations and cause delays in the development of our existing drug candidates, manufacturing and shipment, all of which could cause reputational harm or otherwise have an adverse effect on our business, results of operation and financial condition. In addition, the impacts of climate change on the global economy and our industry are rapidly evolving. Changing market dynamics, global policy developments and the increasing frequency and impact of extreme weather events on critical infrastructure across different countries could have the potential to disrupt our business, the business of our third-party suppliers and the business of our customers, and may cause us to experience higher attrition, losses, and additional costs to maintain or resume operations. We also expect to face increasing regulatory requirements and regulatory scrutiny related to climate matters, resulting in higher associated compliance costs. Failure to uphold, meet, or make timely forward progress against our public commitments

and goals related to climate action could adversely affect our reputation with suppliers and customers, financial performance, or the ability to recruit and retain talent.

Risks Related to Clinical Trials and Regulatory Matters

We may not obtain the necessary U.S., EMA or other worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all, which would have a material adverse effect on our business, results of operations, and financial condition.

To commercialize our drug candidates worldwide, we need FDA approval, EMA approval, and approvals from other countries' regulators to commercialize our drug candidates elsewhere, as applicable. Approvals of marketing authorization applications worldwide generally requires that we demonstrate that the subject drug candidate is safe and effective for its intended use which requires significant research, animal or preclinical trials and human or clinical tests trials. Satisfaction of the regulatory requirements of the FDA, EMA, and other countries' regulatory authorities typically takes many years, depends upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing. The results of preclinical and clinical trials of our product candidates may fail to demonstrate that the candidates are safe and effective for their intended uses.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings or other comparable authorities for such clinical trials. Further, even if favorable testing data is generated by the clinical trials of a drug candidate, the applicable regulatory authority may not accept or approve a marketing application we file for the drug candidate or may require us to conduct additional clinical testing or perform post-marketing studies which would cause us to incur additional costs.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee regulatory approval for such product candidate will be obtained or maintained in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the regulatory submission, preclinical studies, clinical trials, manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we or our partners intend to charge for our products is also subject to approval.

Failure to obtain approval of the FDA, EMA, or comparable foreign authorities of any of our product candidates in a timely manner, if at all, will severely undermine our business, results of operations, and financial condition by decreasing our ability to generate product revenues from the sales of such product candidates. If we or our partners fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, the target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which may have a material adverse effect on our prospects, business, results of operations, and financial condition.

We are subject to extensive governmental regulation including the requirements of the FDA and other comparable regulatory authorities before our drug candidates may be marketed.

Both before and after marketing approval of our drug candidates, if at all, we, our drug candidates, our suppliers, our contract manufacturers, and our contract testing laboratories are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. Failure to comply with applicable requirements of the FDA or comparable foreign regulatory authorities could result in, among other things, any of the following actions:

- warning letters;

- fines and other monetary penalties;
- unanticipated expenditures;
- delays in the FDA's or other foreign regulatory authorities' approving, or the refusal of any regulatory authority to approve, any drug candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval requirements, other numerous and pervasive regulatory requirements apply, both before and after approval, to us, our drug candidates, our suppliers, contract manufacturers, and contract testing laboratories. These include requirements related to:

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with use of the drug candidate; and
- obtaining additional approvals for certain modifications to the drug candidate or its labeling or claims.

We also are subject to inspection by the FDA and comparable foreign regulatory authorities, to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories, and there can be no assurance that the FDA, or any other comparable foreign regulatory authority, will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We may be required to make modifications to our manufacturing operations in response to these inspections which may require significant resources and may have a material adverse effect upon our business, results of operations, and financial condition.

The approval process for any drug candidate may also be delayed by changes in government regulation, future legislation or administrative action, or changes in policy of the FDA and comparable foreign authorities that occur prior to or during their respective regulatory reviews of such drug candidate.

Delays in obtaining regulatory approvals with respect to any drug candidate may materially and adversely affect our prospects, business, results of operations and financial condition.

Delays in obtaining regulatory approvals with respect to any drug candidate may:

- delay commercialization of, and our ability to derive product revenues from, such drug candidate;
- delay any regulatory-related milestone payments payable under outstanding collaboration agreements;
- require us to perform costly procedures with respect to such drug candidate; or
- otherwise diminish any competitive advantages that we may have with respect to such drug candidate.

Delays in the approval process for any drug candidate may have a material adverse effect upon our prospects, business, results of operations, and financial condition.

Preclinical and clinical trials are very expensive, time-consuming, and difficult to design and implement and may result in unforeseen costs, which may have a material adverse effect on our business, results of operations, and financial condition.

Preclinical and clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Preliminary and initial results from a clinical trial do not necessarily predict final results, and failure can occur at any stage of the trial. We may encounter problems that could cause us to abandon or repeat preclinical studies or clinical trials. The clinical trial process is also time-consuming. Failure or delay in the commencement or completion of our clinical trials may be caused by several factors, including:

- slower than expected rates of patient recruitment, particularly with respect to trials of rare diseases;
- determination of dosing issues;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;
- disagreement by applicable regulatory bodies over our trial protocols, the interpretation of data from preclinical studies or clinical trials or conduct and control of clinical trials;
- determination that the patient population participating in a clinical trial may not be sufficiently broad or representative to assess efficacy and safety for our target population;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and
- lack of sufficient funding to finance the clinical trials.

PRX-115 and PRX-119 are still in clinical and preclinical development and their risk of failure is high. Failure or delay can occur at any time during the preclinical or clinical trial process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the safety and effectiveness of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the side effects of product candidates at various doses and regimens. Success in preclinical studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the required safety and effectiveness through clinical trials despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Any failure or delay in commencement or completion of any clinical trials of our product candidates will have a material adverse effect on our business, results of operations, and financial condition. In addition, we, the FDA or other regulatory authorities may suspend a clinical trial at any time if it appears that participants in the trial are being exposed to unacceptable safety or health risks or if the FDA or such other regulatory authorities, as applicable, find deficiencies in our IND submissions or the conduct of the trial. Any suspension of a clinical trial may have a material adverse effect on our business, results of operations, and financial condition.

If the results of our clinical trials do not support our claims relating to a drug candidate, or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.

The results of our clinical trials with respect to any drug candidate might not support our claims of safety or efficacy, the results of our clinical trials may fail to conclusively show superiority over other commercially available treatments for the same or similar indications, the effects of our drug candidates may not be the desired effects or may include undesirable side effects, or the drug candidates may have other unexpected characteristics. Data obtained from tests are susceptible to varying interpretations which may delay, limit, or prevent regulatory approval. The clinical trial process may fail to demonstrate that our drug candidates are safe for humans and effective for indicated uses. In addition, our clinical trials may involve specific and small patient populations. Results of early clinical trials conducted on a small patient population may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of BLAs and NDAs with the FDA, or other filings with other foreign regulatory authorities, and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business, results of operations, and financial condition.

Interim, top-line or preliminary data from clinical trials that we announce or publish may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

We may publicly disclose interim, top-line, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also may make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, any interim, top-line, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different than the preliminary data we previously published. As a result, any top-line data should be viewed with caution until final data are available. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data becomes available. Further, regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or ascribe different weight to the data, which may impact the value of the clinical trial and may affect the particular clinical program and the approvability or commercialization of the particular product candidate and our business in general. If regulatory authorities disagree with the conclusions we reach, we may not be able to obtain approval for and commercialize our product candidates, which will have a material adverse effect on our business, results of operations, and financial condition.

We may find it difficult to enroll patients in our clinical trials, or patients may discontinue their participation in our clinical trials, which could cause significant delays in the completion of such trials or may negatively impact the results of these studies and extend the timeline for completion of our development programs or cause us to abandon one or more clinical trials.

Some of the diseases or disorders that our drug candidates under evaluation are intended to treat are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Our clinical trials generally mandate that a patient cannot be involved in another clinical trial for the same indication. Therefore, subjects that participate in ongoing clinical trials for products that are competitive with our drug candidates are not available for

our clinical trials. An inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, patients who enroll in our clinical trials may discontinue their participation at any time during the study as a result of a number of factors, related to the trials or not, including withdrawing their consent, experiencing adverse clinical events, which may or may not be judged related to our drug candidates, or due to personal reasons, such as planned or actual pregnancies. The discontinuation of patients in any one of our studies may delay the completion of the study or cause the results from the study not to be positive or to not support a filing for regulatory approval of the applicable drug candidate. Any failure to enroll a sufficient number of patients in our clinical trials in a timely manner, if at all, may have a material adverse effect on our business, results of operations, and financial condition.

Our clinical trials depend upon third-party service providers and, accordingly, the results of our clinical trials and such research activities are subject to delays and other risks which are, to a certain extent, beyond our control, which could impair our clinical development programs and our competitive position.

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our clinical development programs. The investigators may not prioritize to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our clinical development programs, or if their performance is substandard, the approval of anticipated NDAs, BLAs, and other marketing applications, and our introduction of new drugs, if any, may be delayed which could impair our clinical development programs and would have a material adverse effect on our business, results of operations, and financial condition. Our collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators also assist our competitors, our competitive position could be harmed.

We have limited experience in regulatory affairs compared to our larger competitors, and some of our drug candidates may be based on new technologies. These factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for medical devices and drug candidates compared to certain large, multinational pharmaceutical companies with whom we compete. Moreover, some of the drug candidates that are likely to result from our development programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of drug candidates may not be well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in obtaining regulatory approvals of any products that we develop, which may have a material adverse effect on our business, results of operations, and financial condition.

Uncertainty surrounding and future changes to healthcare law in the United States and other United States Government related mandates may adversely affect our business.

In the U.S. and in some foreign jurisdictions there has been, and continues to be, significant legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates. This legislation and regulatory activity have created uncertainty as to whether the industry will continue to experience fundamental change as a result of regulatory reform or legislative reform. There is significant interest among legislators and regulators in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

In the coming years, additional changes could be made to U.S. governmental healthcare programs and U.S. healthcare laws that could significantly impact the success of our products. We cannot predict what other legislation relating to our

business or to the health care industry may be enacted, or what effect such legislation or other regulatory actions may have on our business, prospects, operating results, and financial condition.

Risks Related to our Financial Condition and Capital Requirements

We may fail to meet the continued market capitalization-based listing requirement or other continued listing requirements of the NYSE American.

The stock market in general, and the market for pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. The trading price of our common stock has been volatile and has been subject to wide price fluctuations in response to various factors, many of which are beyond our control. The volatility of our stock price has from time to time in recent periods affected our market capitalization. Adverse fluctuations in the price per share of our common stock or our market capitalization may result in our failure to meet the continued listing requirements of the NYSE American, which would require us to take steps to gain compliance with alternate listing standards or take remedial steps to bring us into compliance. A failure to maintain or regain compliance with applicable listing standards could adversely affect the liquidity of our common stock which would have a material adverse effect on our business, results of operations, and financial condition.

We may need to raise additional capital to operate our business, which may not be available on favorable terms, or at all, and which will have a dilutive effect on our stockholders.

Although for the years ended December 31, 2023 and 2024, we ended the fiscal year with positive net incomes, we generally have completed our fiscal years, including the year ended December 31, 2025, with a net loss as we were focused on the development of Elelyso, Elfabrio and now PRX-115. Our net losses were primarily the result of expenses incurred through a combination of research and development activities and expenses supporting those activities, which includes share-based compensation expense. We may incur losses in future fiscal years as we continue to execute on our strategic goals as drug development and commercialization is very capital intensive. We expect to continue to incur significant operating expenditures as we progress with the clinical development of PRX-115, and we anticipate that our expenses will increase in the foreseeable future as we seek to in-license additional technologies, continue to undertake preclinical development and clinical trials for our current and new drug candidates and seek regulatory approvals for our drug candidates. In addition, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, the cost and timing of regulatory approvals, changes in the progress of our research and development efforts and the costs of protecting our intellectual property rights.

Currently, our sources of potential revenues are from product sales, royalties, and commercial milestone payments generated from Pfizer, Fiocruz and Chiesi. In the past, we have also generated revenues from research and development services and milestone and other payments we received in connection with our agreements with our commercialization partners, and generated capital from equity and debt offerings and other sources. The revenues we generate from royalties and commercial milestone payments and other sources may not be sufficient to fund our planned operations and capital expenditures. Accordingly, we may need to finance future cash needs through corporate collaboration, licensing, or similar arrangements, public or private equity offerings or debt financings. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to expand our portfolio of product candidates, commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts, and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Furthermore, any additional source of financing will likely involve the issuance of equity securities, which will have a dilutive effect on our stockholders.

Risks Related to Intellectual Property Matters

If we fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, the value of our intellectual property rights would diminish and our business, competitive position and results of operations would suffer.

As of December 31, 2025, we had approximately 45 pending patent applications. However, the filing of a patent application does not mean that there will be a resulting patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a current patent application may delay the approval of such patent application which may have a material adverse effect on our business, results of operations, and financial condition. In addition, there are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology. Our competitive position and future revenues depends in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our products, methods, processes, and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights, and to operate without infringing the proprietary rights of third parties. We have filed U.S. and international patent applications for process patents, as well as composition of matter patents, for our products and product candidates. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors and those who infringe upon our patents, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings, which may be costly, whether we win or lose.

As of December 31, 2025, we held, or had license rights to, approximately 70 patents. If patent rights covering our products or technologies are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors and those who infringe upon our patents.

Furthermore, the term of our patents is limited. For example, the patents we hold relating to our ProCellEx protein expression system recently expired and the patents covering Elelyso have expired or are expiring in the next few years, depending on the jurisdiction.

We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position.

Our policy is to enter into agreements relating to the non-disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors, and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek

to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors and others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements may have a material adverse effect on our business and competitive position.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business, results of operations, and financial condition.

We have not received to date any claims of infringement by any third parties. However, as our drug candidates progress into clinical trials and commercialization, if at all, our public profile and that of our drug candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes, and other technologies infringe the proprietary rights of other parties, we may incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

Any costs incurred in connection with such events or the inability to sell our products may have a material adverse effect on our business, results of operations, and financial condition.

If we cannot meet requirements under our license agreements, we could lose the rights to our products, which could have a material adverse effect on our business.

We expect to enter into licensing agreements with third-parties with respect to the intellectual property rights necessary to expand our product candidate pipeline. Such license agreements generally require that we make payments and satisfy performance obligations in order to maintain our rights under the agreements, and remain in effect either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology which could have a material adverse effect on our business, results of operations, and financial condition.

Risks Relating to our Operations in Israel

Significant parts of our operations are located in Israel and, therefore, our results may be adversely affected by political, economic, and military conditions in Israel.

Our executive office and operations are located in the State of Israel. Accordingly, military, economic, and geopolitical conditions in Israel and the surrounding region could directly and adversely affect our business. Any armed conflicts,

political instability, terrorism, cyberattacks, or any other hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations. Since October 2023, Israel has suffered from missile and other similar attacks and has been engaged in military activity on a number of fronts, including with the Hamas in the Gaza Strip, Hezbollah in Lebanon, Iran, the Houthis terrorist group that controls parts of Yemen, and others, and both civilian and military targets in Israel have been attacked. Such clashes may escalate in the future into a greater regional conflict. In October 2025, Israel and Hamas entered into a ceasefire agreement intended to permanently end the war between Israel and Hamas. However, there are no assurances regarding continued compliance with such agreement. While the conflict created and continues to create heightened security concerns, disruptions to business operations, and economic instability within Israel, the ceasefire may contribute to improved regional stability. However, the security situation remains fluid and any renewed military actions, restrictions, or government-imposed measures could have a material adverse effect on our business, results of operations, and financial condition. On February 28, 2026, the US and Israeli militaries commenced air-based campaigns in Iran which have resulted in a larger regional event and has resulted in increased missile and similar attacks on civilian and military targets in Israel and in other countries in the region. This has resulted in global security concerns that may result in a greater or lasting regional conflict. It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, results of operations, and financial conditions.

Our facilities are in range of certain of the rockets that are being fired from Lebanon and elsewhere. As of the issuance of this Annual Report on Form 10-K, the impact of the current conflicts has not had an adverse effect on our operations. To mitigate the risk of loss due to the military operations, we have elected to store manufactured drug substance in multiple locations, both within and outside of Israel. Our insurance policies do not cover damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. Any damage to our facilities as a result of war or other hostile action may have a material adverse effect on our business, results of operations, and financial condition.

Ongoing and revived hostilities or other Israeli political or economic factors, could prevent or delay shipments of our products, harm our operations and product development, interrupt or delay our clinical activities, and cause any future sales to decrease. If hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies, materials, drug substance and other products, our business, results of operations, and financial condition may be materially and adversely affected.

Parties with whom we do business may sometimes decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary to meet our business partners face to face. Further, shifting economic and political conditions in the United States and in other countries may result in changes in how the United States and other countries conduct business and other relations with Israel, which may have an adverse impact on our Israeli operations and a material adverse impact on our business. In addition, several countries, principally in the Middle East, restrict doing business with Israel, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. Moreover, there have been increased efforts by organizations and movements to cause companies and consumers to boycott Israeli goods.

Our operations may be disrupted by the obligations of our personnel to perform military service which could have a material adverse effect on our business.

Many of our male employees in Israel, including members of senior management, are obligated to perform up to one month (in some cases more) of annual military reserve duty until they reach the age of 45 and, in the event of a military conflict, could be called to active duty. To date, we have not suffered any disruptions to our operations from the absence of employees in connection with the current military actions. However, we continue to face the risk that our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of military service of one or more of our key employees. Any such disruption may have a material adverse effect on our business, results of operations, and financial condition.

A certain portion of our expenses is incurred in non-U.S. Dollar currencies, including New Israeli Shekels and the Euro, and, accordingly, our results of operations may be seriously harmed by currency fluctuations and inflation.

We report our financial statements in U.S. dollars, our functional currency. Although most of our expenses are incurred in U.S. dollars, we pay a portion of our expenses in foreign currencies, including New Israeli Shekel and the Euro, and as a result, we are exposed to risk to the extent that the inflation rates in the jurisdictions in which we operate exceed the rate of devaluation of the applicable local currencies in relation to the U.S. dollar, or if the timing of these devaluations lags behind inflation in such jurisdictions. In that event, the U.S. dollar cost of our operations in Israel, and other such jurisdictions, will increase, and our U.S. dollar-measured results of operations will be adversely affected. To the extent that the value of any such foreign currency, including the NIS or the Euro, increases against the U.S. dollar, our expenses on a dollar cost basis increase. Our operations also could be adversely affected if we are unable to guard against currency fluctuations in the future. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS, the Euro or other foreign currencies in which we incur expenses. These measures, however, may not adequately protect us from material adverse effects.

The tax benefits available to us require that we meet several conditions and may be terminated or reduced in the future, which would increase our taxes.

We are able to take advantage of tax exemptions and reductions resulting from the "Approved Enterprise" status of our facilities in Israel. To remain eligible for these tax benefits, we must continue to meet certain conditions, including making specified investments in property and equipment, and financing at least 30% of such investments with share capital. If we fail to meet these conditions in the future, the tax benefits would be canceled and we may be required to refund any tax benefits we already have enjoyed. These tax benefits are subject to investment policy by the Investment Center and may not be continued in the future at their current levels or at any level. In recent years the Israeli government has reduced the benefits available and has indicated that it may further reduce or eliminate some of these benefits in the future. The termination or reduction of these tax benefits or our inability to qualify for additional "Approved Enterprise" approvals may increase our tax expenses in the future, which would reduce our expected profits and adversely affect our business and results of operations. Additionally, if we increase our activities outside of Israel, for example, by future acquisitions, such increased activities generally may not be eligible for inclusion in Israeli tax benefit programs.

The Israeli government grants we received for certain research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties which could have a material adverse effect on our business and results of operations.

In the past, our research and development efforts were financed, in part, through grants that we received from NATI. We, therefore, must comply with the requirements of the Research Law. Under the Research Law we are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, we may be required to pay an increased total amount of royalties (possibly up to 600% of the grant amounts plus interest), depending on the manufacturing volume that is performed outside of Israel, as well as a possibly increased royalty rate. This restriction may impair our ability to outsource manufacturing or engage in similar arrangements for those products or technologies.

Additionally, under the Research Law, Protalix Ltd. is prohibited from transferring NATI-financed technologies and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the approval of NATI Council or the Research Committee. Protalix Ltd. may not receive the required approvals for any proposed transfer and, if received, Protalix Ltd. may be required to pay NATI a portion of the consideration that it receives upon any sale of such technology by a non-Israeli entity. Approval of the transfer of technology to residents of the State of Israel is required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurance can be made that approval of any such transfer, if requested, will be granted.

These restrictions may impair our ability to sell our technology assets or to outsource manufacturing outside of Israel. The restrictions will continue to apply for a certain period of time even after we have repaid the full amount of royalties payable for the grants. If we fail to satisfy the conditions of the Research Law, we may be required to refund certain grants previously received together with interest and penalties, and may become subject to criminal charges, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us, our executive officers and most of our directors or asserting U.S. securities laws claims outside the U.S.

A majority of our directors and all of our executive officers are residents of either Israel or other non-U.S. countries, and accordingly, most of their assets and our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers and enforcement of judgments against us or our non-U.S. resident directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our non-U.S. resident officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our non-U.S. resident officers and directors.

Moreover, among other reasons, including but not limited to, fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

Risks Related to Investing in our Common Stock

The market price of our common stock may fluctuate significantly.

The market price of our common stock has experienced significant volatility. The securities of life sciences companies often experience significant volatility in connection with clinical trial and regulatory announcements.

We anticipate that the market price of our common stock is likely to continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- Chiesi's sales of Elfabrio;
- purchases of BioManguinhos alfataliglicerase in Brazil;
- the progress and results of the studies of our product candidates under development;
- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- developments in the biotechnology industry; and

- general market conditions and other factors, including factors unrelated to our operating performance, such as the local military conflict.

Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock may be worse when the trading volume of our common stock is low. We have not paid, and do not expect to pay, any cash dividends on our common stock as any earnings generated from future operations will be used to finance our operations. As a result, investors will not realize any income from an investment in our common stock until and unless their shares are sold at a profit.

Future sales of our common stock could reduce our stock price.

If our stockholders sell substantial amounts of our common stock or if we sell a substantial amount of our common stock in any public or private offering, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock may also depress the trading price of our common stock.

A substantial majority of our outstanding shares of our common stock are freely tradable without restriction or further registration under the federal securities laws. In addition, we may sell additional shares of our common stock in the future to raise capital. At December 31, 2025, there were outstanding options to purchase common stock issued covering approximately 8.3 million shares of our common stock with a weighted average exercise price of $1.76 per share. Also at December 31, 2025, there were 2,092,933 shares of common stock available for future for issuance in connection with future grants of incentives under our Amended and Restated Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan, as amended. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

If securities analysts stop publishing research or reports about us or our business or if they downgrade our common stock, the market price of our common stock could decline.

The market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If any analyst who covers us downgrades our stock or lowers its future stock price targets or estimates of our operating results, the market price for our common stock could decline rapidly. Furthermore, if any analyst ceases to cover us, we could lose visibility in the market, which in turn could cause the market price of our common stock to decline.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses, divert management's attention from operating our business which could have a material adverse effect on our business.

The laws, rules, regulations, and standards including the rules promulgated by the national securities exchanges, including the NYSE American, to which we are subject are changed and/or amended from time to time. New or changed laws, rules, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, rules, regulations, and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Members of our Board of Directors and our executive officers, could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified directors and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with standards set by regulatory authorities or governing bodies which may have a material adverse effect on our business, results of operations, and financial condition.

Delaware law and our organizational documents contain certain provisions, including anti-takeover provisions that limit the ability of our stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our organizational documents and Delaware General Corporation Law, or the DGCL, contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition that our stockholders may consider favorable. Among other things, our organizational documents include the following provisions or features:

- the ability of our Board of Directors to, at any time without any further action on the part of our stockholders, authorize the issuance of a series of preferred stock, including "blank check" preferred stock, and to fix and determine the voting rights, rights of redemption and other rights and preferences of preferred stock. Any series of such preferred stock, could, for example, grant to holders, among other terms, the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of our common stock and the right to the redemption of the preferred shares, together with a premium, before the redemption of our common stock, which may have a material adverse effect on the rights of the holders of our common stock. In addition, our Board of Directors, without further stockholder approval, may, at any time, issue large blocks of preferred stock. The issuance of preferred stock may impede a takeover of our company and may prevent a transaction that is favorable to our stockholders.

- the right of our Board of Directors to elect a director to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors;

- the ability of our Board of Directors to amend the Bylaws, which may allow our Board of Directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Bylaws to facilitate an unsolicited takeover attempt; and

- our Bylaws contain advance notice procedures with which stockholders must comply to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our Board of Directors and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Any provision of our organizational documents or the DGCL that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a related premium for their common stock and could also affect the price that some investors are willing to pay for our common stock.

Our Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended and Restated Bylaws, or our Bylaws, provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, stockholders, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the DGCL or our Certificate of Incorporation, as amended, or our Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine.

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the Exchange Act against any person in connection with any offering of the corporation's securities.

The choice of forum provisions above may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or could result in increased costs for a stockholder to bring a claim, both of which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which may have a material adverse effect on our business, results of operations, and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

Our operations include the creation, collection and maintenance of sensitive information, including proprietary and confidential business information, intellectual property, third-party information and employee information. To protect this information, we use external and internal services to managed detection and response services to monitor our network infrastructure and associated endpoints for possible cybersecurity threats on a constant basis. In addition, we use multi-factor authentication (MFA) for external use, perform penetration testing and engage third parties to assess the effectiveness of our cybersecurity practices. We conduct a thorough risk assessment by identifying critical assets, recognizing potential threats and vulnerabilities, and implement strategies to mitigate these risks and their possible impacts. We establish incident response plans and provide cybersecurity and phishing training to our employees and monitor their activity to ensure adherence to our security protocols. A material cyber-attack on our systems, or any other third-party partners or vendors and their key operating systems, may interrupt our ability to operate our business, damage our reputation, or result in monetary damages.

We have implemented a Data Protection Policy, or the DPP, in order to establish the high-level direction for properly managing the use, privacy, security, retention, and disposal of our information, data and assets, and to manage identified material cybersecurity risks. The DPP was prepared using relevant guidance issued and technology standards that are used across various industries. It applies to all entities who are using our equipment and resources, including but not limited to, employees and temporary workers. Our Senior Director, Information Technology, is a certified information security officer (CISO). He is primarily responsible for implementing and overseeing the DPP and identifying, measuring, monitoring, and reporting on key enterprise-wide risks, including cybersecurity risks.

Our DPP includes an incident response process that includes reporting thresholds and follows standardized identification and authentication practices. If an incident is identified, it is documented by our Senior Director, Information Technology, who is required to report the incident to management.

We work with third-party service providers that monitor our systems on a continuous, round-the-clock basis, and assist us to identify, assess and manage cybersecurity risks, including professional SEIM SOC and other services firms, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, and penetration testing.

No risks from cybersecurity threats have occurred that have materially affected or are reasonably likely to materially affect our business, results of operations or financial condition.

Governance

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including our Senior Director, Information Technology, who reports to our Sr. Vice President, Operations. Management is also responsible for hiring appropriate personnel, integrating cybersecurity considerations into our overall risk management strategy, and for communicating key priorities to employees, as well as for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security

assessments and other security-related reports. Our incident response process involves management, who participates in our disclosure controls and procedures.

Our incident response process is designed to escalate certain cybersecurity incidents and vulnerabilities to members of management depending on the circumstances, including work with our incident response team to help the company mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to our Board of Directors for certain cybersecurity incidents.

Management is involved with our efforts to prevent, detect, and mitigate cybersecurity incidents by overseeing preparation of cybersecurity policies and procedures, testing incident response plans and engaging vendors to conduct penetration tests. Management participates in cybersecurity incident response efforts by being a member of the incident response team and helping direct our response to cybersecurity incidents.

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. Our Chief Financial Officer and IT consultant provide periodic briefings to the Board of Directors regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, if any, cybersecurity systems testing, activities of third parties, and the like.

See "Risk Factors – Our internal computer systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches, resulting in liability and harm to our reputation, which could negatively affect our business, results of operation and financial condition. We may face liability if we breach our obligations related to the protection, security, nondisclosure of confidential information or disclosure of sensitive data or fail or are perceived to fail to comply with applicable data protection laws and regulations, or consumer protection laws, regulations and standards."

Item 2. Properties

Our headquarters, including a manufacturing facility, executive offices and other facilities, are located in Carmiel, Israel. We also maintain a U.S. corporate office in Hackensack, New Jersey. Our facilities in Israel currently contain approximately 1,466 sq/m of manufacturing space and 316 sq/m for a pilot plant, 1,057 sq/m for offsite warehouse space and approximately 4,400 sq/m of laboratories, front warehouse and office space, and are leased at a rate of approximately $90,000 per month. In addition, we are entitled to use an additional 1,347 sq/m in the same facility, which we may utilize in connection with any future expansion of our manufacturing facilities. Our facilities are equipped with the requisite laboratory services required to conduct our business, and we believe that the existing facilities are adequate to meet our needs for the foreseeable future. Our original lease for the facility was in effect until 2016 and included three options to extend the leases for additional five-year periods. The leases have been amended to provide that the third option period for all leases will end on December 31, 2031, and will be associated with a uniform rent increase equal to 7.5%. Thereafter, each lease will extend automatically, on an individual basis, for up to four additional five-year periods unless we provide the lessor with six months' advance notice that we do not intend that any individual option extension become effective. Each option to renew a lease in each of the four option periods shall include a rent increase equal to 5% of the rent payable for the applicable previous option period.

Item 3. Legal Proceedings

We are not involved in any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the NYSE American under the symbol "PLX." In 2023, we decided to voluntarily delist our common stock from the Tel Aviv Stock Exchange.

Holders

As of March 1, 2026, there were approximately 96 holders of record of our common stock. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held of record by banks, brokers, and other financial institutions.

Dividend Policy

To date, we have not declared or paid any cash dividends on our common stock. We do not anticipate paying any dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2025 with respect to the shares of our common stock that may be issued under our existing equity compensation plan.

	A	B	C
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A)
Equity Compensation Plans Approved by Stockholders	8,274,278	$ 1.76	2,092,933
Equity Compensation Plans Not Approved by Stockholders	-	-	—
Total	8,274,278	$ 1.76	2,092,933

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to help the reader understand our results of operations and financial condition. The MD&A is provided as a supplement to, and should be together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, include forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in Item 1A of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial stage biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs. We are the first and only company to gain FDA approval of a protein produced through plant cell-based expression in suspension. ProCellEx®, our unique, proprietary plant cell-based protein expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Our corporate strategy includes development of treatments for rare and orphan diseases. To execute on the strategy, we are turning our focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. We believe our treatments of interest will address both genetic and non-genetic diseases. We currently intend to use our ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. We are also exploring novel platform technologies.

Consistent with this strategy. we are developing PEGylated uricase, or PRX-115, for the treatment of uncontrolled gout, Long Acting (LA) DNase I, or PRX-119, for the treatment of NETs-related diseases, and a number of other technologies and preclinical assets. We have completed a Phase 1 First-in-Human clinical trial of PRX-115. Currently, we are actively recruiting for, and the first patients have been randomized in the RELEASE study, a Phase 2 clinical trial of PRX-115 for the treatment of uncontrolled gout.

To date, we have successfully developed two commercial ERTs: Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and older with Gaucher disease and Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease.

Our first product, Elelyso, an ERT for the treatment of patients with Gaucher disease, was first approved by the FDA in May 2012 and is now approved for marketing in more than 40 markets including Brazil, Israel and others. It is not approved for marketing in the EU. We have granted the marketing rights to Elelyso globally, excluding Brazil, to Pfizer through an exclusive licensing agreement. We maintain the distribution rights to Elelyso in Brazil, where it is currently marketed as BioManguinhos alfataliglicerase, through the Brazil Agreement. In 2025, we generated $18.2 million from sales of Elelyso to Pfizer and $11.1 million from sales of BioManguinhos alfataliglicerase to the Brazilian MoH.

Elfabrio, our second commercial product, an ERT for the treatment of Fabry disease, was approved by the EC for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients. Both approvals cover the 1 mg/kg E2W dosage. Subsequently, it has been approved in more than 10 additional markets. Commercialization of Elfabrio is governed by the Chiesi Agreements. In 2025, we generated $22.5 million from sales of Elfabrio to Chiesi.

On March 5, 2026, the EC ratified the CHMP positive opinion issued in January 2026. The EC decision approves, in the EU, the 2 mg/kg E4W dosing regimen for Elfabrio in Fabry disease adult patients stable with an ERT treatment.

We continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutions. Except with respect to Elfabrio and Elelyso, we hold the worldwide commercialization rights to our other proprietary development candidates.

Our product pipeline currently includes, among other candidates:

(1) PRX-115, our plant cell-expressed recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme to treat uncontrolled gout; and

(2) PRX-119, our plant cell-expressed PEGylated recombinant human DNase I product candidate which we have designed for long and customized systemic circulation in the bloodstream for NETs-related diseases.

Obtaining marketing approval with respect to any product candidate in any country is dependent on our ability to implement the necessary regulatory steps required to obtain such approvals, and demonstrate the safety and efficacy of its product candidates. We cannot reasonably predict the outcome of these activities.

We have completed a Phase 1 First-in-Human clinical trial of PRX-115. This study included 64 adult male and female subjects in a dose escalation design with eight sequential dosing cohorts, each composed of eight subjects (six active and two placebo) which is now complete. The results are summarized in Item 1 of this annual report on Form 10-K. Currently, we are actively recruiting patients for, and the first patients have been randomized in, the RELEASE study.

On February 27, 2023, we entered into that certain At The Market Offering Agreement, as may be amended from time to time, or the 2023 Sales Agreement, with H.C. Wainwright & Co., LLC, as our sales agent, or the Agent, for the sale of up to $20.0 million of our common stock from time to time. Subsequently, on March 17, 2025, we entered into an amendment to the 2023 Sales Agreement pursuant to which the aggregate gross sales price of shares of common stock available for sale under the 2023 Sales Agreement was increased by $20.0 million. As of December 31, 2025, approximately $15.7 million in shares of common stock remain available to be sold under the 2023 Sales Agreement.

Under each of the Chiesi Agreements, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of each agreement and Protalix Ltd. received additional payments of $25.0 million under the Chiesi Ex-US Agreement, and $20.0 million under the Chiesi US Agreement, to cover pegunigalsidase alfa development costs, all of which have been received in full. Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $270.0 million, in the aggregate and including the $25.0 million currently payable, subject to the satisfaction of certain regulatory and commercial milestones under the Chiesi Ex-US Agreement. Under the Chiesi US Agreement, Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $740.0 million, in the aggregate, subject to the satisfaction of certain regulatory and commercial milestones. Following the approval of Elfabrio by the FDA, we received a milestone payment equal to $20.0 million.

Under the terms of the Chiesi Agreements, Chiesi is solely responsible for the global commercialization and medical programs of Elfabrio, including patient acquisition and retention, and distribution of Elfabrio to patients. We manufacture Elfabrio drug substance and, after the fill\finish process is complete, we sell the resulting drug product to Chiesi. Operationally, Chiesi conducts its own internal commercial forecasting to guide inventory needs. To date, Chiesi has placed bulk orders for Elfabrio. As a result, the orders we receive from Chiesi may not be timed precisely to Chiesi's pace of patient acquisition and retention. Accordingly, our sales of Elfabrio to Chiesi may not reflect patient demand for Elfabrio as we sell the fulfilled orders to Chiesi's inventory. In addition, on a period-to-period basis, there may be variations in the orders placed by Chiesi resulting in variability in our period-to-period results as we, in turn, recognize revenues from sales of Elfabrio upon delivery of the drug product to Chiesi. There may be periods during which no orders are placed by Chiesi, whether as a result of inventory de-stocking or other factors. We do not anticipate that these Chiesi ordering patterns will change until the demand characteristics for Elfabrio stabilize, the launch of Elfabrio matures and Elfabrio's share of the market for Fabry disease treatment increases globally. The consideration for Protalix Ltd. is based on the drug product supplied to Chiesi and the average selling price of the drug product in each relevant territory multiplied by payments as described in the relevant agreement. Under the Chiesi Ex-US Agreement, the price payable to us for drug product supplied is based on a range of 15% to 35% of the average selling price of the drug product in the applicable territory, and, under the Chiesi US Agreement, such price is based on a range of 15% to 40% of the average selling price of the drug product in the United States.

Since its approval by the FDA, Elelyso has been marketed by Pfizer. In October 2015, Protalix Ltd. and Pfizer entered into the Amended Pfizer Agreement, pursuant to which we sold to Pfizer our share in the collaboration created under our original agreement with Pfizer for the commercialization of Elelyso. As part of the sale, we agreed to transfer our rights

to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where we are responsible for all expenses and retain all revenues.

On June 18, 2013, we entered into the Brazil Agreement. Fiocruz's purchases of BioManguinhos alfataliglicerase to date under such agreement have been significantly below certain agreed-upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the termination right, we are, at this time, continuing to supply BioManguinhos alfataliglicerase to Fiocruz and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

Our sales of Elelyso to Pfizer and Fiocruz are made at a fixed price directly to Pfizer and Fiocruz who maintain product in inventory, and we recognize revenue from those sales upon delivery. As with the sales to Chiesi, the timing of such sales does not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by each of Pfizer and Fiocruz resulting in variability in our period-to-period results. There may be periods during which no orders are placed by either Pfizer or Fiocruz, whether as a result of inventory de-stocking or other factors.

Because our operations are conducted in the State of Israel, the business and operations may be directly affected by economic, political, geopolitical and military conditions in Israel. Since October 2023, Israel has suffered from missile and other similar attacks and has been engaged in military activity on a number of fronts, including with the Hamas in the Gaza Strip, Hezbollah in Lebanon, Iran, the Houthis terrorist group that controls parts of Yemen, and others, and both civilian and military targets in Israel have been attacked. Such clashes may escalate in the future into a greater regional conflict. In October 2025, Israel and Hamas entered into a ceasefire agreement intended to permanently end the war between Israel and Hamas. However, there are no assurances regarding continued compliance with such agreement. While the conflict created and continues to create heightened security concerns, disruptions to business operations, and economic instability within Israel, the ceasefire may contribute to improved regional stability. However, the security situation remains fluid and any renewed military actions, restrictions, or government-imposed measures could have a material adverse effect on our business, results of operations, and financial condition. On February 28, 2026, the US and Israeli militaries commenced air-based campaigns in Iran which have resulted in a larger regional event and has resulted in increased missile and similar attacks on civilian and military targets in Israel and in other countries in the region. This has resulted in global security concerns that may result in a greater or lasting regional conflict The security situation remains fluid and any renewed military actions, restrictions, or government-imposed measures could adversely affect our business, operations, and financial condition. Our facilities are deemed an "essential enterprise" which means they operate or can be operated for the purposes of state defense or public security or for the maintenance of essential supplies or services, allowing us to maintain operations during emergencies. We have elected to store manufactured drug substance in multiple locations, both within and outside of Israel, to mitigate the risk of loss. As of the issuance of these financial statements, the impact of the military action has not had an adverse effect on our operations. See "Risk Factors—Significant parts of our operations are located in Israel and, therefore, our results may be adversely affected by political, economic, and military conditions in Israel."

We believe that our cash and cash equivalents and short-term bank deposits as of December 31, 2025 are sufficient to satisfy our capital needs for at least 12 months from the date that these financial statements are issued.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the

carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

Our primary sources of revenues include our sales of drug product to Chiesi under the Chiesi Agreements, of BioManguinhos alfataliglicerase to Brazil and of drug substance to Pfizer under our Amended Pfizer Agreement. For a discussion of our accounting treatment for revenue recognition, see Note 1(t) to our consolidated financial statements.

Income Taxes

We estimate the degree to which deferred tax assets will result in a benefit, after consideration of all positive and negative evidence, and provide a valuation allowance for deferred tax assets that we believe more likely than not will not be realized. In situations in which we are able to determine that our deferred tax assets will be realized, that determination generally relies on future reversals of taxable temporary differences and expected future taxable income. Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, we considered all available evidence, including past operating results, the most recent projections for taxable income, and prudent and feasible tax planning strategies. We reassess our valuation allowance periodically and if future evidence allows for a partial or full release of the valuation allowance, we reverse the related valuation allowance. The tax valuation allowance totaled approximately $50.4 million at December 31, 2025 (see Note 12 to our consolidated financial statements for additional information). Should our actual future taxable income by tax jurisdiction vary from estimates, additional allowances or reversals thereof may be necessary.

Significant judgment is required in evaluating our uncertain tax positions. In evaluating the exposure associated with our various tax filing positions, we record reserves for uncertain tax positions in accordance with U.S. GAAP based on the technical support for the positions and our past audit experience with similar positions. For those tax positions where it is more likely than not that a tax benefit will be sustained, we record the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. We believe our tax positions comply with applicable tax laws and we intend to defend our positions, no assurance can be given that the final tax outcome of these matters will not be different from that which is reflected in our historical income tax reserves and accruals. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the provision for income taxes in the period in which such determination is made. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate. Uncertain tax position totaled approximately $0.8 million at December 31, 2025 (see Note 12 to our consolidated financial statements for additional information).

Research and Development Expense

We expect our research and development expense to remain our primary expense in the near future as we continue to develop PRX-115 and our product candidates. Research and development expense consists of:

- internal costs associated with research and development activities, in particular with respect to the RELEASE study;
- payments made to third-party contract research organizations, investigative/clinical sites, and consultants;
- manufacturing development costs;
- personnel-related expenses, including salaries, benefits, travel, and related costs for the personnel involved in research and development;
- activities relating to the advancement of product candidates through preclinical studies and clinical trials; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, as well as laboratory and other supplies.

The following table identifies our current major research and development projects:

Project	Status	Expected Near Term Milestones
PRX-115 – PEGylated Uricase	Phase I (completed)	Completion of enrollment in the RELEASE study
PRX-119 – Long Acting DNase I	Preclinical	IND-enabling studies
Secarna - novel ASO therapies	Discovery	Lead identification

We anticipate incurring increasing costs in connection with the continued development of PRX-115 and PRX-119 and in the expansion of our pipeline. Our internal resources, employees and infrastructure are not tied to any individual research project and are typically deployed across all of our projects. We currently do not record and maintain research and development costs per project.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of the product candidates in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. Our future research and development expenses for our product candidates will depend on the preclinical and clinical success of each product candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Risk Factors—We may not obtain the necessary U.S., EMA, or other worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all, which would have a material adverse effect on our business, results of operations and financial condition."

We expect our research and development expenses to continue to be our primary expense in the future as we continue the advancement of our clinical trials and preclinical product development programs for our product candidates, in particular with respect to the RELEASE study. The lengthy process of completing clinical trials and seeking regulatory approvals for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expense to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects. See "Risk Factors—Preclinical and clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs, which may have a material adverse effect on our business, results of operations, and financial condition."

Results of Operations

The following table sets forth certain statements of operations data:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025
REVENUES FROM SELLING GOODS	$ 40,418	$ 52,981	$ 51,802
REVENUES FROM LICENSE AND R&D SERVICES	25,076	418	942
TOTAL REVENUE	65,494	53,399	52,744
COST OF GOODS SOLD	(22,982)	(24,319)	(26,993)
RESEARCH AND DEVELOPMENT EXPENSES	(17,093)	(12,970)	(19,569)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(14,959)	(12,193)	(11,682)
OPERATING INCOME (LOSS)	10,460	3,917	(5,500)
FINANCIAL EXPENSES	(3,180)	(1,062)	(1,191)
FINANCIAL INCOME	1,286	1,299	1,083
FINANCIAL INCOME (EXPENSES), NET	(1,894)	237	(108)
INCOME (LOSS) BEFORE TAXES ON INCOME	8,566	4,154	(5,608)
TAXES ON INCOME	(254)	(1,222)	(996)
NET INCOME (LOSS)	8,312	2,932	(6,604)

Year ended December 31, 2025 Compared to the Year Ended December 31, 2024

Revenues from Selling Goods

Revenues from selling goods consisted of the following:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Pfizer	$ 12,522	$ 12,617	$ 18,227	$ 5,610	$ 95
Fiocruz	10,401	11,031	11,062	31	630
Chiesi	17,495	29,333	22,513	(6,820)	11,838
Total revenues from selling goods	40,418	52,981	51,802	(1,179)	12,563

Revenues from selling goods for the year ended December 31, 2025 reflects a decrease of 2%, compared to revenues from selling goods for the year ended December 31, 2024. The decrease in revenues recorded from sales to Chiesi for the year ended December 31, 2025 resulted primarily from a change in the average net selling price of drug product in the applicable territory as well as changes in the quantities sold to Chiesi's inventory. The increase in revenues recorded from sales to Pfizer resulted primarily from increased purchases of Elelyso by Pfizer to address unexpected manufacturing issues on their end.

Revenues from License and R&D services

Revenues from license and R&D services were as follows:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Revenues from license and R&D services	$ 25,076	$ 418	$ 942	$ 524	$ (24,658)

Revenues from license and R&D services for the year ended December 31, 2025 represent a 125% increase compared to revenues for the year ended December 31, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. Other than potential regulatory milestone payments that may become payable, we expect to generate minimal revenues from license and R&D services.

Cost of Goods Sold

Cost of goods sold were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Cost of goods sold	$ 22,982	$ 24,319	$ 26,993	$ 2,674	$ 1,337

Cost of goods sold for the year ended December 31, 2025 represents an increase of 11%, compared to cost of goods sold for the year ended December 31, 2024. The increase in cost of goods sold was primarily the result of an increase in sales to Pfizer and Fiocruz (Brazil) partially offset by a decrease in sales to Chiesi.

Research and Development Expenses

Research and development expenses were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Salary and related expenses	$ 7,758	$ 7,068	$ 9,696	$ 2,628	$ (690)
Subcontractor-related expenses	6,345	2,432	5,631	3,199	(3,913)
Materials-related expenses	596	885	1,288	403	289
Other expenses	2,394	2,585	2,954	369	191
Total research and development expenses	17,093	12,970	19,569	6,599	(4,123)

Total increase in research and developments expenses for the year ended December 31, 2025 represent a 51% increase, compared to research and developments expenses for the year ended December 31, 2024. The increase in research and development expenses resulted primarily from preparations for the RELEASE study.

We expect to continue to incur significant, increasing research and development expenses as we progress with the RELEASE study and commence more advanced stages of preclinical and clinical trials for certain of our other product candidates.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
SG&A expenses	$ 14,959	$ 12,193	$ 11,682	$ (511)	$ (2,766)

Selling, general, and administrative expenses for the year ended December 31, 2025 represent a 4% decrease compared to selling, general, and administrative expenses for the year ended December 31, 2024. The decrease resulted primarily from a decrease in share-based compensation.

Financial Expenses and Income, Net

Financial expenses and income, net were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Financial expenses (income), net	$ 1,894	$ (237)	$ 108	$ 345	$ (2,131)

The difference from financial expenses, net for the year ended December 31, 2025 compared to financial income, net for the year ended December 31, 2024 resulted primarily from approximately $1.3 million exchange rate costs partially offset by approximately $1.0 million lower notes interest expenses due to the September 2024 repayment in full of all

the outstanding principal and interest payable under the 2024 senior secured convertible promissory notes, or the 2024 Notes.

Taxes on Income (Tax Benefit)

Income taxes (tax benefit) were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Income taxes	$ 254	$ 1,222	$ 996	$ (226)	$ 968

Income taxes recorded for the year ended December 31, 2025 represent an 18% decrease compared to income taxes for the year ended December 31, 2024. The tax expenses resulted primarily from taxes on income mainly derived from global intangible low-taxed income resulting primarily from limitations under IRC Section 174. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, The One Big Beautiful Bill Act, which includes significant corporate tax changes, including a restoration of the current deductibility of domestic research expenditures beginning in 2025 under Section 174A, with transition options for previously capitalized amounts. Foreign research expenditures continue to require capitalization subject to the mandatory 15-year amortization period under existing IRC Section 174. We implemented the permitted transition options.

Year ended December 31, 2024 Compared to the Year Ended December 31, 2023

For a discussion of the year ended December 31, 2024 compared to the year ended December 31, 2023, see Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2024.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and bank deposits. At December 31, 2025, we had $30.3 million in cash and cash equivalents and short-term bank deposits. In September 2024, we satisfied the outstanding principal and accrued interest under the 2024 Notes with a cash payment of approximately $21.2 million which was available primarily from the withdrawal of short-term deposits. We have primarily financed our operations through sales proceeds, equity and debt financings, business collaborations, and grants funding.

During the year ended December 31, 2025, we sold, in the aggregate, 2,775,215 shares of common stock under the 2023 Sales Agreement. We generated gross proceeds equal to approximately $7.0 million in connection with such sales. All such sales were effected during the first half of 2025. In addition, during the first quarter of the year ended December 31, 2025, we issued 908,000 shares of our common stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately $2.1 million. The warrants expired on March 11, 2025. Accordingly, no warrants remain outstanding.

During the year ended December 31, 2024, we raised gross proceeds equal to approximately $3.8 million from the sale, in the aggregate, of 2,216,692 shares of our common stock under our ATM program.

Cash Flows

Our cash flows for each of the years ended December 31, 2025 and 2024 were as follows:

	Year ended December 31,				
(U.S. dollars in thousands)	2023	2024	2025	2025 vs. 2024	2024 vs. 2023
Net cash provided by (used in) operating activities	$ (1,318)	$ 8,674	$ (11,993)	$ (20,667)	$ 9,992
Net cash provided by (used in) investing activities	$ (16,711)	$ 4,221	$ (2,366)	$ (6,587)	$ 20,932
Net cash provided by (used in) financing activities	$ 24,666	$ (16,794)	$ 9,326	$ 26,120	$ (41,460)

Net cash used in operations was $12.0 million for the year ended December 31, 2025. The net loss for the year ended December 31, 2025 of $6.6 million was increased by a $5.9 million increase in accounts receivable-trade and other assets and a $4.5 million increase in inventories, and was offset by $2.3 million in share-based compensation and $1.5 million in depreciation.

Net cash used in investing activities for the year ended December 31, 2025, was $2.4 million and consisted of $1.6 million purchase of property and equipment, $0.7 million increase in restricted deposit and $5.0 million investment in bank deposit offset by $5.0 million deposit withdrawal.

Net cash provided by financing activities for the year ended December 31, 2025, was $9.3 million and consisted of $6.8 million proceeds from issuance of Common Stock under the Sales Agreement, net and $2.5 million from the exercise of warrants and options.

Net cash provided by operations was $8.7 million for the year ended December 31, 2024. The net income for the year ended December 31, 2024, of $2.9 million was increased by a $0.7 million increase in accounts payable and accruals, a $2.3 million decrease in accounts receivable-trade and other assets, $3.3 million in share-based compensation and $1.3 million in depreciation, partially offset by a $2.2 million increase in inventories.

Net cash provided by investing activities for the year ended December 31, 2024, was $4.2 million and consisted primarily of $20.4 million in proceeds from the sale of deposits partially offset by $15.0 million in bank deposits and a $1.3 million purchase of property and equipment.

Net cash used in financing activities for the year ended December 31, 2024 was $16.8 million representing the $20.4 million payment of the outstanding principal under our 2024 Notes which matured in September 2024, partially offset by $3.6 million from the sale of common stock under our ATM program.

Future Funding Requirements

Since our inception, we have incurred significant research and development expenditures which have not been offset by revenues. We have not generated significant revenues from sales of Elelyso or Elfabrio. We have generated operating losses from our continuing operations since our inception although the revenues generated in the years ended December 31, 2023 and 2024 exceeded our expenditures for the same periods.

As the 2024 Notes were paid in full during the year ended December 31, 2024, we are no longer subject to the financial limitations related to such notes.

As we increase our research and developments efforts with respect to our current and future product candidates, we expect to continue to incur significant expenditures. We cannot anticipate the costs or the timing of the occurrence of such costs. Although we expect the revenues generated from the sales of Elfabrio and Elelyso will increase, such revenues may not be sufficient to fund the expenditures. To the extent we need to obtain additional financing in excess of such anticipated revenues, it may be difficult for us to do so given the volatility of the price of our Common Stock. Currently, our material cash needs include, among other expenses, (i) costs of preclinical and clinical trials, in particular

those of our RELEASE study, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patent advisors, and fees for service providers in connection with our research and development efforts, (v) expansion of addition manufacturing space within our current facility, and (vi) tax payments. We believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months from the date this report is issued.

As discussed above, we may be required to raise additional capital to develop our product candidates and continue research and development activities. Our ability to raise capital, and the amounts of necessary capital, will depend on many other factors, including:

- the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates;
- Chiesi's progress in commercializing Elfabrio;
- our progress in commercializing BioManguinhos alfataliglicerase in Brazil;
- the timing and outcome of regulatory review of our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights; and
- the costs associated with any litigation claims.

We expect to finance our future cash needs through sales of Elfabrio and Elelyso, corporate collaborations, licensing or similar arrangements, public or private equity offerings and/or debt financings. We currently do not have any commitments for future external funding, except with respect to the milestone payments that may become payable under the Chiesi Agreements.

Contractual obligations

Our contractual obligations include operating lease obligations, purchase obligations, certain clinical contracts, and the liability for employee rights upon retirement.

We lease certain assets under operating leases which are currently in effect until December 31, 2031 with up to four five-year automatic extensions at our discretion. The leases relate primarily to office, laboratory and manufacturing space and vehicles used by our employees. Our aggregate future minimum commitments under these facility and vehicles leases over the next five fiscal years is approximately $1.7 million as of December 31, 2025.

As of December 31, 2025, we are subject to open purchase orders issued to certain suppliers and other vendors mainly in connection with our outstanding research and development and manufacturing activities of approximately $11.2 million over the next five fiscal years.

We have a contractual obligation of approximately $17.7 million as of December 31, 2025 payable over the fiscal year ending December 31, 2025 in connection with contractual arrangements we enter into in the normal course of business with CROs, CMOs and other clinical providers and consultants for clinical trials, preclinical and other research studies and manufacturing services in connection with our primary product development process. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

As of December 31, 2025, we had a contractual obligation of approximately $0.7 million for employee rights upon retirement.

We are also party to certain research and license agreements. If all of the contingencies with respect to milestone payments under our research and license agreements are met, as of December 31, 2025, the aggregate milestone

payments payable would be approximately $8.4 million, and would be payable, if at all, as our projects progress over the course of a number of years. The royalty payments payable by our company in connection with sales of each of our product candidates, if any, shall not exceed low, single-digit percentages of net sales of the relevant product.

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. For the year ended December 31, 2025, the currency fluctuations were expenses of $1.2 million. We do not believe currency fluctuations have had a material effect on our results of operations during the years ended December 31, 2023 or 2024

Recently Issued Accounting Pronouncements

Certain recently issued and recently adopted accounting pronouncements are discussed in Note 1(t) of the financial statements included in Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar. Most of our revenues and above 50% of our expenses and capital expenditures are incurred in dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 41% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our loss before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Year Ended December 31,		
	2023	2024	2025
Average rate for period	3.687	3.700	3.452
Rate at period-end	3.627	3.647	3.190

As of December 31, 2025, we have not engaged in hedging transactions. In 2026, we entered into certain currency hedging transactions, and we expect to continue to enter into currency hedging transactions, to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 8. Financial Statements and Supplementary Data

See the Index to Consolidated Financial Statements on Page F-1 attached hereto.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Form 10-K. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

The evaluation of our disclosure controls and procedures included a review of the controls' objectives and design, our implementation of the controls and their effect on the information generated for use in this Annual Report on Form 10-K. This type of evaluation will be performed on a quarterly basis so that the conclusions of management, including the Chief Executive Officer and Chief Financial Officer, concerning the effectiveness of the disclosure controls and procedures can be reported in our periodic reports on Form 10-Q and Form 10-K. The overall goals of these various evaluation activities are to monitor our disclosure controls and procedures, and to modify them as necessary. Our intent is to maintain the disclosure controls and procedures as dynamic systems that change as conditions warrant.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Form 10-K, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information related to our company and our consolidated subsidiaries are made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and our directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management assessed our internal control over financial reporting as of December 31, 2025, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies and our overall control environment.

Based on our assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Attestation Report of Independent Registered Public Accounting Firm

Not applicable.

Changes in internal controls

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended December 31, 2025 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 17, 2026, a majority of the independent members of our Board of Directors approved the promotion of Yaron Naos, our Sr. Vice President, Operations to Chief Operating Officer, a position that more accurately reflects the performance of Mr. Naos during recent years as our second commercial product was launched and as we progress with the clinical development of PRX-115, our potential third commercial product. The promotion involved a raise in Mr. Naos' monthly salary from NIS 65,500 (approximately $21,150) to NIS 70,000 (approximately $22,600).

Rule 10b5-1 Trading Plans

During the quarter ended December 31, 2025, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information in our 2026 Proxy Statement regarding directors and executive officers appearing under the headings "Security Ownership of Certain Beneficial Owners and Management — Section 16(a) Beneficial Ownership Reporting Compliance" and "Election of Directors" is incorporated by reference in this section.

We have adopted an insider trading policy governing the purchase, sale, and other disposition of our securities by our directors, officers, and employees, and by our company. We believe this policy is reasonably designed to promote compliance with insider trading laws, rules, and regulations and listing standards applicable to our company. A copy of our insider trading policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information appearing in our 2026 Proxy Statement under the headings "Director Compensation," "Compensation Discussion and Analysis," "Report of the Compensation Committee," and "Executive Compensation" is incorporated by reference in this section.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information appearing in our 2026 Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management" is incorporated by reference in this section.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information appearing in our 2026 Proxy Statement under the headings "Election of Directors—Corporate Governance" and "—Certain Relationships and Related Transactions" is incorporated by reference in this section.

Item 14. Principal Accountant Fees and Services

Our independent registered public accounting firm is Kesselman & Kesselman, Certified Public Accountants (Isr.), a member of PricewaterhouseCoopers International Limited, Tel Aviv, Israel, PCAOB ID. No. 1309.

The information appearing in our 2026 Proxy Statement under the heading "Ratification of Appointment of Independent Registered Public Accounting Firm" is incorporated by reference in this section.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements.* The following Consolidated Financial Statements of Protalix BioTherapeutics, Inc. are included in Item 8 of this Annual Report on Form 10-K:

2. *Financial Statement Schedule.* Financial statement schedules have been omitted since they are either not required, are not applicable or the required information is shown in the consolidated financial statements or related notes.

3. *Exhibits.*

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit	Date	Filed Herewith
1.1	At the Market Offering Agreement, dated February 27, 2023, between the Company and H.C. Wainwright & Co., LLC	8-K	001-33357	1.1	February 27, 2023	
1.2	Letter Agreement dated March 17, 2025 to the At the Market Offering Agreement, dated February 27, 2023, between the Company and H.C. Wainwright & Co., LLC	8-K	001-33357	1.1	March 17, 2025	
1.3	Letter Agreement dated August 22, 2025 to the At the Market Offering Agreement, dated February 27, 2023, between the Company and H.C. Wainwright & Co., LLC	8-K	001-33357	3.1	August 22, 2025	
3.1	Certificate of Incorporation of the Company	8-K	001-33357	10.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 20, 2019	

3.5	Fourth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.5	August 15, 2022	
3.6	Fifth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.6	August 7, 2023	
3.7	Second Amended and Restated Bylaws of the Company	10-Q	001-33357	3.7	May 9, 2025	
4.1†	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.3	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
4.4	Description of Capital Stock					X
10.1	Lease Agreement between Protalix Ltd. and Angel Science Park (99) Ltd., dated as of October 28, 2003 as amended on April 18, 2005	8-K	001-33357	10.9	January 8, 2007	
10.2	Unprotected Lease Agreement	10-K	001-33357	10.21	March 17, 2008	
10.3††	Amended and Restated Agreement between Protalix Ltd. and Comercio e Serviços Ltda. dated June 17, 2013	10-Q	001-33357	10.1	May 14, 2021	
10.4††	Technology Transfer and Supply Agreement made as of June 18, 2013 by and between Protalix Ltd. and Fundação Oswaldo Cruz	10-Q	001-33357	10.2	May 14, 2021	
10.5††	Binding Term Sheet between Protalix Ltd. and Chiesi Farmaceutici S.p.A.	10-Q	001-33357	10.3	May 14, 2021	
10.6††	Amended and Restated Exclusive License and Supply Agreement by and between Pfizer Inc. and Protalix Ltd., dated October 12, 2015	10-Q	001-33357	10.1	November 13, 2025	
10.7††	Exclusive License and Supply Agreement dated as of October 17, 2017, made by and between Protalix Ltd. and Chiesi Farmaceutici S.p.A.	10-K	001-33357	10.16	March 6, 2018	
10.8††	Exclusive U.S. License and Supply Agreement dated as of July 23, 2018,	10-Q	001-33357	10.1	November 7, 2018	

	made by and between Protalix Ltd. and Chiesi Farmaceutici S.p.A.					
10.9†	Employment Agreement made effective as of May 20, 2019, by and between Protalix Ltd. and Mr. Dror Bashan	8-K	001-33357	10.1	May 21, 2019	
10.10†	Amended and Restated Pro BioTherapeutics, Inc. 2006 Stock Incentive Plan, as amended	8-K	001-33357	10.1	June 28, 2024	
10.11††	Fill/Finish Agreement effective on August 29, 2022 made by and between Chiesi Farmaceutici S.p.A and Protalix Ltd.	10-Q	001-33357	10.1	November 14, 2022	
10.12††	Letter Agreement dated August 29, 2022 from Chiesi Farmaceutici S.p.A to Protalix Ltd.	10-Q	001-33357	10.2	November 14, 2022	
10.13†	Employment Agreement made effective as of June 13, 2025, by and between Protalix Ltd. and Mr. Gilad Mamlok	8-K	001-33357	10.1	July 21, 2025	
19	Insider Trading and Blackout Policy	10-K	001-33357	19	March 17, 2025	
21.1	Subsidiaries	10-K	001-33357	19	March 17, 2025	
23.1	Consent of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Registrant					X
24.1	Power of Attorney (included on the signature page to this Annual Report on Form 10-K)					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer					X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer					X
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation	10-K	001-33357	97.1	March 14, 2024	
101.INS	XBRL INSTANCE DOCUMENT - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	XBRL SHEMA FILE					X
101.CAL	XBRL CALCULATION FILE					X
101.DEF	XBRL DEFINITION FILE					X
101.LAB	XBRL LABEL FILE					X
101.PRE	XBRL PRESENTATION FILE					X
104	Cover Page Interactive Data File - formatted in Inline XBRL and included as Exhibit 101					X

† Management contracts or compensation plans or arrangements in which directors or executive officers are eligible to participate.

†† Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment under Rule 24b-2 of the Exchange Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, as of March 18, 2026.

PROTALIX BIOTHERAPEUTICS, INC.

By:/s/ Dror Bashan
Dror Bashan

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dror Bashan and Gilad Mamlok, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dror Bashan Dror Bashan	President, Chief Executive Officer (Principal Executive Officer) and Director	March 18, 2026
/s/ Gilad Mamlok Gilad Mamlok	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 18, 2026
/s/ Eliot Richard Forster Eliot Richard Forster, Ph.D.	Chairman of the Board	March 18, 2026
/s/ Amos Bar Shalev Amos Bar Shalev	Director	March 18, 2026
/s/ Shmuel Ben Zvi Shmuel Ben Zvi, Ph.D.	Director	March 18, 2026
/s/ Pol F. Boudes Pol F. Boudes, M.D.	Director	March 18, 2026
/s/ Christian Elze Christian Elze	Director	March 18, 2026
/s/ Gwen A. Melincoff Gwen A. Melincoff	Director	March 18, 2026
/s/ Aharon Schwartz Aharon Schwartz, Ph.D.	Director	March 18, 2026

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

TABLE OF CONTENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Protalix BioTherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Protalix BioTherapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity (capital deficiency) and cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Tel Aviv, Israel

March 18, 2026

We have served as the Company's auditor since 2000.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2024	2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,760	$ 14,680
Short-term bank deposits	15,070	15,593
Restricted deposit	-	702
Accounts receivable	2,909	8,840
Other assets	1,096	1,129
Inventories	21,243	25,729
Total current assets	$ 60,078	$ 66,673
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 462	$ 578
Property and equipment, net	4,591	4,879
Deferred income tax asset	2,856	2,516
Operating lease right of use assets	5,430	7,700
Total assets	$ 73,417	$ 82,346
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,533	$ 5,259
Other	19,588	19,875
Operating lease liabilities	1,500	1,384
Total current liabilities	$ 25,621	$ 26,518
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 559	$ 661
Operating lease liabilities	4,026	6,937
Total long term liabilities	$ 4,585	$ 7,598
Total liabilities	$ 30,206	$ 34,116
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2024 and 2025, 185,000,000 shares; issued and outstanding - as of December 31, 2024 and 2025, 75,850,275 and 80,425,981 shares, respectively	76	80
Additional paid-in capital	421,528	433,147
Accumulated deficit	(378,393)	(384,997)
Total stockholders' equity	43,211	48,230
Total liabilities and stockholders' equity	$ 73,417	$ 82,346

The accompanying notes are an integral part of the consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share amounts)

	Year Ended December 31,		
	2023	**2024**	**2025**
REVENUES FROM SELLING GOODS	$ 40,418	$ 52,981	$ 51,802
REVENUES FROM LICENSE AND R&D SERVICES	25,076	418	942
TOTAL REVENUE	65,494	53,399	52,744
COST OF GOODS SOLD	(22,982)	(24,319)	(26,993)
RESEARCH AND DEVELOPMENT EXPENSES	(17,093)	(12,970)	(19,569)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(14,959)	(12,193)	(11,682)
OPERATING INCOME (LOSS)	10,460	3,917	(5,500)
FINANCIAL EXPENSES	(3,180)	(1,062)	(1,191)
FINANCIAL INCOME	1,286	1,299	1,083
FINANCIAL INCOME (EXPENSES), NET	(1,894)	237	(108)
INCOME (LOSS) BEFORE TAXES ON INCOME	8,566	4,154	(5,608)
TAXES ON INCOME	(254)	(1,222)	(996)
NET INCOME (LOSS)	$ 8,312	$ 2,932	$ (6,604)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:			
BASIC	$ 0.12	$ 0.04	$ (0.08)
DILUTED	$ 0.09	$ 0.04	$ (0.08)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	67,512,527	72,530,698	78,546,234
DILUTED	82,424,016	81,057,176	78,546,234

The accompanying notes are an integral part of the consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(CAPITAL DEFICIENCY)
(U.S. dollars in thousands)

	Common Stock	Common Stock	Additional Paid–In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2023	**53,790,167**	**$ 54**	**$ 379,167**	**$ (389,861)**	**$ (10,640)**
Changes during 2023:					
Issuance of common stock under the Sales Agreement, net	12,560,150	13	23,941		23,954
Convertible notes conversions	4,691,623	5	7,778		7,783
Share-based compensation related to stock options			1,928		1,928
Share-based compensation related to restricted stock award	1,371,362	1	1,519		1,520
Exercise of warrants	538,822	*	712		712
Net income				8,312	8,312
Balance at December 31, 2023	**72,952,124**	**$ 73**	**$ 415,045**	**$ (381,549)**	**$ 33,569**
Changes during 2024:					
Initial adoption of ASU 2020-06			(393)	224	(169)
Issuance of common stock under the Sales Agreement, net	2,216,692	2	3,624		3,626
Share-based compensation related to stock options			1,593		1,593
Share-based compensation related to restricted stock award	681,459	1	1,659		1,660
Net income				2,932	2,932
Balance at December 31, 2024	**75,850,275**	**$ 76**	**$ 421,528**	**$ (378,393)**	**$ 43,211**
Changes during 2025:					
Issuance of common stock under the Sales Agreement, net	2,775,215	3	6,809		6,812
Share-based compensation related to stock options			1,494		1,494
Share-based compensation related to restricted stock award	564,010	*	803		803
Exercise of warrants and options	1,236,481	1	2,513		2,514
Net loss				(6,604)	(6,604)
Balance at December 31, 2025	**80,425,981**	**$ 80**	**$ 433,147**	**$ (384,997)**	**$ 48,230**

* Represents an amount less than $1.

The accompanying notes are an integral part of the consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year Ended December 31,		
	2023	2024	2025
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 8,312	$ 2,932	$ (6,604)
Adjustments required to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Share-based compensation	3,448	3,253	2,297
Depreciation	1,191	1,304	1,465
Financial (income) expenses, net	(446)	310	606
Changes in accrued liability for employee rights upon retirement	3	(151)	22
Changes in deferred income tax asset	(3,092)	236	340
Gain on amounts funded in respect of employee rights upon retirement	(50)	(18)	(20)
Loss (gain) on sale of fixed assets	9	(3)	-
Gain on conversions of convertible notes	(421)	-	-
Amortization of debt issuance costs and debt discount	267	-	-
Changes in operating assets and liabilities:			
Decrease in contracts liability	(13,178)	-	-
Decrease (increase) in accounts receivable-trade and other assets	(428)	2,317	(5,890)
Changes in operating lease right of use assets, net	13	(4)	(15)
Increase in inventories	(2,241)	(2,198)	(4,486)
Increase in accounts payable and accruals	5,295	696	292
Net cash provided by (used in) operating activities	$ (1,318)	$ 8,674	$ (11,993)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Investment in bank deposits	(20,420)	(15,000)	(5,000)
Short-term deposit withdrawal	5,000	20,420	5,000
Purchase of property and equipment	(1,149)	(1,282)	(1,638)
Proceeds from sale of property and equipment	-	3	-
Amounts paid (funded) in respect of employee rights upon retirement, net	(142)	80	(26)
Increase in restricted deposit	-	-	(702)
Net cash provided by (used in) investing activities	$ (16,711)	$ 4,221	$ (2,366)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payment for convertible notes redemption	$ -	$ (20,420)	$ -
Proceeds from issuance of common stock under the Sales Agreement, net	23,954	3,626	6,812
Exercise of warrants and options	712	-	2,514
Net cash provided by (used in) financing activities	$ 24,666	$ (16,794)	$ 9,326
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (114)	$ 25	$ (47)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,523	(3,874)	(5,080)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	17,111	23,634	19,760
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 23,634	$ 19,760	$ 14,680

The accompanying notes are an integral part of the consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
(U.S. dollars in thousands)

	Year Ended December 31,		
	2023	2024	2025
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Purchase of property and equipment	$ 614	$ 254	$ 369
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 1,567	$ 376	$ 3,185
Convertible notes conversions	$ 7,783	$ -	$ -
Partial settlement of liability for employee rights upon retirement through transfer of the related funds	$ 882	$ -	$ -
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS			
Tax paid	$ -	$ 385	$ 1,183
Interest paid	$ 2,742	$ 1,532	$ -
Interest received	$ 355	$ 1,487	$ 651

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiary, the "Company") and its wholly-owned subsidiary, Protalix Ltd., are commercial stage biopharmaceutical companies focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs. ProCellEx®, the Company's proprietary plant cell-based protein expression system ("ProCellEx"), represents a new method for developing recombinant proteins in an industrial-scale manner.

To date, the Company has successfully developed two enzyme replacement therapies (ERTs); Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and older with Gaucher disease.

Elelyso, the Company's first commercial product, was approved by the U.S. Food and Drug Administration ("FDA") in 2012 for injection as an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in 40 markets including the United States, Brazil, Israel and others. It is not approved in the European Union (EU). In August 2014, the FDA approved Elelyso for injection for children four years of age and older.

Elfabrio, the Company's second commercial product which was referred to as PRX-102 during its development stage, for the treatment of adult patients with Fabry disease, is our proprietary, plant cell culture expressed enzyme, and a chemically modified stabilized version of, the recombinant α-Galactosidase-A protein, a lysosomal enzyme. It was approved by the European Commission ("EC") for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease, and subsequently in more than 10 additional markets. The approvals cover the 1 mg/kg every-two-weeks (E2W) dosage.

On March 5, 2026, the EC ratified the positive opinion issued in January 2026 by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA"). The EC decision approves, in the EU, the 2 mg/kg E4W dosing regimen for Elfabrio in Fabry disease adult patients stable with an ERT treatment.

The Company is committed to leveraging its record of success as the Company progresses with the development of treatments for rare and orphan diseases. In addition, the Company continuously works on the further development and enhancement of its ProCellEx technology. Accordingly, the Company is turning its focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. The Company believe that its treatments of interest will address both genetic and non-genetic diseases. The Company intends to use its ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. The Company is also exploring novel platform technologies. Consistent with its strategy, the Company continuously evaluates potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutions. Except with respect to Elfabrio and Elelyso, the Company holds the worldwide commercialization rights to its other proprietary development candidates.

The Company's product pipeline currently includes, among other candidates:

PRX-115, the Company's plant cell-expressed recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme to treat uncontrolled gout; and

PRX-119, the Company's plant cell-expressed PEGylated recombinant human DNase I product candidate for long and customized systemic circulation in the bloodstream for NETs-related diseases.

Obtaining marketing approval with respect to any product candidate in any country is dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approvals, and demonstrate the safety and efficacy of its product candidates. The Company cannot reasonably predict the outcome of these activities.

Since its approval by the FDA, Elelyso has been marketed by Pfizer Inc. ("Pfizer") originally pursuant to an exclusive license and supply agreement between Protalix Ltd. and Pfizer which was amended and restated in October 2015 (the "Amended Pfizer Agreement"). Pursuant to the Amended Pfizer Agreement, the Company sold to Pfizer its share in the collaboration worldwide except for Brazil. Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH") for BioManguinhos alfataliglicerase. Fiocruz's purchases of BioManguinhos alfataliglicerase to date have been significantly below certain agreed-upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the termination right, the Company is, at this time, continuing to supply BioManguinhos alfataliglicerase to Fiocruz and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

The Company, through its wholly-owned subsidiary, Protalix Ltd., has licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer, and in Brazil to Fiocruz. Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil.

The Company has partnered with Chiesi Farmaceutici S.p.A. ("Chiesi") for the development and commercialization of Elfabrio through two exclusive global licensing and supply agreements. On October 19, 2017, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi Ex-US Agreement") pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize Elfabrio. On July 23, 2018, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi US Agreement"), with respect to the commercialization of Elfabrio in the United States.

Because the Company's operations are conducted in the State of Israel, the business and operations may be directly affected by military, economic, political and geopolitical conditions in Israel. Since October 2023, Israel has suffered from missile and other similar attacks and has been engaged in military activity on a number of fronts, including with the Hamas in the Gaza Strip, Hezbollah in Lebanon, Iran, the Houthis terrorist group that controls parts of Yemen, and others, and both civilian and military targets in Israel have been attacked. Such clashes may escalate in the future into a greater regional conflict. In October 2025, Israel and Hamas entered into a ceasefire agreement intended to permanently end the war between Israel and Hamas. However, there are no assurances regarding continued compliance with such agreement. While the conflict created and continues to create heightened security concerns, disruptions to business operations, and economic instability within Israel, the ceasefire may contribute to improved regional stability. The security situation remains fluid and any renewed military actions, restrictions, or government-imposed measures could have a material adverse effect on the Company's business, results of operations, and financial condition. On February 28, 2026, the US and Israeli militaries commenced air-based campaigns in Iran which have resulted in a larger regional event and has resulted in increased missile and similar attacks on civilian and military targets in Israel and in other countries in the region. This has resulted in global security concerns that may result in a greater or lasting regional conflict. It is currently

not possible to predict the duration or severity of the ongoing conflict or its effects on the Company's business, results of operations, and financial conditions.

The Company expects to continue to incur significant expenditures in the near future due to research and developments efforts with respect to its product candidates. The Company believes that its cash and cash equivalents and short-term bank deposits are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued.

b. Basis of presentation

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP").

c. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

d. Functional currency

The dollar is the currency of the primary economic environment in which the operations of the Company and its Subsidiaries are conducted. The Company's revenues are derived in dollars. Most of the Company's expenses and capital expenditures are incurred in dollars, and the major source of the Company's financing has been provided in dollars.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items (stated below) reflected in the statements of operations, the following exchange rates are used: (i) for transactions – exchange rates at the transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) – historical exchange rates. Currency translation gains and losses are recorded as financial income or expenses, as appropriate.

e. Cash equivalents

The Company considers all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents.

f. Short-term bank deposits

Bank deposits with original maturity dates of more than three months but less than one year are included in short-term deposits. Such short-term deposits bore interest at an average annual rate of approximately 5.05%-5.75% for the years ended December 31, 2025 and 2024.

g. Restricted deposit

Restricted deposit is deposited in an interested-bearing saving account which is used as a security for the Company's potential hedging activities.

h. Accounts Receivables

Accounts receivable are recorded net of an allowance for credit losses. The Company maintains the allowance for estimated losses resulting from the inability of the Company's customers to make required payments. The allowance represents the current estimate of lifetime expected credit losses over the remaining duration of existing accounts receivable considering historical collection experience, current market conditions and supportable forecasts when appropriate. The estimate is a result of the Company's ongoing evaluation of collectability, customer creditworthiness, historical levels of credit losses and future expectations. As of December 31, 2025 and 2024, the allowance was negligible.

No write-off activity and recoveries for the periods presented were recognized.

i. Inventories

Inventories are valued at the lower of cost or net realizable value. Cost of raw and packaging materials and purchased products is determined using the "moving average" basis.

Cost of finished products is determined as follows: the value of the raw and packaging materials component is determined primarily using the "moving average" basis; the value of the labor and overhead component is determined on an average basis over the production period.

Inventory is written down for estimated obsolescence based upon management assumptions about future demand and market conditions.

j. Property and equipment

1. Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2. The Company's assets are depreciated by the straight-line method on the basis of their estimated useful lives as follows:

	Years
Laboratory equipment	5
Furniture	10-15
Computer equipment	3

Leasehold improvements are amortized by the straight-line method over the shorter of (i) the expected lease term and (ii) the estimated useful life of the improvements.

k. Impairment of long-lived assets

The Company tests long-lived assets for impairment if an indication of impairment exists. If the sum of expected undiscounted future cash flows of definite life assets is less than the carrying amount of such assets, the Company recognizes an impairment loss in the amount by which the carrying amount of the assets exceeds their fair value.

l. Income taxes

1. Deferred income taxes

Deferred taxes are determined utilizing the assets and liabilities method based on the estimated future tax effects of the differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when

those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

2. Uncertainty in income taxes

Tax benefits recognized in the financial statements are those that the Company's management deems at least more likely than not to be sustained, based on technical merits. The amount of benefits recorded for these tax benefits is measured as the largest benefit the Company's management deems more likely than not to be sustained. Liabilities relating to uncertain tax positions are classified as current in the consolidated balance sheets to the extent the Company anticipates making payments within one year.

m. Revenue Recognition

Under Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers, a contract with a customer exists only when: the parties to the contract have approved it and are committed to perform their respective obligations, the Company can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations"), the Company can determine the transaction price for the goods or services to be transferred, the contract has commercial substance and it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for performance obligations upon transfer of control to the customer.

Revenue is recognized net of any taxes collected from customers which are subsequently remitted to governmental entities (e.g., indirect taxes).

1. Revenues from selling products

The Company recognizes revenues from selling goods at a point in time when control over the product is transferred to customers (upon delivery).

The consideration promised in a contract with a Company's customer is based on either fixed amounts or variable amounts. Variable amounts are based on the average net selling price of the drug product in the applicable territory. The Company estimates the variable consideration and recognizes revenue only to the extent the variable consideration is probable and that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Prior to recognizing revenue from variable consideration, the Company uses significant judgment to determine the probability of significant reversal of such revenue. The Company's payment terms are generally 45 days or less.

2. Revenues from license and R&D services

The Company has identified two performance obligations in each of the Chiesi Ex-US Agreement and the Chiesi US Agreement (collectively, the "Chiesi Agreements") as follows: (1) the license and research and development services and (2) the contingent performance obligation regarding future manufacturing.

The Company determined that the license together with the research and development services should be combined into a single performance obligation since Chiesi cannot benefit from the license without the research and development services. The research and development services are highly specialized and are dependent on the supply of the drug.

The future manufacturing was contingent on regulatory approvals of the drug and the Company deems these services to be separately identifiable from other performance obligations in the contract. Manufacturing services post-regulatory approval are not interdependent or interrelated with the license and research and development services. Following the regulatory approvals for Elfabrio received in May 2023, the Company started recognizing revenue from manufacturing. See also revenue from selling products above.

The transaction price was comprised of fixed consideration and variable consideration (capped research and development reimbursements). Under ASC 606, the consideration to which the Company would be entitled upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. The Company estimates variable consideration using the most likely amount method. Amounts included in the transaction price are recognized only when it is probable that a significant reversal of cumulative revenues will not occur. Prior to recognizing revenue from variable consideration, the Company uses significant judgment to determine the probability of significant reversal of such revenue. Following the approval of Elfabrio by the FDA in 2023, the Company received a milestone payment equal to $20.0 million which was recognized as revenue from license and R&D services.

Since the customer benefits from the research and development services as the entity performs the service, revenue from granting the license and the research and development services is recognized over time using the cost-to-cost method since the customer benefits from the research and development services as the entity performs the service.

Revenue from additional research and development services ordered by Chiesi, is recognized over time using the cost-to-cost method.

n. Research and development costs

Research and development costs are expensed as incurred and consist primarily of personnel, subcontractors and consultants (mainly in connection with clinical trials), facilities, equipment and supplies for research and development activities. In connection with purchases of assets, amounts assigned to intangible assets to be used in a particular research and development project that have no alternative future use are charged to research and development costs at the purchase date. Costs incurred for performing research and development services are included in research and development expenses.

o. Concentration of credit risks and trade receivable

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, bank deposits, restricted deposit and account receivables - trade. The Company's deposits are instruments with highly rated financial institutions, mainly in Israeli banks, and, as a matter of policy, limits the amounts of credit exposure to any one financial institution. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to any significant credit risk on these instruments. The Company's trade receivables represent amounts to be received from its customers. The Company does not require its customers to post collateral with respect to receivables.

As of December 31, 2024 and 2025, the accounts receivables trade balance was composed of the following:

(U.S. dollars in thousands)	December 31, 2024	December 31, 2025
Chiesi	$ -	$ 5,473
Pfizer	1,192	1,426
Fiocruz	1,717	1,941
	$ 2,909	$ 8,840

p. Share-based compensation

The Company accounts for share-based payment awards classified as equity awards, including stock-based option awards and restricted stock, using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period.

The Company calculates the fair value of stock-based option awards on the date of grant using the Black-Scholes option pricing model. This option pricing model requires estimates as to the option's expected term and the price volatility of the underlying stock.

The Company measures compensation expense for restricted stock based on the market value of the underlying stock at the date of grant.

The Company elected to recognize compensation cost for awards to employees with only service conditions that have a graded vesting schedule using the accelerated method.

The Company elects to account for forfeitures as they occur.

q. Net earnings (loss) per share

Basic earnings (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock, par value $0.001 per share (the "Common Stock"), outstanding during each period.

Diluted earnings per share is calculated by dividing (a) the net income that includes addition of financial expenses related to convertible notes by (b) the weighted-average number of shares of Common Stock outstanding during each period increased to include the number of additional shares of Common Stock that would have been outstanding if the potentially dilutive shares had been issued.

In computing diluted earnings per share, basic earnings per share are adjusted to take into account the potential dilution that could occur upon: (i) the exercise of options and non-vested restricted stock granted under employee stock compensation plans using the treasury stock method; (ii) the exercise of warrants using the treasury stock method; and (iii) the conversion of convertible notes using the "if-converted" method.

r. Convertible notes

In September 2024, the Company repaid in full all of the outstanding principal and interest payable under its 7.50% Senior Secured Convertible Promissory Notes due 2024 (the "2024 Notes"). The repayment of the convertible notes at maturity was financed entirely with available cash.

Prior to January 1, 2024, the Company accounted for its outstanding convertible notes using the guidance set forth in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 which required that the Company determine whether the embedded conversion option must

be separated from the other features of the applicable note instrument and accounted for separately. ASC 470-20 regarding debt with conversion and other options requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's nonconvertible debt borrowing rate. The Company's outstanding 2024 Notes were accounted for as a liability (debt) and equity component (conversion option) as the convertible notes may be settled wholly or partly in cash, at the option of the Company, when converted.

Starting from January 1, 2024, the convertible debt instruments were accounted for as a single liability measured at amortized cost.

s. Leases

Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The Company determines if an arrangement is a lease at inception. Lease classification is governed by five criteria in ASC 842-10-25-2. If any of these five criteria is met, the Company classifies the lease as a finance lease. Otherwise, the Company classifies the lease as an operating lease. The Company does not have any finance leases.

Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments.

The Company elected the short-term lease recognition exemption for all leases with a term shorter than 12 months. This means, for those leases, the Company does not recognize ROU assets or lease liabilities.

Lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will either exercise or not exercise the option to renew or terminate the lease. The Company recognizes lease expenses over the lease term on a straight-line basis.

The Company applies the portfolio approach to account for the operating lease ROU assets and liabilities for certain car leases and incremental borrowing rates.

t. New accounting pronouncements

Recently adopted accounting pronouncements

In December 2023, the FASB issued Accounting Standards Update (ASU) 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis with the option to apply the standard retrospectively. The Company adopted this standard on a prospective basis. See Note 12.

Recently issued accounting pronouncements, not yet adopted

In November 2024, the FASB issued ASU 2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In December 2025, the FASB issued ASU 2025-10 "Government Grants (Topic 832)" to establish authoritative guidance on the accounting for government grants received by business entities. This update is effective beginning with the Company's 2029 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11 to amend the guidance in "Interim Reporting" (Topic 270). The update provides clarifications intended to improve the consistency and usability of interim disclosure requirements, including a comprehensive listing of required interim disclosures and a new disclosure principle for reporting material events occurring after the most recent annual period. The amendments do not change the underlying objectives of interim reporting but are designed to enhance clarity in application. The ASU is effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years. The Company is currently evaluating the effects that ASU 2025-11 will have on its interim consolidated financial statements and related disclosures.

NOTE 2 - COMMERCIALIZATION AGREEMENTS

a. In October 2015, the Company entered into the Amended Pfizer Agreement with Pfizer that amended and restated the Pfizer Agreement of November 30, 2009. Pursuant to the amendment, the Company granted Pfizer an exclusive, worldwide license, excluding Brazil. Pfizer acquired all the information, knowledge and permission to manufacture and sell Elelyso.

Protalix Ltd. also agreed to provide Pfizer with:

1. Manufacturing and supply of the drug substance for its incorporation into the licensed product in consideration of an agreed price per unit.

2. Assistance in arranging for the manufacture of the drug substance by Pfizer or by alternative supplier chosen by Pfizer in consideration of an agreed hourly rate plus reimbursement of expenses.

b. In October 2017, Protalix Ltd. entered into the Chiesi Ex-U.S. Agreement with respect to the commercialization of pegunigalsidase alfa (hereafter – the drug) for the treatment of Fabry disease. Under the terms of the Chiesi Ex-U.S. Agreement, Protalix Ltd. granted to Chiesi exclusive licensing rights for the commercialization of the drug for all markets outside of the United States. At the effective date, Protalix Ltd. had maintained the exclusive commercialization rights to the drug in the United States, which rights were subsequently granted to Chiesi in July 2018.

Protalix Ltd. is mainly responsible for (i) continuing the development of the drug until a regulatory approval is granted and (ii) manufacture and supply the drug to Chiesi, based on Chiesi's requests.

The consideration consists of the following:

1. Upfront, non-refundable payment of $25.0 million.

2. Additional payments of up to $25.0 million in development costs, capped at $10.0 million per year.

3. Payments for additional studies, as may be approved from time to time by Chiesi.

4. Milestone payments of up to $320.0 million with respect to certain regulatory and commercial events as defined in the Chiesi Ex-U.S. Agreement, which has been reduced to $295.0 million.

5. Additional payments as consideration for the supply of the drug. The payment will vary from 15% to 35% of Chiesi's average selling price of the drug, depending on the amount of annual sales.

6. Protalix Ltd. will be the sole manufacturer of the drug.

Chiesi does not have sublicensing rights (except for certain territories).

In July 2018, Protalix Ltd. entered into the Chiesi US Agreement with respect to the commercialization of the drug for the treatment of Fabry disease. Under the terms of the Chiesi US Agreement, Protalix Ltd. granted to Chiesi exclusive licensing rights for the commercialization of the drug for all markets in the United States. Protalix Ltd. is mainly responsible for (i) continuing the development of the drug until a regulatory approval is granted, (ii) continuing certain clinical development efforts in relation to the drug after a regulatory approval is granted and (iii) manufacture and supply the drug to Chiesi, based on Chiesi's requests.

The consideration consists of the following:

1. Upfront, non-refundable payment of $25.0 million.

2. Additional payments of up to $20.0 million in development costs, capped at $7.5 million per year.

3. Payments for additional studies, as may be approved from time to time by Chiesi.

4. Milestone payments of up to $760.0 million with respect to certain regulatory and commercial events as defined in the Chiesi US Agreement.

5. Additional payments as consideration for the supply of the drug. The payment will vary from 15% to 40% of Chiesi's average selling price of the drug, depending on the amount of annual sales.

6. Protalix will be the sole manufacturer of the drug.

Chiesi does not have sublicensing rights.

c. On June 18, 2013, Protalix Ltd. entered into the Brazil Agreement with Fiocruz for BioManguinhos. Fiocruz's purchases of BioManguinhos alfataliglicerase to date have been significantly below certain agreed upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding, the Company is, at this time, continuing to supply BioManguinhos alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

NOTE 3 - PROPERTY AND EQUIPMENT

a. Composition of property and equipment grouped by major classifications is as follows:

(*U.S. dollars in thousands*)	December 31, 2024	December 31, 2025
Laboratory equipment	$ 19,043	$ 20,090
Furniture and computer equipment	3,374	3,765
Leasehold improvements	17,913	18,070
	$ 40,330	$ 41,925
Less – accumulated depreciation and amortization	(35,739)	(37,046)
	$ 4,591	$ 4,879

b. Depreciation in respect of property and equipment during the years ended December 31, 2023, 2024, and 2025 were as follows:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025
Depreciation in respect of property and equipment	$ 1,191	$ 1,304	$ 1,465

NOTE 4 - INVENTORIES

a. Inventories at December 31, 2024 and 2025 consisted of the following:

(*U.S. dollars in thousands*)	December 31, 2024	December 31, 2025
Raw materials	$ 4,549	$ 5,980
Work in progress	11,245	9,375
Finished goods	5,449	10,374
Total inventory	$ 21,243	$ 25,729

b. Write-down of inventory under cost of goods sold recorded during the years ended December 31, 2023, 2024, and 2025 were as follows:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025
Write-down of inventory under cost of goods sold	$ 800	$ 90	$ 30

NOTE 5 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT

The Israeli Subsidiary is required to make a severance payment upon dismissal of an employee or upon termination of employment in certain circumstances. The severance pay liability to the employees (based upon length of service and the latest monthly salary - one month's salary for each year employed) is recorded on the Company's balance sheets under "Liability for employee rights upon retirement." The liability is recorded as if it were payable at each balance sheet date on an undiscounted basis.

The liability is funded in part from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the Company's balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Company's assets. However, under labor agreements and subject to certain limitations, any policy may be transferred to the ownership of the individual employee for whose benefit the funds were deposited.

For the years ended December 31, 2023, 2024, and 2025, the Company's deposits with insurance companies in connection with its severance payment obligations were approximately as follows:

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025
Deposits with insurance companies in connection with severance payment obligations	$ 142	$ 32	$ 26

In accordance with the current employment agreements with certain employees, the Company makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's rights upon retirement. The Company is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Company's balance sheets, as the amounts funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plans").

(U.S. dollars in thousands)	Year ended December 31, 2023	2024	2025
Total Severance Expenses	$ 801	$ 820	$ 1,044
Severance Expenses in respect of Contribution Plans	$ 798	$ 859	$ 1,022
Gain on amounts funded in respect of employee rights upon retirement	$ 50	$ 18	$ 20

The Company expects to contribute approximately $1,180,000 in the year ending December 31, 2026 to insurance companies in connection with its severance liabilities, approximately $1,152,000 of which will be contributed to one or more Contribution Plans.

During the five-year period following December 31, 2025, the Company expects that up to 15 employees may retire upon normal retirement age.

NOTE 6 - COMMITMENTS

a. Royalty Commitments

The Company is obligated to pay royalties to the National Authority for Technological Innovation ("NATI") on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from NATI or its predecessor, the Office of the Israeli Innovation Authority (IIA). At the time the grants were received, successful development of the related projects was not assured.

In the case of failure of a project that was partly financed as described above, the Company is not obligated to pay any such royalties or repay funding received from NATI or the IIA.

Under the terms of the applicable funding arrangements, royalties of 3% to 6% are payable on the sale of products developed from projects funded by NATI or the IIA, which payments shall not exceed, in the aggregate, 100% of the amount of the grant received (dollar linked), plus, commencing upon January 1, 2001, interest at an annual rate based on SOFR. In addition, if the Company receives approval to manufacture products developed with government grants outside the State of Israel, it will, subject to certain exceptions, be required to pay an increased total amount of royalties, depending on the manufacturing volume that is performed outside the State of Israel, and, possibly, an increased royalty rate.

Royalty expenses to NATI or the IIA are included in the statement of operations as a component of the cost of revenues during the years ended December 31, 2023, 2024, and 2025 were approximately as follows:

	Year ended December 31,		
(U.S. dollars in thousands)	2023	2024	2025
Royalty expenses to NATI or the IIA	$ 1,868	$ 1,582	$ 1,557

The maximum total royalty amount payable by the Company under these funding arrangements at December 31, 2024 and 2025 (without interest, assuming 100% of the funds are payable) is as follows:

	December 31,	
(U.S. dollars in thousands)	2024	2025
Maximum total royalty amount payable (without interest, assuming 100% of the funds are payable)	$ 33,900	$ 32,391

b. Subcontracting Agreements

The Company has entered into sub-contracting agreements with several clinical providers and consultants in Israel, the United States and certain other countries in connection with its primary product development process. As of December 31, 2025, total commitments under said agreements were approximately $17.7 million.

c. Fill/Finish Agreement

On August 29, 2022, the Company entered into a Fill/Finish Agreement (the "F/F Agreement") and a Letter Agreement, in each case with Chiesi. The Company agreed to supply Chiesi with drug substance for pegunigalsidase alfa and, following relevant technology and technical information transfer activities, Chiesi has agreed, among other things, to provide the Company with commercial fill/finish services for pegunigalsidase alfa. The F/F Agreement did not change the terms and conditions of the Chiesi Agreements. Subsequently, in November 2024, the Company and Chiesi amended the F/F Agreement to provide that a different Chiesi facility may act as a secondary supplier of such services and that the F/F Agreement shall have an initial term of 10 years, unless terminated earlier in accordance with the terms of the F/F Agreement. Prior to expiration of the initial term, the term may be extended by mutual agreement for an additional period of seven years upon mutual written agreement prior to expiration of the initial term. Under the F/F Agreement, the Company is obligated to pay to Chiesi an amount equal to €2.5 million in connection with the necessary technology transfer, QA tests and capital expenditures. Such amount is to be paid over the term of the F/F agreement based on the actual vials produced by Chiesi thereunder. Under the amendment, the Company and Chiesi agreed to share equally the costs of establishing the new facility as an alternative source for Fill/Finish. The Company's share of such costs amounting to €400,000 shall be due and payable upon Chiesi's completion of the manufacture of the requisite validation batches and issuance of the process validation report.

NOTE 7 - OPERATING LEASES

The Company is a party to several lease agreements for its facilities that included varying lease periods and options for extensions. The Company is currently in the second option period for each of the three leases, which periods are not uniform. In September 2025, the Company amended all of the facility leases, collectively, to provide that the third option period for each lease will end on December 31, 2031 and will be associated with a uniform rent increase equal to 7.5%. Thereafter, each lease will extend automatically, on an individual basis, for up to four additional five-year periods unless the Company provides the lessor with six months' advance notice that it does not intend that any individual option extension become effective. Each option to renew a lease in each of the four option periods shall include a rent increase equal

to 5% of the rent payable for the applicable previous option period. Prior to the amendment, the options to extend the leases were associated with increases of either 7.5% or 10%. The Company expects to exercise the final option in future periods. As of December 31, 2025, the Company provided bank guarantees of approximately $586,000, in the aggregate, to secure the fulfillment of its obligations under the lease agreements. The Company adjusted the operating lease right of use assets by $3.1 million reflecting the amount of remeasurement of the lease liability using a new discount rate at the amendment date.

The Company has entered into several three-year leases for vehicles which are regularly amended as new vehicles are leased.

The following table sets forth data regarding the Company's operating leases for the years ended December 31, 2023, 2024, and 2025:

	Year Ended December 31,		
(*U.S. dollars in thousands*)	2023	2024	2025
Operating lease costs	$1,471	$1,639	$1,815
Cash paid for amounts included in the measurement of lease liabilities	1,484	1,634	1,804
Weighted average remaining lease term (in years)	6.8	6.0	22.6
Weighted average discount rate	12.8 %	12.8 %	13.4 %

The following table sets forth a maturity analysis of the Company's operating lease liabilities as of December 31, 2025:

(*U.S. dollars in thousands*)	December 31, 2025
First year	$ 1,384
Second year	$ 1,192
Third year	$ 1,104
Fourth year	$ 1,058
Fifth year and thereafter	$ 22,445
Total undiscounted cash flows	$ 27,183
Less: imputed interest	$ 18,862
Present value of operating lease liabilities	$ 8,321

NOTE 8 - SHARE CAPITAL

a. Authorized Capital

Under the Company's Certificate of Incorporation, as amended, the Company is authorized to issue 185,000,000 shares of Common Stock, par value $0.001 per share, and 100,000,000 shares of preferred stock, par value $0.0001 per share.

b. Rights of the Company's Common Stock

The Company's Common Stock is listed on the NYSE American. The Company voluntarily delisted its Common Stock from the Tel Aviv Stock Exchange effective March 22, 2023. Each share of Common Stock is entitled to one vote. The holders of shares of Common Stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

c. Stock based compensation

On December 14, 2006, the Board of Directors adopted the Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan, as amended (the "Plan"). The Plan has since been amended to, among other things, increase the number of shares of Common Stock available under the Plan to 17,475,171 shares. The grant of options to Israeli employees under the Plan is subject to the terms stipulated by Sections 102 and 102A of the Israeli Income Tax Ordinance (the "Ordinance"). Each option grant made to an Israeli citizen is subject to the track chosen by the Company, either Section 102 or Section 102A of the Ordinance, and pursuant to the terms thereof, the Company is not allowed to claim, as an expense for tax purposes, the amounts credited to employees as a benefit, including amounts recorded as salary benefits in the Company's accounts, in respect of options granted to employees under the Plan, with the exception of the work-income benefit component, if any, determined on the grant date. For Israeli non-employees, the share option plan is subject to Section 3(i) of the Ordinance.

As of December 31, 2025, 2,092,933 shares of Common Stock remain available for grant under the Plan.

The vesting period of the outstanding options and restricted shares is generally three or four years from the date of grant. The rights of common stock obtained from the exercise of options (once vested) and the restricted stock are identical to those of other common stock of the Company. The contractual term of these options is primarily for ten years.

1. **Options and restricted stock granted to employees and directors:**

A summary of share option plans, and related information, under all of the Company's equity incentive plans for the year ended December 31, 2025, and the effect of share-based compensation on the statement of operations for the year ended December 31, 2025, is as follows:

a) Options granted to employees and directors:

	Year ended December 31, 2025	
	Number of options	Weighted average exercise price
Outstanding at beginning of year	7,402,295	$ 1.98
Changes during the year:		
Granted	1,458,990	1.56
Expired and forfeited	(258,526)	7.53
Exercised	(328,481)	1.13
Outstanding at end of year	8,274,278	$ 1.76
Exercisable at end of year	5,464,917	$ 1.94

b) Restricted stock granted to employees and directors:

	Year Ended December 31, 2025	
	Number of Restricted Stock	Weighted average of fair value at grant date
Outstanding at beginning of year	862,816	$ 1.70
Changes during the year:		
Granted	564,010	1.66
Vested	(687,232)	$ 1.81
Non vested at end of year	739,594	$ 1.58

c) The following table summarizes information concerning outstanding and exercisable options as of December 31, 2025:

	December 31, 2025			
	Options outstanding		Options exercisable	
Exercise prices	Number of options outstanding at end of year	Weighted average remaining contractual life	Number of options exercisable	Weighted average remaining contractual life
$1.03-$2.00	7,017,970	7.44	4,208,609	6.64
$3.55-$3.73	836,308	3.65	836,308	3.65
$4.69-$5.60	420,000	2.76	420,000	2.76
	8,274,278		5,464,917	

As of December 31, 2025, the aggregate intrinsic value of all the outstanding options and exercisable options was approximately $3.4 million and $2.3 million, respectively.

d) The weighted average grants date per share fair value of restricted stock granted in 2023, 2024, and 2025 was as follows:

	Year ended December 31,		
	2023	2024	2025
Weighted average grants date per share fair value (USD)	$ 1.99	$ 1.24	$ 1.66

e) The fair value of each option granted during 2023, 2024, and 2025 for both employees and directors is estimated at the date of grant using the Black-Scholes option-pricing model. The following weighted average assumptions were applied in determining the options' fair value on their grant date:

	Year Ended December 31,		
	2023	2024	2025
Weighted average grants date fair value (USD)	1.84	1.10	1.56
Exercise price (USD)	1.84	1.10	1.56
Risk free rate	4.44 %	3.55 %	3.89 %
Volatility	79.41 %	79.29 %	73.64 %
Dividend yield	0 %	0 %	0 %
Expected life (Years)	5.75	5.75	5.75

f) The total unrecognized compensation cost of employee stock options at December 31, 2025 is approximately $1.3 million. The unrecognized compensation cost of employee stock options is expected to be recognized over a weighted average period of 0.84 years.

During the years ended December 31, 2023 and 2024, there were no exercises of stock options, and the Company did not realize any tax benefit in connection with any exercises. During the year ended December 31, 2025, employees and former employees exercised options to purchase 328,481 shares of the Company's common stock in the aggregate, and the Company did not realize any tax benefits equal in connection with such exercises.

The total vesting-date value of equity classified restricted stock vested during the year ended December 31, 2025 was $1.3 million. As of December 31, 2025, the unrecognized compensation cost related to all unvested equity classified restricted stock of $0.7 million is expected to be recognized as an expense over a weighted-average period of 0.87 years.

g) The following table illustrates the effect of share-based compensation on the statement of operations:

	Year ended December 31,		
(U.S. dollars in thousands)	**2023**	**2024**	**2025**
Cost of goods sold	$ 596	$ 631	$ 431
Research and development expenses	777	589	680
Selling, general, and administrative expenses	2,075	2,033	1,186
	$ 3,448	$ 3,253	$ 2,297

d. Private and 144A Offerings

During the year ended December 31, 2023, the Company issued (i) 301,810 shares of Common Stock in connection with the cash exercise of a warrant issued in 2020 and generated proceeds equal to $0.7 million from such exercise and (ii) 237,012 shares of Common Stock in connection with the cashless exercise of a warrant to purchase 845,000 shares of Common Stock issued in 2020. The Company did not generate any proceeds from the cashless exercise.

During the year ended December 31, 2023, the Company issued, in the aggregate, 4,691,623 shares of Common Stock in connection with the conversions of 2024 Notes. In connection with such conversions, during the year ended December 31, 2023, the Company paid to the converting holders $0.9 million representing cash payments due to accrued but unpaid interest, make-whole interest payments and payments in lieu of fractional shares.

During the year ended December 31, 2025, the Company issued:

(i) 908,000 shares of Common Stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately $2.1 million from such exercises. All unexercised warrants expired on March 11, 2025. Accordingly, as of March 12, 2025, no warrants remained outstanding.

(ii) 328,481 shares of Common Stock in connection with the cash exercise of options to purchase 328,481 shares of Common Stock by certain current and former employees of the Company. The Company received cash proceeds equal to $0.4 million in connection with such exercises.

e. At-the-Market (ATM) Offering

On July 2, 2021, the Company entered into an At The Market Offering Agreement (the "2021 Sales Agreement") with H.C. Wainwright & Co., LLC, as the Company's sales agent (the "Agent") which was amended on May 2, 2022. Pursuant to the terms of the 2021 Sales Agreement, the Company was able to sell from time to time through the Agent, shares of Common Stock having an aggregate offering price of up to $20.0 million (the "ATM Shares"). During the term of the 2021 Sales Agreement which ended during the quarter ended March 31, 2023, the Company sold a total of 13,980,060 ATM Shares for total gross proceeds of approximately $20.0 million, thereby completing the ATM program under said agreement.

On February 27, 2023, the Company entered into an At The Market Offering Agreement (the "2023 Sales Agreement") with the Agent. Pursuant to the terms of the 2023 Sales Agreement, the Company may sell, from time to time through the Agent, ATM Shares having an aggregate offering price of up to $20.0 million. On March 17, 2025, the Company entered into an amendment to the 2023 Sales Agreement pursuant to which the Company increased the aggregate gross sales price of shares of Common Stock available for offer and sale under the Sales Agreement by $20.0 million.

The Company has no obligation to sell any shares of Common Stock under the 2023 Sales Agreement, and may at any time suspend sales under the 2023 Sales Agreement or terminate the 2023 Sales Agreement in accordance with its terms. The Agent is entitled to a commission of up to 3.0% of the aggregate gross proceeds from the shares of Common Stock sold under the 2023 Sales Agreement.

During the year ended December 31, 2023, the Company sold, in the aggregate, 12,560,150 shares of Common Stock under the 2021 Sales Agreement and 2023 Sales Agreement. The Company generated gross proceeds equal to approximately $24.9 million in connection with such sales (issuance cost was approximately $0.9 million).

During the year ended December 31, 2024, the Company sold, in the aggregate 2,216,692 shares of Common Stock under the 2023 Sales Agreement. The Company generated gross proceeds equal to approximately $3.8 million in connection with such sales (issuance cost was approximately $0.1 million).

During the year ended December 31, 2025, the Company sold, in the aggregate, 2,775,215 shares of Common Stock under the 2023 Sales Agreement. The Company generated gross proceeds equal to approximately $7.0 million in connection with such sales (issuance costs were $0.2 million). All such sales were effected during the first and second quarters of 2025.

As of December 31, 2025, shares of Common Stock for total gross proceeds of approximately $15.7 million remain available to be sold under the Sales Agreement.

NOTE 9 - CONVERTIBLE NOTES

In September 2024, the Company repaid all of the $20.42 million outstanding principal and interest payable under the 2024 Notes. The repayment of the convertible notes at maturity was financed entirely with available cash.

The 2024 Notes were issued pursuant to an indenture entered into between the Company, the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee and Wilmington Savings Fund Society, FSB, as collateral agent. Interest on the 2024 Notes was payable semi-annually at a rate of 7.50% per annum. The outstanding 2024 Notes matured three years after the issuance thereof and were guaranteed by the Company's subsidiaries. The 2024 Notes were secured by perfected liens on all of the assets of the Company and its subsidiaries.

The following table sets forth total interest expense recognized related to the 2024 Notes:

(*U.S. dollars in thousands*)	Year Ended December 31, 2023	2024
Contractual interest expense	$ 2,534	$ 1,022
Amortization of debt issuance costs and debt discount	267	—
Total	$ 2,801	$ 1,022

NOTE 10 - FAIR VALUE MEASUREMENT

The Company discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received from the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value.

NOTE 11 – NET EARNINGS (LOSS) PER SHARE

Basic and diluted net earnings (loss) per share attributable to common stockholders were calculated as follows:

(In thousands, except share data)	Year Ended December 31, 2023	2024	2025
Numerator:			
Net income (loss)	$ 8,312	$ 2,932	$ (6,604)
Add:			
Financial expenses of 2024 Notes*	(1,168)	39	
Net income (loss) for diluted calculation	$ 7,144	$ 2,971	$ (6,604)
Denominator:			
Weighted average shares of Common Stock outstanding for basic calculation	67,512,527	72,530,698	78,546,234
Weighted average dilutive effect of 2024 Notes	13,335,430	7,667,323	
Weighted average dilutive effect of stock options and restricted stock	1,576,059	859,155	
Weighted average shares of Common Stock outstanding for diluted calculation	82,424,016	81,057,176	78,546,234

* Financial expenses on 2024 Notes consists of add back of financial expense incurred during the year and inclusion of make-whole interest payments that will be incurred upon conversion.

In the year ended December 31, 2023, the diluted earnings per share do not include 18,254,264 shares of Common Stock underlying outstanding warrants and stock options because the effect would be anti-dilutive. In the year ended December 31, 2024, the diluted earnings per share do not include 16,661,907 shares of Common Stock underlying outstanding stock options, unvested restricted shares and warrants because the effect would be anti-dilutive. In the year ended December 31, 2025, the diluted earnings per share do not include 10,672,506 shares of Common Stock underlying outstanding stock options, unvested restricted shares and warrants because the effect would be anti-dilutive.

NOTE 12 - TAXES ON INCOME

a. The Company

Protalix BioTherapeutics, Inc. is taxed according to U.S. tax laws. The Company's income is taxed in the United States at a rate of up to 21%.

The U.S. Tax Cuts and Jobs Act, which was enacted into law in December 2017 (the "TCJA") represents fundamental and dramatic modifications to the U.S. tax system. It contains several key tax provisions that impacted the Company including the reduction of the maximum U.S. federal corporate income tax rate from 35% to 21%, effective January 1, 2018. Other significant changes under the TCJA includes, among others, a one-time repatriation tax on accumulated foreign earnings, a limitation of NOL deduction to 80% of taxable income, and indefinite carryover of post-2017 NOLs. The TCJA also repealed the corporate alternative minimum tax for tax years beginning after December 31, 2017. Losses generated prior to January 1, 2018 will still be subject to the 20-year carryforward limitation and the alternative minimum tax. Other impacts due to the TCJA included the repeal of the domestic manufacturing deduction, modification of taxation of controlled foreign corporations, a base erosion anti-abuse tax, modification of interest expense limitation rules, modification of limitation on deductibility of excessive executive compensation, and taxation of global intangible low-taxed income.

Modification of interest expense limitation rules under the TCJA provides generally that for taxable years 2019-2022 interest expense deduction shall be limited to 50% of the EBITDA and for taxable years 2022 onwards to 30% of EBIT. Disallowed interest deduction may be carried forward indefinitely. The Company believes that any potential impact (if applicable) of this limitation will be offset by utilization of available NOLs.

On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, The One Big Beautiful Act, which includes significant corporate tax changes, including a restoration of the current deductibility of domestic research expenditures beginning in 2025 under IRC Section 174A, with transition options for previously capitalized amounts. Foreign research expenditures continue to require capitalization subject to the mandatory 15-year amortization period under existing IRC Section 174. The Company implemented the transition options permitted.

Section 174 which requires taxpayers to capitalize and amortize research and development expenses for tax years beginning after December 31, 2021, resulted in the capitalization of research and development costs of approximately $14.4 million, $11.9 million and $14.6 million in 2023, 2024, and 2025, respectively. The Company will amortize these costs for tax purposes over 15 years for research and development performed outside the United States.

The Company believes that all future profits of its Subsidiary will be indefinitely reinvested or that there is no expectation to distribute any taxable dividends from the Subsidiary. The determination of the amount of the unrecognized deferred tax liability related to the undistributed earnings is estimated as an immaterial amount.

b. Protalix Ltd.

The Company as a "foreign-investment company" measures its results for tax purposes in dollar based on Income Tax Regulations (Bookkeeping Principles of Foreign Invested Companies and of Certain Partnerships and the Determination of Their Taxable Income), 1986. The Israeli Subsidiary is taxed according to Israeli tax laws:

1. **Tax rates**

   The income of the Israeli Subsidiary, other than income from "Approved Enterprises," is taxed in Israel at the regular corporate tax rates.

   The corporate tax rate was 23% for 2018 and thereafter.

   Capital gain on a sale of assets is subject to capital gain tax according to the corporate tax rate in effect in the year during which the assets are sold.

2. **The Law for the Encouragement of Capital Investments, 1959 (the "Encouragement of Capital Investments Law")**

   Under the Encouragement of Capital Investments Law, including Amendment No. 60 to the Encouragement of Capital Investments Law as published in April 2005, by virtue of the "Approved Enterprise" status the Israeli Subsidiary is entitled to various tax benefits as follows:

   a. **Reduced tax rates**

      Income derived from the Approved Enterprise during a 10-year period commencing upon the year in which the enterprise first realizes taxable income is tax exempt, provided that the maximum period to which it is restricted by the Encouragement of Capital Investments Law has not elapsed.

      The Israeli Subsidiary has an "Approved Enterprise" plan since 2004. The period of benefits in respect of the main enterprise of the Company has not yet commenced.

      If the Israeli Subsidiary subsequently pays a dividend out of income derived from the "Approved Enterprise" during the tax exemption period, it will be subject to tax on the gross amount distributed (including the company tax on these amounts), at the rate which would have been applicable if such income not been exempted.

   b. **Conditions for entitlement to the benefits**

      The Israeli Subsidiary's entitlement to the benefits described above is subject to its fulfillment of conditions stipulated by the law, rules and regulations published thereunder, and the instruments of approval for the specific investment in an approved enterprise. Failure by the Israeli Subsidiary to comply with these conditions may result in the cancellation of the benefits, in whole or in part, and the Israeli Subsidiary may be required to refund the amount of the benefits with interest. The Israeli Subsidiary received a final implementation approval with respect to its "Approved Enterprise" from the Investment Center.

c. **Amendment of the Law for the Encouragement of Capital Investments, 1959**

In recent years, several amendments have been made to the Encouragement of Capital Investments Law which have enabled new alternative benefit tracks, subject to certain conditions.

The Encouragement of Capital Investments Law was amended as part of the Economic Policy Law for the years 2011-2012 (amendment 68 to the Encouragement of Capital Investments Law), which was passed by the Israeli Knesset on December 29, 2010. The amendment sets alternative benefit tracks to those currently in effect under the provisions of the Encouragement of Capital Investments Law. On December 29, 2016, Amendment 73 to the Encouragement of Capital Investments Law was published. This amendment sets new benefit tracks, inter alia, "Preferred Technological Enterprise" and "Special Preferred Technological Enterprise" (the "Capital Investments Law Amendment").

To date, the Company has elected not to have the Capital Investments Law Amendment apply to the Company.

c. Tax losses carried forward to future years

As of December 31, 2024 and 2025, the Company had aggregate NOL carry-forwards equal to approximately $227.2 million and $219.8 million, respectively, that are available to reduce future taxable income as follows:

1. **The Company**

The Company's carry-forward NOLs, equal to approximately $22.2 million and $20.0 million as of December 31, 2024 and 2025, respectively, may be restricted under Section 382 of the Internal Revenue Code ("IRC"). IRC Section 382 applies whenever a corporation with NOL experiences an ownership change. As a result of IRC Section 382, the taxable income for any post change year that may be offset by a pre-change NOL may not exceed the general IRC Section 382 limitation, which is the fair market value of the pre-change entity multiplied by the IRC long-term tax exempt rate.

2. **Protalix Ltd.**

At December 31, 2024 and 2025, the Israeli Subsidiary had approximately $205.0 million and $199.8 million, respectively, of carry-forward NOLs that are available to reduce future taxable income with no limited period of use.

Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, the Company considered all available evidence, including past operating results, the most recent projections for taxable income, and prudent and feasible tax planning strategies. The Company reassesses its valuation allowance periodically and if future evidence allows for a partial or full release of the valuation allowance, a tax benefit will be recorded accordingly.

d. Deferred income taxes:

The components of the Company's net deferred tax assets at December 31, 2024 and 2025 were as follows:

(*U.S. dollars in thousands*)	December 31, 2024	December 31, 2025
In respect of:		
Research and development expenses	$ 3,055	$ 3,717
Other timing differences	452	684
Net operating loss carry forwards	50,014	48,479
Valuation allowance	(50,665)	(50,364)
	2,856	2,516

Deferred taxes are computed using the tax rates expected to be in effect when those differences reverse.

e. Reconciliation of the theoretical tax expense to actual tax expense

A reconciliation of the statutory U.S. federal income tax rate of 21% in 2025 to the effective income tax rate is as follows:

(U.S. dollars in thousands)	Year Ended December 31, 2025 $	%
U.S Federal Statutory tax rate	(1,178)	(21)
Foreign Tax Effects (Israel):		
Change in Valuation allowances	(301)	(5)
Share based compensation	528	9
Other	(10)	-
Effect of changes in tax law enacted in the current period	105	2
Effect of Cross Border Tax Laws, net	1,735	31
Non-taxable or non-deductible items	117	2
Effective tax rate	996	18

A reconciliation of the statutory U.S. federal income tax rate of 21% in 2024 and 2023 to the effective income tax rate is as follows:

(U.S. dollars in thousands)	Year Ended December 31, 2023	2024
Tax computed at the statutory U.S. income tax rate	$ 1,799	$ 872
Differences in tax rate	(899)	(436)
Statutorily non-deductible expenses	1,684	506
Change in Valuation allowances	(6,932)	(953)
Utilization of carry-forward losses and other temporary items without deferred taxes recognition	3,602	1,233
Withholding tax	1,000	-
	$ 254	$ 1,222

f. Valuation allowance roll-forward

The following table presents the change in the Company's valuation allowance during the periods presented:

(*U.S. dollars in thousands*)	
Balance at December 31, 2022	$ (58,550)
Additions to valuation allowance	(728)
Reductions to valuation allowance	7,660
Balance at December 31, 2023	$ (51,618)
Balance at December 31, 2023	$ (51,618)
Reductions to valuation allowance	953
Balance at December 31, 2024	$ (50,665)
Balance at December 31, 2024	$ (50,665)
Reductions to valuation allowance	301
Balance at December 31, 2025	$ (50,364)

g. Uncertain tax position

Provisions of ASC 740-10, Income Taxes, clarify whether to recognize assets or liabilities for tax positions taken that may be challenged by a tax authority. A reconciliation of the beginning and ending amount of unrecognized tax benefits, is as follows:

(U.S. dollars in thousands)	
Balance at December 31, 2022	$ 530
Increase for tax position related to current year	275
Balance at December 31, 2023	$ 805
Balance at December 31, 2023	$ 805
Increase for tax position related to current year	-
Balance at December 31, 2024	$ 805
Balance at December 31, 2024	$ 805
Increase for tax position related to current year	-
Balance at December 31, 2025	$ 805

h. Tax assessments

In accordance with the Income Tax Ordinance, as of December 31, 2025, all of Protalix Ltd.'s tax assessments through tax year 2020 are considered final.

A summary of open tax years by major jurisdiction is presented below:

Jurisdiction:	Years:
Israel	2021-2025
United States (*)	2022-2025

(*) Includes federal, state and local (or similar provincial jurisdictions) tax positions.

i. Income (loss) before taxes on income is composed of the following:

	Year ended December 31,		
(U.S. dollars in thousands)	2023	2024	2025
Domestic	(7,061)	(4,548)	(4,579)
Foreign	15,627	8,702	(1,029)
	$ 8,566	$ 4,154	$ (5,608)

j. The following table summarizes the Company's taxes on income:

	Year Ended December 31,		
(U.S. dollars in thousands)	2023	2024	2025
Current taxes on income - US (federal)	$ 3,346	$ 986	$ 656
Deferred taxes on income - US (federal)	(3,092)	236	340
Total taxes on income	$ 254	$ 1,222	$ 996

Following the regulatory approvals of Elfabrio in May 2023, the receipt of the $20.0 million milestone payment and the launch of Elfabrio in the United States, the Company released the valuation allowance previously recorded on deferred tax assets in respect of its NOLs in the United States resulting in a net tax benefit of $3.1 million. The Company concluded that, based upon the preponderance of positive evidence over negative evidence and the anticipated ability to use the deferred tax assets, it was more likely than not that these deferred tax assets would be realizable due to forecasted profits. The Company considered the following: (i) cumulative profits for tax over the previous 12 quarters in its U.S. operations; (ii) the impact of IRC Section 174 which requires the Company to capitalize and amortize its research and development expenses over 15 years; and (iii) its forecasted profits in the United States following the regulatory approvals of Elfabrio.

k. Income taxes paid:

The income taxes paid by the Company are as follows:

	Year ended December 31,		
(U.S. dollars in thousands)	2023	2024	2025
United States (federal)	$ -	$ 385	$ 1,183

NOTE 13 – SEGMENT INFORMATION

a. The Company operates in Israel as a single operating segment. The Company's President and Chief Executive Officer is the chief operating decision maker (the "CODM"). The CODM makes decisions on resource allocation, assesses performance of the business and monitors budget versus actual results on a consolidated basis. For additional information see Note 14.

b. Segment information:

(U.S. dollars in thousands)	Year Ended December 31, 2023	2024	2025
Revenues from customers	$ 65,494	$ 53,399	$ 52,744
Less:			
Employee salaries and related expenses	24,075	21,780	24,722
Sub-contractors expense	14,008	8,682	12,275
Interest expense	3,180	1,062	-
Interest income	(1,286)	(1,299)	(1,083)
Depreciation	1,191	1,304	1,465
Other segment expenses*	15,760	17,716	20,973
Income (loss) before taxes on income	8,566	4,154	(5,608)
Taxes on income	254	1,222	996
Segment net income (loss)	$ 8,312	$ 2,932	$ (6,604)

* Other expenses included in net income (loss) includes raw materials, rent and utilities and others.

c. The following table summarizes the Company's disaggregation of revenues:

(U.S. dollars in thousands)	Year Ended December 31, 2023	2024	2025
Gaucher disease:			
Pfizer (Ireland)	$ 12,522	$ 12,617	$ 18,227
Fiocruz (Brazil)	$ 10,401	$ 11,031	$ 11,062
Fabry disease:			
Chiesi (Italy)	$ 17,495	$ 29,333	$ 22,513
Total revenues from selling goods	$ 40,418	$ 52,981	$ 51,802
Revenues from license and R&D services	$ 25,076	$ 418	$ 942

d. Long lived assets are located in Israel.

NOTE 14 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Balance sheets:

(*U.S. dollars in thousands*)	December 31, 2024	2025
a. Other assets:		
Institutions	$ 486	$ 634
Prepaid expenses	500	394
Sundry	110	101
	$ 1,096	$ 1,129

(*U.S. dollars in thousands*)	December 31, 2024	2025
b. Accounts payable and accruals – other:		
Payroll and related expenses	$ 1,343	$ 1,629
Provision for vacation	1,811	2,309
Accrued expenses	9,568	9,790
Royalties payable	1,080	799
Income tax payable	3,476	2,950
Payable to customer	2,056	2,029
Property and equipment suppliers	254	369
	$ 19,588	$ 19,875

b. Statements of operations:

(U.S. dollars in thousands)	Year ended December 31,		
Research and development expenses:	**2023**	**2024**	**2025**
Employee salaries and related expenses	$ 7,758	$ 7,068	$ 9,696
Subcontractor-related expenses	6,345	2,432	5,631
Materials-related expenses	596	885	1,288
Depreciation	391	428	515
Other expenses	2,003	2,157	2,439
	$ 17,093	$ 12,970	$ 19,569

NOTE 15 - RELATED PARTY TRANSACTIONS

a. Non-Executive Director Compensation

(*U.S. dollars in thousands*)	Year Ended December 31, 2023	2024	2025
Compensation (including share-based compensation) to the non-executive directors	$ 429	$ 555	$ 478

b. In September 2023, with the consent of the Audit Committee of the Board of Directors, the Company engaged one of its non-executive directors to advise the Company regarding business development and licensing efforts on a consultancy basis. The engagement expired in September 2025. For the years ended December 31, 2023, 2024, and 2025, we recorded an expense of a total of $35,475, $1,350, and $0 for consulting fees under such engagement, respectively.

NOTE 16 - SUBSEQUENT EVENTS

a. Since December 31, 2025, the Company has collected approximately $5.5 million from sales to Chiesi $1.4 million from sales to Pfizer and approximately $1.9 million from sales to Brazil.

b. The Company became entitled to a regulatory milestone payment of $25.0 million from Chiesi in connection with the EC's approval of the E4W dosing regimen.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-237736 and No. 333-286802) and on Form S-8 (No. 333-148983, No. 333-182677, No. 333-203960, No. 333-225526, No. 333-239101, No. 333-266131, No. 333-273396 and No. 280644) of Protalix BioTherapeutics, Inc. of our report dated March 18, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ Kesselman & Kesselman

Certified Public Accountants (lsr.)

A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 18, 2026

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)**)** for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 18, 2026

/s/ Dror Bashan
Dror Bashan
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Gilad Mamlok, certify that:

1. I have reviewed this Annual Report on Form 10-K of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 18, 2026

/s/ Gilad Mamlok
Gilad Mamlok
Sr. Vice President, Chief Financial Officer, Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the Annual Report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, Dror Bashan, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certificate is being furnished to the Securities and Exchange Commission as an exhibit to the Report.

Dated: March 18, 2026

/s/ Dror Bashan
Dror Bashan
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the Annual Report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, Gilad Mamlok, Sr. Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certificate is being furnished to the Securities and Exchange Commission as an exhibit to the Report.

Dated: March 18, 2026

/s/ Gilad Mamlok
Gilad Mamlok
Sr. Vice President and Chief Financial Officer